English translation

SymBio Pharmaceuticals Limited

Summary of Financial Statements for the Fiscal Year Ended December 31, 2021
[Japanese GAAP] (Non-consolidated)

February 10, 2022

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Stock Exchange	
Securities Code	4582	URL: https://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Corporate Officer and Chief Financial Officer	Takaaki Fukushima	TEL +81-3-5472-1125
Ordinary Annual General Meeting of Shareholders	March 29, 2022	Date of Dividend Payment (plan)	—
Scheduled Date to File Securities Report	March 29, 2022		

Supplementary materials for the financial statements: Yes [No]

Holding of earnings performance review: [Yes] No (For securities analysts and institutional investors)

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

1. Business Results for FY 2021 (January 1, 2021 to December 31, 2021)

(1) Operating Results

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
FY 2021	8,256	176.4	1,016	—	1,001	—	2,032	—
FY 2020	2,987	5.3	(4,506)	—	(4,615)	—	(4,090)	—

	Earnings (Loss) per Share	Diluted Earnings per Share	Ratio of Profit (Loss) to Equity (ROE)	Ratio of Ordinary Profit (Loss) to Total Assets (ROA)	Ratio of Operating Profit (Loss) to Net Sales
	Yen	Yen	%	%	%
FY 2021	53.04	52.32	39.6	13.6	12.3
FY 2020	(124.13)	—	(104.7)	(79.9)	(150.9)

(Reference) Equity in earnings of affiliates: FY 2021 — million yen
FY 2020 — million yen

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio	Net Assets per Share
	Millions of yen	Millions of yen	%	Yen
FY 2021 (as of December 31, 2021)	8,452	6,745	73.7	162.26
FY 2020 (as of December 31, 2020)	6,274	4,657	64.3	105.76

(Reference) Shareholders' equity: FY 2021 (as of December 31, 2021) 6,226 million yen
FY 2020 (as of December 31, 2020) 4,037 million yen

(3) Cash Flows

	Cash Flows from Operating Activities	Cash Flows from Investing Activities	Cash Flows from Financing Activities	Cash and Cash Equivalents at End of Period
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
FY 2021	140	(70)	(71)	3,860
FY 2020	(4,122)	(160)	4,222	3,848

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 2020	—	0.00	—	0.00	0.00	—	—	—
FY 2021	—	0.00	—	0.00	0.00	—	—	—
FY 2022 (Forecast)	—	0.00	—	0.00	0.00		—	

3. Earnings Forecasts for FY 2022 (January 1, 2022 to December 31, 2022)

(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	10,992	33.1	1,770	74.2	1,750	74.8	1,480	(27.2)	38.63

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・[No]

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

(c) Changes in accounting estimates: Yes・[No]

(d) Restatements after error corrections: Yes・[No]

(2) Number of issued shares (common stock)

(i) Total number of issued shares at the end of the year (including treasury shares)	FY 2021	38,457,206 shares	FY 2020	38,202,956 shares
(ii) Total number of treasury shares at the end of the year	FY 2021	82,618 shares	FY 2020	30,143 shares
(iii) Average number of shares during the year	FY 2021	38,313,220 shares	FY 2020	32,950,201 shares

* 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 financial statement, including earnings forecasts, are based on the information currently available to management and assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the assumptions on which the Company's earnings forecasts are based and their usage, please refer to "1. Overview of Business Results, etc. (4) Future outlook," on Page 9 of the attachment.

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1. Overview of Business Results, etc.

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

(Business results for the fiscal year under review)

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

(i) Domestic business

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

With the expiration of the business partnership agreement with Eisai Co., Ltd. in December 2020, the Company began selling TREAKISYM® (generic name: bendamustine hydrochloride) through its own sales organization. As a result, the Company attained profitability in FY 2021, which was its top priority for the fiscal year, and solidified the foundation for future business growth. The Company aims to achieve sustainable growth going forward.

With the shift to in-house sales, the Company began providing information tailored to the needs of each target market and worked to cultivate demand. It also offered detailed information on its products and held seminars. Through these efforts, the Company was able to further improve the productivity of its salesforce. In addition to sales representatives, the Company assigned hematology experts with more in-depth knowledge of the field to each region of its operation. Moreover, to build a nationwide distribution network, we have entered into agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd., making both companies exclusive wholesalers of our products. We have also begun working with S.D. Collabo Co., Ltd. to build a nationwide logistics system and set up two logistics centers—one in Eastern Japan and the other in Western Japan.

During the fiscal year under review, the Company commenced sales of the ready-to-dilute (RTD) intravenous formulation of TREAKISYM® in January 2021, having obtained marketing approval in September 2020, and promoted the shift from the existing freeze-dried (FD) formulation to the newly approved formulation. In March 2021, the Company obtained approval for a partial change to the marketing authorization of the FD formulation of TREAKISYM®, allowing the product to be used in the bendamustine-rituximab (BR) therapy as well as in the genetically engineered polatuzumab vedotin plus bendamustine-rituximab (P+BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). After the approval was granted, the FD formulation of TREAKISYM® immediately became available for use in the BR therapy, and the Company further promoted the switch from the conventional multidrug therapy.

In April 2021, the Company obtained approval for a partial change to the marketing approval of the RTD formulation of TREAKISYM® for its use in the BR and P+BR therapy for the treatment of r/r DLBCL. In May 2021, genetically engineered polatuzumab vedotin was listed in the NHI drug price list, allowing TREAKISYM® to be used in the P+BR therapy.

[Stable product supply]

The Company commenced sales of the RTD formulation of TREAKISYM® in January 2021, and has steadily worked to promote the switch from the FD formulation to the RTD formulation.

The Company currently imports the FD formulation of TREAKISYM® from Astellas Deutschland GmbH, a subsidiary of Astellas Pharma Inc., and it imports the RTD formulation of TREAKISYM® from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.).

The Company conducts secondary packaging and quality screening on imported batches of both the FD and RTD formulations of TREAKISYM® in Japan and works to maintain stable quality.

In terms of supply, we diligently worked to replace the FD formulation of TREAKISYM® with the RTD formulation. Due to slower than anticipated conversion, the risk of the FD formulation going out of stock arose and controls were implemented on shipments of the FD product from September 2021. Owing to the understanding and collaboration of healthcare providers, the conversion from the FD to RTD formulation has made rapid progress. The Company has secured sufficient inventory of RTD formulation to ensure stable supply.

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

SymBio obtained marketing approval for TREAKISYM® for the indication as first-line treatment of low-grade non-Hodgkin's lymphoma (low-grade NHL) (Note 1) and mantle cell lymphoma (MCL) in December 2016, and for the indications of recurrent/refractory low-grade NHL and MCL in October 2010 and chronic lymphocytic leukemia (CLL) in August 2016. TREAKISYM® is thus being used to treat a wide array of malignant lymphoma. Further, bendamustine-rituximab (BR) therapy

was added to the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues published by the Japanese Society of Hematology in July 2018, and recommended as a standard treatment for all previously approved indications. With this development, TREAKISYM® has established its foothold as the standard treatment for malignant lymphoma.

In July 2018, the Company obtained approval for a partial change to the marketing authorization of TREAKISYM®, allowing the product to be used in combination with not only rituximab but also other new anti-CD20 antibodies for the treatment of CD-20 positive follicular lymphoma (FL), a typical histologic type of low-grade NHL. Having obtained approval for the partial change, TREAKISYM® is available to patients as a new treatment option in combination with obinutuzumab (Note 2). In March 2019, the Company obtained approval for a partial change to the marketing authorization, allowing the use of TREAKISYM® as a pretreatment agent for tumor-specific T-cell infusion therapy (Note 3). This allowed TREAKISYM® to be used as a pretreatment agent for Kymriah® intravenous infusion (Note 4), the first chimeric antigen receptor T-cell (CAR-T) therapy (Note 5) to be approved in Japan. Owing to the spread of its use as a pretreatment agent for regenerative medicine and other pharmaceutical products, the status of TREAKISYM® as the standard treatment for malignant lymphoma has further solidified.

In addition to the already-approved indications, SymBio conducted a Phase III clinical trial of BR therapy targeting r/r DLBCL, and in May 2020 it applied for a partial change to the marketing authorization to include this additional indication. The approval was granted in March 2021. In April 2021, the Company obtained approval for a partial change to the marketing approval of the RTD formulation of TREAKISYM® for its use in BR and P+BR therapies for the treatment of r/r DLBCL. Further, the Company conducted a follow-up study with overall survival as the primary endpoint, since survival data (e.g., overall survival and progression-free survival) for BR therapy is crucial in establishing TREAKISYM® as a DLBCL treatment. The Company presented the results of the study at the annual meeting of the Japanese Society of Hematology and other academic conferences, and is currently preparing to publish the results in academic journals. In June 2020, Chugai Pharmaceutical Co., Ltd. filed for marketing approval of genetically engineered polatuzumab vedotin (Note 6) used in combination with BR therapy in treating r/r DLBCL. In response, in July 2020 the Company applied for a partial change to the marketing authorization of TREAKISYM® used in combination with genetically engineered polatuzumab vedotin and rituximab and obtained approval in March 2021. In May 2021, genetically engineered polatuzumab vedotin was included in the NHI drug price list, allowing TREAKISYM® to be used in the combination therapy of genetically engineered polatuzumab vedotin and BR therapy (P+BR). Because there existed no effective treatment for r/r DLBCL, combination therapies comprising multiple anticancer drugs had been used as rescue chemotherapy, and the development of highly effective and safe drugs was in dire need. BR therapy is already used to treat patients with r/r DLBCL in Europe and the U.S. In Japan, patient organizations and relevant academic societies have requested to the Ministry of Health, Labour and Welfare to make BR therapy available as soon as possible. Going forward, the Company expects TREAKISYM® to be widely available as a treatment option for many patients by promoting the shift from the conventional multidrug therapies.

In September 2017, SymBio concluded an exclusive license agreement with Eagle Pharmaceuticals for the RTD formulation and rapid infusion (RI; enabling shorter administration time) injection (Note 7) of TREAKISYM® in Japan. The Company obtained marketing approval for the RTD formulation in September 2020, and launched the product in January 2021. For the RI injection, the Company concluded clinical trials aimed at confirming the drug's safety, and in May 2021, submitted a partial change application. Further, in November 2021, the Company was granted approval for its partial change application to extend the shelf life of the RTD formulation to 30 months based on the results of long-term stability studies.

Unlike the current FD formulation, RTD formulation of TREAKISYM® does not require the cumbersome manual work of dissolving the drug (i.e., drug reconstitution), shortening preparation time and reducing burdens on healthcare providers.

Further, the RI injection significantly reduces the infusion time from the one hour required by the conventional FD and RTD formulations, providing great benefit and value to both patients and healthcare providers.

(Note 1) Non-Hodgkin's lymphoma (NHL) refers to malignant lymphoma other than Hodgkin's lymphoma. Malignant lymphoma is a cancer of the lymphatic system in which lymphocytes develop malignant growths. The majority of Japanese malignant lymphoma patients are suffering from NHL.

(Note 2) Obinutuzumab (Gazyva®, marketed by Chugai Pharmaceutical Co., Ltd.): Like rituximab recommended by treatment guidelines for non-Hodgkin's lymphoma in Japan and overseas, obinutuzumab is a glycoengineered type II anti-20 monoclonal antibody that directly binds to CD20 (a protein expressed on B-cells other than stem cells or plasma cells) on target B-cells to attack and destroy them along with the body's immune system.

(Note 3) Tumor-specific T-cell infusion therapy is a treatment method in which tumor-specific T-cells (T-cells that specifically recognize cancer cells) taken from cancer patients are artificially bestowed with cancer specificity extracorporeally, amplified and then administered to the patient.

(Note 4) Kymriah® intravenous infusion (generic name: tisagenlecleucel, marketed by Novartis Pharma K.K.): Kymriah® intravenous infusion is the first chimeric antigen receptor T-cell (CAR-T) therapy approved within Japan. Novartis Pharma received manufacturing and marketing approval for Kymriah® for use in the treatment of CD19 positive recurrent/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive DLBCL in March 2019. Kymriah® intravenous infusion was included in NHI price listings in May 2019.

(Note 5) Chimeric antigen receptor T-cell (CAR-T) therapy is a type of tumor-specific T-cell infusion therapy that introduces genes that code chimeric antigen receptors (CARs) into T-cells, amplifies these cells and then infuses them. These chimeric antigen receptors are produced by combining the intracellular domains of T-cell receptors with the antigen binding sites of antibodies capable of recognizing membrane antigens attached to tumor cells. In clinical trials using CARs to target CD19 that expresses on B-cells, CD19-targeting CARs were introduced into T-cells that were later administered to patients with B-cell tumors. These modified cells produced clear clinical effects.

(Note 6) Developed by Roche using Seattle Genetics' antibody-drug conjugate (ADC) technology, genetically engineered polatuzumab vedotin is a first-in-class anti-CD79b ADC (targeting CD79b) built by conjugating humanized monoclonal antibody targeting CD79b to a tubulin polymerization inhibitor. CD79b protein is specifically expressed on the surface of many B-cells, and is expected to be a promising target in new drug development. Genetically engineered polatuzumab vedotin selectively binds to CD79b while minimally affecting normal cells, and destroys B-cells with the chemotherapeutic agent it contains.

(Note 7) Ready-to-dilute (RTD) and rapid infusion (RI) are pre-dissolved liquid formulations that differ from the conventional freeze-dried (FD) formulation. The RTD formulation significantly reduces the preparation time and labor cost for healthcare providers, and the RI injection substantially reduces infusion duration from the current one hour, providing significant benefit and value to both patients and healthcare providers.

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

U.S. licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) has conducted global Phase III clinical trials (with trial sites in more than 20 countries; INSPIRE study) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which failed to respond to the current standard treatment with hypomethylating agents, relapsed after treatment under the current standard of care, or were intolerant to hypomethylating agents; the primary endpoint of the study is overall survival. In August 2020, Onconova announced that the primary endpoint—improved survival compared to physician's choice of treatment—was not met. The Company is responsible for clinical development in Japan, and is reviewing ways to use the findings from the additional analysis of the INSPIRE study in the future development of rigosertib (intravenous formulation).

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

With the aim of maximizing the business value of rigosertib and TREAKISYM®, the Company will conduct joint research with the University of Tokyo and Gunma University to investigate the efficacy of the drugs used in combination with each other as well as in combination with other existing drugs, and to look for new indications.

(Note 8) Azacitidine (Vidaza®, marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (for injection) was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS, and is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation. MDS is a preleukemic state, and decrease in tumor suppressor gene due to excessive methylation of DNA is thought to be related to the disease. Hypomethylating agents such as azacitidine are thought to suppress progress to leukemia by restoring tumor suppressor gene with a deterrent effect against methylation of DNA.

[Antiviral drug: SyB V-1901 (generic name: brincidofovir)]

In September 2019, the Company concluded an exclusive global licensing agreement for intravenous and oral formulation of antiviral drug brincidofovir (Note 9) (SyB V-1901; "BCV IV" and "BCV Oral," respectively) with Chimerix Inc. (head office:

North Carolina, U.S.). Under this agreement, the Company acquired exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding orthopox viruses.

The Company decided to prioritize the global development of BCV IV, primarily in Japan, the U.S. and Europe, targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, an area with high unmet medical needs as there currently exists no effective treatment. In March 2021, the Company submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a Phase II clinical trial targeting AdV infections primarily in pediatric patients (also including adult patients). In April 2021, the FDA granted the development program a fast-track designation. In August 2021, the investigational drug was administered to the first patient enrolled (first patient in or FPI) in the clinical trial. Further, In January 2022, the Company successfully filed a Clinical Trial Application (CTA) to the Medicines and Healthcare products Regulatory Agency (MHRA) of the U.K.

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

In addition to strong antiviral effects, BCV is also expected to have antitumor effects. Through joint research with the National Cancer Centre Singapore and University of California San Francisco (UCSF) Brain Tumor Center, SymBio is investigating new indications for BCV in oncology, including rare brain tumors and Epstein-Barr (EB) virus-positive lymphoma.

In December 2020, Chimerix announced that the FDA accepted its New Drug Application (NDA) for BCV Oral as a medical countermeasure against smallpox; Chimerix obtained FDA approval in June 2021.

(Note 9) Brincidofovir is a lipid conjugate of cidofovir (CDV). CDV is an antiviral drug already approved and marketed in the United States and the European Union, but unapproved in Japan. It is quickly absorbed into the lipid bilayer membrane and efficiently transferred into cells, and the bound lipid chain is metabolized and separated from the structure by intracellular phospholipases. This process generates an activator (CDV-PP; CDV diphosphate) that is retained in the cells for a long period of time, significantly raising the compound's antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, as the lipid conjugation prevents the accumulation of the compound in renal tubular epithelial cells through organic anion transporter 1 (OAT1) and CDV is released at low levels in the bloodstream.

(Note 10) Double-stranded DNA (dsDNA) viruses include herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as cytomegalovirus (CMV), adenovirus (AdV), human herpesvirus 6 (HHV-6), herpes simplex virus type 1 or 2 (HSV-1/2), BK virus (BKV), varicella zoster virus (VZV), human papillomavirus (HPV), JC virus, and smallpox virus.

(ii) Business outside Japan

The Company's U.S.-based wholly-owned subsidiary SymBio Pharma USA, Inc. (President: Fuminori Yoshida) appointed Dr. Carolyn Yanavich as its Vice President and Head of Project Management and Clinical Operations in October 2021, and launched full-scale operations aimed at accelerating global development of antiviral drug brincidofovir toward commercialization.

(iii) Licensing of new drug candidates

SymBio is moving ahead with global development of brincidofovir, an antiviral drug in-licensed in September 2019. At the same time, the Company continues to evaluate new drug candidates for potential in-licensing. Through these efforts, it aims to create medium- to long-term business value as a profitable biopharmaceutical company with growth potential.

(iv) Business results

As a result of the above, sales in FY 2021 grew substantially to 8,256,924 thousand yen (+176.4% year-on-year), driven by the transition to in-house sales of TREAKISYM®. The contributions from the sales transition more than offset the negative impacts of residual inventories of TREAKISYM® FD formulation in the market sold by Eisai before the transition and the resurgence of

COVID-19 cases, which resulted in postponed medical treatments as well as constrained sales activities due to tighter restrictions on visits to facilities. From the third quarter of FY 2021 in particular, postponed medical treatments resumed as COVID-19 vaccination of the elderly patients made progress. Sales of TREAKISYM® for r/r DLBCL also began to increase from the third quarter owing to approval of BR and P-BR therapies for the additional indication of r/r DLBCL granted in March 2021, and the inclusion of Chugai Pharmaceutical's genetically engineered polatuzumab vedotin in the NHI drug price list in May 2021. As a result, net sales in the second half of FY 2021 increased substantially year-on-year from 1,626,402 thousand yen a year ago to 5,110,316 thousand yen.

Gross profit rose substantially to 5,800,110 thousand yen (+569.1% year-on-year) on the back of sales growth and improved gross profit margin resulting from the rapid progress in the switch from the freeze-dried (FD) formulation of TREAKISYM® to ready-to-dilute (RTD) formulation. On the other hand, an inventory loss of 331,866 thousand yen of the FD formulation of TREAKISYM® was recorded primarily as a result of the switch from the FD to RTD formulation.

Selling, general and administrative expenses totaled 4,784,109 thousand yen (-11.0% year-on-year), including research and development expenses of 1,736,126 thousand yen (-23.4% year-on-year) primarily due to expenses associated with clinical trials for TREAKISYM®, rigosertib, and brincidofovir, as well as other selling, general and administrative expenses of 3,047,982 thousand yen (-1.8% year-on-year), including higher selling expenses due to the transition to in-house sales.

As a result, the Company recorded operating profit of 1,016,001 thousand yen in FY 2021 (versus an operating loss of 4,506,220 thousand yen in FY 2020). Although the Company recorded non-operating income of 17,462 thousand yen, consisting mainly of 14,757 thousand yen in commission income, it also recorded non-operating expenses of 32,330 thousand yen, primarily comprising foreign exchange losses of 20,186 thousand yen and commission expenses of 9,499 thousand yen. As a result, ordinary profit totaled 1,001,133 thousand yen (versus an ordinary loss of 4,615,903 thousand yen in FY 2020). Bottom-line profit totaled 2,032,203 thousand yen (versus a loss of 4,090,216 thousand yen in FY 2020) due mainly to the recording of 1,275,759 thousand yen in deferred tax assets as a result of a careful assessment of the recoverability of deferred tax assets in light of business results for FY 2021.

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

(Assets, liabilities, net assets, and cash flows)

Total assets as of December 31, 2021 stood at 8,452,997 thousand yen, an increase of 2,178,290 thousand yen from the previous fiscal year-end. This was primarily due to increases of 1,740,521 thousand yen in accounts receivable–trade, 149,081 thousand yen in advance payments, and 64,366 thousand yen in prepaid expenses, offsetting decreases of 412,950 thousand yen in semi-finished goods, 314,761 thousand yen in consumption taxes receivable, and 146,284 thousand yen in merchandise and finished goods.

Total liabilities stood at 1,707,324 thousand yen, an increase of 89,935 thousand yen from the previous fiscal year-end, due mainly to increases of 516,036 thousand yen in accrued consumption taxes, 301,671 thousand yen in income taxes payable and 186,437 thousand yen in provision for product changeover, offsetting decreases of 595,776 thousand yen in accounts payable–trade and 130,738 thousand yen in accounts payable–other.

Total net assets stood at 6,745,672 thousand yen, an increase of 2,088,354 thousand yen from the previous fiscal year-end. This was mainly owed to increases of 2,032,203 thousand yen in retained earnings due to the recording of bottom-line profit, 113,015 thousand yen in capital surplus, and 112,684 thousand yen in share capital, and a decrease of 101,041 thousand yen in share acquisition rights.

The equity ratio consequently rose 9.3 percentage points from the previous fiscal year-end to 73.7%.

Cash and cash equivalents ("cash") as of December 31, 2021 increased 11,480 thousand yen from the previous fiscal year-end to 3,860,106 thousand yen.

(Cash flows from operating activities)

Net cash provided by operating activities amounted to 140,042 thousand yen, compared with 4,122,483 thousand yen in cash used by these activities in the previous fiscal year. The key drivers were1,001,331 thousand yen in profit before income taxes, a decline of 830,797 thousand yen in consumption taxes receivable, and decrease of 559,235 thousand yen in inventory. Cash outflows were mainly due to an increase of 1,740,521 thousand yen in accounts receivable–trade, a decrease of 595,776 thousand yen in notes and accounts payable–trade.

(Cash flows from investing activities)

Net cash used in investing activities amounted to 70,849 thousand yen, compared with 160,309 thousand yen used in these activities in the previous fiscal year. Principal contributing factors included 38,383 thousand yen in purchase of intangible assets, 25,454 thousand yen in purchase of property, plant and equipment, and 7,011 thousand yen in leasehold and guarantee deposits.

(Cash flows from financing activities)

Net cash used by financing activities was 71,922 thousand yen, compared with 4,222,090 thousand yen provided by these activities in the previous fiscal year. This mainly reflected cash outflows of 68,825 thousand yen in purchase of treasury shares and 4,001 thousand yen in payments for issuance of shares, offsetting cash inflows of 649 thousand yen in proceeds from disposal of treasury shares and 254 thousand yen in proceeds from issuance of shares resulting from the exercise of share acquisition rights.

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

	13th Term FY 2017	14th Term FY 2018	15th Term FY 2019	16th Term FY 2020	17th Term FY 2021
Equity ratio (%)	63.6	70.1	71.7	64.3	73.7
Equity ratio on a fair market value basis (%)	278.4	250.9	304.0	230.6	520.0
Debt redemption period (years)	—	—	—	—	—
Interest coverage ratio	—	—	—	—	—

Equity ratio: Equity (total shareholders' equity)/total assets
Equity ratio on a fair market value basis: Total market value of common stock/total assets
Debt redemption period: Interest-bearing debt/cash flows from operating activities
Interest coverage ratio: Cash flows from operating activities/interest payments
(Notes) 1. Total market value is calculated based on the number of shares issued, excluding treasury shares.
2. Debt redemption period and interest coverage ratio are not available due to negative cash flows from operating activities through FY 2020 and the absence of interest payments in FY 2021.

(4) Future outlook

SymBio expects net sales to reach 10,992 million yen in FY 2022, a 33.1% increase from FY 2021, as a result of a full-year sale of TREAKISYM® for r/r DLBCL with the approval of the drug's use in BR and P-BR therapies for the additional indication in March 2021 and the inclusion of Chugai Pharmaceutical's genetically engineered polatuzumab vedotin in the NHI drug price list in May 2021. The Company also expects a positive impact from its efforts to promote the shift from the conventional multidrug therapy for treating r/r DLBCL to TREAKISYM® and further penetration of TREAKISYM® for the indication of first-line treatment of low-grade non-Hodgkin's lymphoma (low-grade NHL).

For research and development, the Company intends to accelerate the global development of antiviral drug brincidofovir for multiple indications. Further, to increase business value for the long term, the Company will explore new indications for its pipeline drugs in collaboration with academia and increase efforts to search for new in-licensing candidates and consider forming new alliances. Through these efforts, the Company aims to advance the development of its pipeline as a whole. At the same time, the Company will strive to maintain profitability it achieved in FY 2021 and aim for sustainable earnings growth going forward. It will also steadily work to expand its business globally.

As a result, the Company anticipates R&D expenses of 3,056 million yen (1,736 million yen in FY 2021) and selling, general and administrative expenses of 7,026 million yen (4,784 million yen in FY 2021) including R&D expenses.

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

[TREAKISYM®]

For the indication of r/r DLBCL, the Company submitted a partial change application to the Pharmaceuticals and Medical Devices Agency (PMDA) in May 2020. The approval was granted in March 2021, and the FD formulation of TREAKISYM® became available for use in the bendamustine-rituximab (BR) therapy.

In regard to the liquid formulations of TREAKISYM® in-licensed from Eagle Pharmaceuticals, the Company obtained manufacturing and marketing approval for the RTD formulation in September 2020 and launched the product in January 2021. In April 2021, the Company obtained approval for a partial change to the marketing approval of the RTD formulation of

TREAKISYM® for its use in the BR and P+BR therapy for the treatment of r/r DLBCL. For the RI injection, the Company completed clinical studies on safety and filed a partial change application in May 2021.

The Company will actively conduct further research on TREAKISYM®, such as specified clinical research with Saitama Medical University and joint research with Kyoto University, to explore new possibilities of the drug.

[Intravenous and oral formulation of rigosertib]

Onconova Therapeutics, Inc. announced in August 2020 that in the global Phase III clinical trial of the intravenous formulation of rigosertib (INSPIRE study), the primary endpoint—improved overall survival compared to physician's choice of treatment—was not met. The Company is in charge of clinical development in Japan, and is reviewing ways to utilize findings from the additional analysis of the INSPIRE study in the future development of rigosertib.

For rigosertib and TREAKISYM®, the Company is searching for new indications as well as new applications for the two drugs used in combination with each other or with other existing drugs, through joint research with the University of Tokyo, and Gunma University.

[Antiviral drug brincidofovir]

In the development of antiviral drug brincidofovir, for which the Company envisions a global rollout, SymBio is working with renowned researchers in each field, and is designing a global study based on the knowledge and insight gained from these collaborations.

As a result of the review at the Global Advisory Board held in February 2020, the Company has decided to prioritize the global development of the intravenous formulation of brincidofovir (BCV IV) primarily in Japan, the U.S., and Europe targeting disseminated adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, a niche area with a high unmet medical need. In March 2021, the Company filed an IND application with the FDA to conduct a Phase II clinical trial primarily in pediatric patients suffering from AdV infections (also includes adults). This development program was granted a fast-track designation by the FDA, and the investigational drug was administered to the first patient enrolled (first patient in or FPI) in August 2021. Further, in January 2022, the Company successfully filed a CTA to the MHRA.

Using the knowledge and insight on the safety and efficacy of BCV gained from clinical trials targeting AdV infections, the Company intends to investigate the effectiveness of the investigational drug against various other dsDNA virus infections after hematopoietic stem cell transplantation and expand target indications to include multiviral infections. It will also explore the possibility of expanding the target indications to viral infections associated with kidney and other organ transplants. The Company aims to expand the market for BCV and maximize its business value. Clinical trials conducted by Chimerix in Europe and the US have demonstrated that BCV Oral has strong antiviral activity against a broad range of viruses. BCV Oral's antiviral activity against a range of dsDNA viruses suggests that BCV IV may also be safe and effective in the prevention and treatment of various viral infections after hematopoietic stem cell transplantation.

In addition to its potent antiviral activity, BCV is also expected to have antitumor effects. Through joint research with the National Cancer Centre Singapore and UCSF Brain Tumor Center, the Company is exploring new indications in oncology including rare brain tumors and EB virus-positive lymphoma.

In June 2021, Chimerix obtained approval for BCV Oral as a medical countermeasure against smallpox from the FDA.

As a result of these planned activities, the Company anticipates net sales of 10,992 million yen, operating profit of 1,770 million yen, ordinary profit of 1,750 million yen, and profit of 1,480 million yen for FY 2022.

(5) Basic policies concerning profit distribution and dividends

The Company has not distributed dividends to date.

Although the Company has begun 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 research and development 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 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

Key business risks are described below. 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 financial statement. 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 financial statement.

(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 development of a pharmaceutical drug to launch 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 discontinue or delay product development. In pharmaceutical development, the different stages 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 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 as required 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 are identified that could lead to further damage to the health of patients, there remains a risk that approval for the product may be revoked due to concerns over efficacy and side effects (see (f): "risk associated with side effects"). To reduce and disperse these risks, the Company aims to have several drug candidates in its development pipeline and to prioritize insofar as possible the in-licensing of drug candidates with confirmed proof of concept (POC) (Note 11) 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 material and could have a significant impact on the Company's financial position, business performance, and cash flow.

(Note 11) 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 manufacture and market the product either on our own or in partnership with a third party. There is no guarantee 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.

The Company obtained marketing approval for the RTD formulation of TREAKSYM® in September 2020 and began sales in January 2021. For the RI injection of TREAKISYM®, the Company filed a partial change application in May 2021. Partial changes to marketing authorization approving use of the FD and RTD formulations for use in treating recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) were received in March and April 2021, respectively.

With respect to rigosertib, Onconova announced in August 2020 that in the global Phase III clinical trial (INSPIRE study), the primary endpoint—improved overall survival compared to physician's choice of treatment—was not met. The Company is in charge of clinical development in Japan, and is reviewing ways to utilize findings from the additional analysis of the INSPIRE study to the future development of rigosertib.

The Company has prioritized the global development of antiviral drug brincidofovir as a treatment for adenovirus (AdV)

infection in immunocompromised patients, including in patients after hematopoietic stem cell transplantation, an area with high unmet needs. It is also considering the development of the drug for viral infections associated with organ transplants and virus-induced cancers.

We are engaged in the development of these compounds, seeking to successfully launch them as commercial products. In some cases, we may consider entering into an alliance with other pharmaceutical companies in development and marketing to expedite the inflow of income. Notwithstanding our efforts, the drug candidates in our pipeline will require a considerable amount of time in 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 identifying alliance and marketing 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 on 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 in Japan, together with drug pricing guidelines that derive from the PMD Act. There is also 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

In addition to Japan, we have identified the U.S., Europe, and Asia among other regions as our strategic business areas. We are developing global business expansion plans for the future worldwide development, sale, and manufacture of antiviral drug brincidofovir, including in the U.S., Europe, and Asia. In overseas markets or in Japan, pharmaceutical development and marketing generally require 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 will select the licensee after careful due diligence; we will monitor the licensees' activities when necessary after out-licensing the rights. The development and sales of out-licensed products are subject to business conditions of the licensee or any changes in the regulatory and competitive environment in respective countries, and may fall below initial expectations, resulting in lower than anticipated milestone revenue or royalty income. In such cases, there may be an impact on our financial position, business performance, and cash flow. Similarly, we regularly consider strategically utilizing partnerships with other pharmaceutical companies through methods such as joint development, joint marketing, and insourcing or outsourcing agreements. However, the Company acknowledges the possibility that actual earnings may not reach target levels if development or sales do not progress according to projections due to factors such as economic conditions at partner companies, regulations in various countries, or competitive environments. Such cases could potentially affect the Company's financial position, business performance, and cash flow.

e) Competition in the pharmaceutical industry

The pharmaceutical industry is highly competitive. 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 competing products, which are more effective than the Company's developed products. In addition to the risks posed by competing products and biosimilars, the Company is aware of potential business risks from the emergence of novel technologies in life sciences, including the development of treatments that go beyond the scope of conventional medicine. If changes to the external business environment are beyond what is anticipated, for instance due to the emergence of novel technologies and treatments that could fundamentally change the way the diseases our products target and development candidates are treated, our financial position, business performance, and cash flows may be significantly affected.

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 obtained 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 its drugs, 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 in-licensing drug candidates, mainly targeting orphan drugs (Note 12) in the areas of oncology and hematology, from pharmaceutical and bio venture companies with POC established through human subjects, and developing and marketing pharmaceutical products in Japan, Asia (China, South Korea, Taiwan, Singapore, etc.), and other countries globally. Furthermore, we have acquired exclusive rights for the worldwide development, sale, and manufacture of antiviral drug brincidofovir (BCV) for all human indications except orthopox viruses, through an exclusive global licensing agreement with Chimerix Inc. Utilizing these rights, we will transform into a specialty pharmaceutical company that is capable of expanding into global markets and is equipped with an integrated system for supplying high quality pharmaceutical products.

In developing and marketing the pipeline products, the Company plans to engage in alliances with other pharmaceutical companies. However, there is no guarantee that the Company can continuously in-license drug candidate compounds that satisfy in-house criteria and secure a partnership with these corporate partners. In addition, as the Company mainly targets orphan drugs for in-licensing (Note 13), it may not be able to generate expected sales turnover. Furthermore, in the event that development by a licensor is delayed or fails, there may be impact on the corresponding development in Japan. The Company also acknowledges the possibility that global business expansion may not proceed according to initial projections due to uncontrollable factors that affect the progress of development, sales, and manufacturing plans of either the Company or its corporate partners. These factors could impact the Company's financial position, business performance, and cash flow. Needless to say, intense competition within the pharmaceutical sector and changes in the Company's financial position may force the Company to revise its business model. Should this occur, there may be a significant impact on the Company's business.

(Note 12) 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 13) "In-licensed drug candidates" are compounds or products for which obtaining the rights of development and commercialization from other companies is under consideration.

b) Dependency on specific partners and suppliers

The Company holds exclusive rights to manufacture antiviral drug brincidofovir for all human indications except for orthopox viruses. As a specialty pharmaceutical company without production facilities, the Company currently needs to depend on the supply of products from other companies when conducting clinical trials and marketing approved drugs. Given this fact, the financial position and production conditions of the product suppliers may have a significant impact on the Company's financial position, business performance, and cash flow. Typically, in license agreements with partner companies, revenues before the drug reaches the market include an upfront payment upon signing the contract, funding for co-development, and milestone payments. The timing of milestone payments is not always predictable. 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 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. The Company engages in joint research with research institutions and other organizations. In such cases, the Company must discuss the ownership of research outcomes with partnering research institutions in accordance with each institution's policies, and it may not always obtain the sole ownership of intellectual property rights. As of the submission date of this financial statement, 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 risks relating to confidential information about the Company's pipeline development or other business activities leaking outside the Company, the Company takes appropriate steps to protect its confidential information. The Company requires directors and employees, Scientific Advisory Board (SAB) members, research institutions, outsourcing partners, and other business partners to sign confidentiality agreements. Even with agreements in place, directors and employees, SAB members, research institutions, outsourcing partners, and other business partners may not adhere to confidentiality, and should this occur, confidential information may be divulged elsewhere, which may impact the Company's business, financial position, business performance, and cash flow.

e) Risk concerning important contracts

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

(iii) Risk associated with organization

a) Risk of being a young company

SymBio was 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 before arise in the future. At the moment, however, it is difficult to

accurately predict changes in the external environment 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) Risks relating to company size

The Company retains contract research organizations (CROs (Note 14)) in research and development, thereby forming a development framework requiring relatively small staff numbers. With the development of the existing pipeline (including global expansion) and with newly in-licensed drug candidates to be added to the pipeline, the Company may need to develop human resources in research and development. However, for whatever reason if an alliance with a CRO terminates, or if the Company fails to secure the planned number of staff, or existing employees 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 14) 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' 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, sharing each member's own perspective on an in-licensed drug candidate in order to build a pipeline portfolio with a balanced risk–return trade-off, while taking into consideration healthcare needs and profitability of in-licensed drug candidates gathered from all over the world. The Company will continue to retain outstanding members for the SAB. However, if difficulty arises in retaining members for reasons such as the cancellation, expiration, or renewal refusal of contracts with existing members, there may be an impact on the Company's ability to evaluate and in-license quality drug candidates.

(iv) Business results

a) Business performance in previous years

The Company's key business indicators are given below:

Term	13th Term	14th Term	15th Term	16th Term	17th Term
Fiscal Year	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Net sales (thousands of yen)	3,444,206	3,835,530	2,837,753	2,987,051	8,256,924
Operating profit (loss) (thousands of yen)	(3,947,061)	(2,656,072)	(4,301,615)	(4,506,220)	1,016,001
Ordinary profit (loss) (thousands of yen)	(3,976,784)	(2,748,730)	(4,376,655)	(4,615,903)	1,001,133

Until the 16th Term, with the exception of the 4th Term, the Company's total R&D expenses and other general and administrative expenses exceeded the Company's income, resulting in the posting of an operating loss, an ordinary loss, and a bottom-line loss. For this reason, the Company does not consider the financial statements and indicators of previous years in which it recorded losses to provide adequate reference data in making comparisons with business performance of the year the Company posted profit and later, 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	13th Term	14th Term	15th Term	16th Term	17th Term
Fiscal Year	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
R&D expenses (thousands of yen)	3,017,812	1,832,746	2,441,552	2,266,556	1,736,126

The Company intends to continue its development activities. Through the recording of product sales revenue upon early approval for the intravenous and oral formulations of rigosertib and antiviral drug brincidofovir, and the income from alliances with pharmaceutical companies, the Company aims to collect early return on its R&D investment and continuously improve business performance as soon as possible; however, there is no guarantee that the Company will be able to achieve these aims as planned.

c) Negative retained earnings (accumulated deficits) brought forward

Specialty pharmaceutical businesses incur significant upfront R&D expenditure until products under development at the clinical stage reach the marketplace so that they can continuously earn stable income through product sales revenue and royalty income. As a result, with the exception of the 4th Term, the Company reported losses since its foundation until the 16th Term. At the end of the 17th Term, FY 2021, the Company recorded a negative balance of 27,977,510 thousand yen as accumulated deficits brought forward. SymBio aims to become profitable at the earliest possible date by advancing its pipeline development in a rapid, precise, and efficient manner and shifting toward marketing through its own internal salesforce. However, the possibility still exists that profits may not be generated in the planned timeline. 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 be considerably delayed.

d) Fundraising

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

e) Tax losses carried forward

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

(v) Other risks

a) Profit distribution to shareholders

Since the foundation of the Company, dividends have not been distributed. SymBio is currently at the business stage of making upfront investment for the development and commercialization (including global rollout) of pharmaceutical drugs, as well as achieving continuous growth through its own internal salesforce. The Company plans to continue to prioritize using funds to strengthen its financial position, continue its R&D activities, and support in-licensing of new drug candidates. Thus, the Company currently has 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 forthcoming fiscal year or in the medium- to long-term strategy. In either of these cases, the Company may obtain additional financing through means such as issuing 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 Articles 236, 238, 239, and 240 of the Companies Act, share acquisition rights are granted to directors and employees.

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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.

As of the end of the current fiscal year, the number of dilutive shares due to warrant is 296,850 shares, which is equivalent to 0.7% of the total number of issued shares of 38,457,206.

d) Stock holding by venture capitals

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

e) Risk of loss on foreign exchange

The Company, which does not currently have a manufacturing 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 disruptions in the supply chain of the Company's products, involving such processes as manufacture, import, inspection and shipment in Japan, and sales to distributors. 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

SymBio owns one unconsolidated subsidiary. However, its impact on financial results is insignificant, and it has therefore been omitted.

3. Management Policies

(1) Basic policy of company management

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Inc. (Note 15) (U.S.) 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 16) based on the guiding principle of mutual harmony, creating an intricate symbiotic relationship between patients, physicians, scientists, regulators, and investors.

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

portfolio, achieve high profitability with high-value products and services, and operate sustainable businesses.

(Note 15) 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 16) "Unmet medical needs" means requirements for medical treatment that have not yet been fulfilled. It refers to a situation in which no effective drugs or treatments are currently available, despite strong demand by patients and/or physicians.

(2) Key performance index

As a pharmaceutical company, SymBio believes that launching new drugs on an ongoing basis through its own salesforce is an important aspect of obtaining higher business value. Accordingly, we have established an integrated sales system that includes an in-house sales organization, as well as logistics and distribution systems. The Company also intends to continue in-licensing drug candidates for development and aggressively investing management resources in 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 in 2010. The Company continued collaborating with Eisai to expand sales of TREAKISYM® until our business partnership agreement expired in December 2020. From 2021, we switched to our own salesforce with the aim of further increasing earnings. We aim to achieve a stable and high level of profitability as soon as possible by obtaining approval for the intravenous and oral formulations of rigosertib and putting this product on the market, launching development of and commercializing antiviral drug brincidofovir in Japan and overseas, and working to in-license, promote the development of, and acquire approval for new pipeline products. Although we have achieved profitability following the transition to in-house sales in FY 2021, we have refrained from setting performance index targets such as ROE or ROA because we intend to continue making aggressive R&D investment.

(3) Pipeline

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

(i) [Anticancer agents: SyB L-0501 (FD formulation), SyB L-1701 (RTD formulation), SyB L-1702 (RI injection), (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM®)]

Bendamustine hydrochloride (the generic name), the active pharmaceutical ingredient of TREAKISYM®, is an anticancer agent that has been in use for a number of years in Germany under the trade name of Ribomustin® for the treatment of non-Hodgkin's lymphoma, multiple myeloma, and chronic lymphocytic leukemia. The Company decided to in-license this product because there is currently no effective medication for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. These are underserved therapeutic areas aligned with the Company's corporate mission and also fall within one of SymBio's targeted therapeutic fields (hematologic cancer). Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., is the worldwide licensor of bendamustine hydrochloride. Cephalon, Inc. (Pennsylvania, U.S.), 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 (U.K.) and Janssen-Cilag Limited (U.K.) 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 licensed from Astellas Deutschland GmbH with exclusive rights for the development and commercialization of bendamustine hydrochloride in Japan, China, South Korea, Singapore, and Taiwan. In Japan, the drug was approved for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in October 2010, and was launched under the trade name TREAKISYM® in December 2010. In December 2015, the Company filed a partial change application to include the additional target indications of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia. The Company obtained approval for the indication of chronic lymphocytic leukemia in August 2016 and of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in

December 2016. In May 2020, the Company submitted a partial change application to include the indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), and obtained approval in March 2021. 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 in September 2017 to develop, market, and sell Eagle's ready-to-dilute ("RTD") and rapid infusion ("RI") liquid formulation injection products in Japan. The Company obtained approval for the RTD formulation in September 2020, and launched the product in January 2021. For the RI injection, the Company completed clinical trials on safety and filed a partial change application in May 2021.

The license agreement concluded with Astellas Deutschland GmbH concerning the rights in Japan and other Asian countries for the freeze-dried formulation of anticancer agent bendamustine has expired.

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

No effective medication is available yet, especially for recurrent/refractory MDS, and it therefore constitutes an underserved therapeutic area. In July 2011, the Company signed a license agreement with Onconova, obtaining the exclusive right to develop and commercialize rigosertib in Japan and South Korea. Based on this agreement, the Company had developed 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, Onconova conducted global Phase III clinical trials (INSPIRE study) with clinical trial sites in more than 20 countries worldwide, for higher-risk myelodysplastic syndromes (HR-MDS) which did not respond to the current standard treatment with hypomethylating agents, which relapsed after treatment under the current standard of care, or which were intolerant to hypomethylating agents. In August 2020, Onconova announced that the primary endpoint of the trial—improved overall survival compared to physician's choice of treatment—was not met. The Company is in charge of clinical development in Japan, and is reviewing ways to utilize findings from the additional analysis of the INSPIRE study in the future development of rigosertib.

The oral formulation of rigosertib was shown to be effective and safe when administered in combination with azacitidine in a Phase I/II clinical trial in first-line higher-risk MDS patients conducted by Onconova in the U.S. The Company commenced a Phase I clinical trial in Japan to confirm the safety of high-dose monotherapy and tolerance in Japanese patients in Japan in June 2017, and completed patient enrollment in June 2019.

With the aim of maximizing the business value of rigosertib and TREAKISYM®, the Company is conducting joint research with the University of Tokyo, and Gunma University to investigate the efficacy of the drugs used in combination with each other as well as with other existing drugs and to look for new indications.

(Note 17) Multikinase inhibitors impede the proliferation, infiltration, and metastasis of cancer cells, thereby eradicating them.

(iii) [Antiviral drug: SyB V-1901 (generic name: brincidofovir)]

On September 30, 2019, the Company concluded an exclusive global licensing agreement for antiviral drug brincidofovir ("BCV") with Chimerix Inc. Under this agreement, the Company acquired the exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding orthopox viruses. With the global rights to BCV, the Company will transition into a global specialty pharmaceutical company with an integrated system for supplying high-quality pharmaceutical products.

The Company has decided to prioritize the global development of the intravenous formulation of BCV primarily in Japan, the U.S., and Europe, targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation—a niche area with a high unmet medical need. In March 2021, the Company filed an IND application with the FDA to conduct a Phase II study primarily in pediatric patients (includes adults) suffering from AdV infections. This development program was granted a fast-track designation from the FDA in April 2021, and the investigational drug was administered to the first patient enrolled in the study (first patient in or FPI) in August 2021. Further, in January 2022, the Company successfully filed a CTA to the MHRA.

Based on the knowledge and insight on the safety and efficacy of BCV obtained from the clinical trials targeting AdV

infections, the Company will investigate the effectiveness of BCV in treating various other dsDNA virus infections following hematopoietic stem cell transplantation and aim to expand target indications to include multiviral infections. The Company will also explore the possibility of expanding target areas to viral infections associated with kidney and other organ transplants. In doing so, we aim to expand the market for BCV and maximize the drug's business value. In clinical studies conducted by Chimerix in Europe and the U.S., BCV Oral has been shown to have strong antiviral activity against a broad range of viruses. BCV Oral's antiviral activity against a range of dsDNA viruses suggests that BCV IV may also be safe and effective in the prevention and treatment of various viral infections following hematopoietic stem cell transplantation.

In addition to potent antiviral activity, BCV is also expected to have antitumor effects. Through joint research with the National Cancer Centre Singapore and UCSF Brain Cancer Center, the Company is searching for new indications in oncology, including rare brain tumors and EB virus-positive lymphoma.

In December 2020, Chimerix announced that the FDA had accepted its NDA for BCV Oral as a medical countermeasure against smallpox; the NDA was approved in June 2021.

(4) Medium- to long-term strategy

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

(i) De-risking by post-POC strategy

We in-license drug candidates for which proof of concept (POC) is already confirmed in human subjects in principle. Accordingly, they should be drugs that are in a relatively late stage of clinical development or already on the market overseas. The advanced development is already conducted overseas for these drug candidates and their efficacy and safety are already confirmed in human subjects, thereby reducing the development risk. We utilize existing clinical data available overseas 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 a vast number 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), reduces development risk and development timelines. It also helps to understand how the drug candidates could meet the healthcare needs and to improve the accuracy of revenue projections after the product launch.

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

The Company does not own any research or manufacturing facilities, which are often regarded as the main 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 18)

Many standard drugs 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. As an extremely high degree of specialization is required and developing new agents in these therapeutic areas is 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 further growth and profitability by continuous indication expansion and bringing new products to the market.

(Note 18) "Blue Ocean strategy" means a strategy of redefining the market, avoiding marketplaces with fierce competition in which competitors seek to gain limited market shares (termed "red oceans"), and instead creating a "blue ocean," an unexploited market with reduced competition, enabling profits to be maximized while providing customers with high-value products and services.

(v) Going global beyond Asia

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

In March 2021, the Company filed an IND application to the FDA to conduct a Phase II clinical trial of BCV primarily in pediatric patients (includes adults) with AdV infection. The development program was granted a fast-track designation from the FDA in April 2021, and the investigational drug was administered to the first patient enrolled in the study (first patient in or FPI) in August 2021. Further, in January 2022, the Company successfully filed a CTA to the MHRA.

Based on the knowledge and insight on the safety and efficacy of BCV gained from clinical trials targeting AdV infections, the Company intends to investigate the effectiveness of the antiviral drug in treating various other dsDNA virus infections after hematopoietic stem cell transplantation and expand target indications to include multiviral infections. Further, the Company will explore the possibility of using the drug to treat viral infections associated with kidney and other organ transplants and cancer. Through these efforts, the Company aims to expand the market for BCV and maximize the drug's business value.

(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 L-1101, SyB C-1101, SyB L-1701, SyB L-1702, and antiviral drug SyB V-1901. 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 business value, both in-licensing new drug candidates and promoting product life cycle management are important. Therefore, it is critical to maximize returns from each drug under development through indication expansion after the in-licensed drugs' initial approval.

TREAKISYM® is approved for manufacturing and marketing in Japan for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, chronic lymphocytic leukemia, and first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. TREAKISYM® was also granted approval for recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) in March 2021. In addition, the Company in-licensed the RTD formulation and RI injection of TREAKISYM® from Eagle Pharmaceuticals in order to maximize the business value of TREAKISYM® by promoting the life cycle management of the product. For the RTD formulation, the Company obtained manufacturing and marketing approval in September 2020, and launched the product in January 2021. For the RI injection, the Company filed a partial change application in May 2021.

With respect to rigosertib, U.S. licenser Onconova had been conducting a global Phase III study (INSPIRE study) of the drug in patients with myelodysplastic syndromes (MDS), but in August 2020, it announced that the primary endpoint of the study—improved overall survival compared to physician's choice of treatment—had not been met. The Company is in charge of clinical development in Japan and is reviewing ways to utilize findings from the additional analysis of the INSPIRE study in future development of rigosertib.

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

The Company has proceeded with the global development of antiviral drug brincidofovir targeting adenovirus infections occurring after hematopoietic stem cell transplantation, an area with a high unmet medical need, ahead of any other indications. It has also begun to explore the potential of the drug in treating viral infections associated with organ transplants and virus-induced cancers. We aim to maximize earnings through managing the lifecycle of our products as we transform into a specialty pharmaceutical company with the capacity to expand into global markets.

(iii) The establishment of the Company's own salesforce

With the business partnership agreement with its sales agent Eisai Co., Ltd. (Eisai) expired in December 2020, the Company began preparing to establish its own sales organization for the domestic sales of TREAKISYM® in October 2018 and completed the process in FY 2020. Following the expiration of its business partnership agreement with Eisai, the Company transitioned the sale of TREAKISYM® to its own sales system in December 2020. 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®.

(iv) Global expansion for further growth

In addition to Japan, the Company identifies China, South Korea, Taiwan, and Singapore as strategic countries in Asia 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 challenging. Such a policy may also be implemented by other Asian countries.

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

(v) Securing personnel

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

(vi) Financial issue

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

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

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 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Assets		
Current assets		
Cash and deposits	3,848,626	3,860,106
Accounts receivable–trade	406,988	2,147,510
Merchandise and finished goods	271,550	125,265
Semi-finished goods	672,891	259,940
Supplies	482	479
Advance payments	43,494	192,576
Prepaid expenses	80,645	145,011
Consumption taxes receivable	314,761	—
Other	175,852	16,946
Total current assets	5,815,292	6,747,838
Non-current assets		
Property, plant and equipment		
Buildings	59,123	64,620
Accumulated depreciation	(16,388)	(19,959)
Buildings, net	42,735	44,660
Tools, furniture and fixtures	90,043	72,734
Accumulated depreciation	(56,076)	(33,760)
Tools, furniture and fixtures, net	33,966	38,974
Total property, plant and equipment	76,701	83,634
Intangible assets		
Software	296,005	254,774
Software in progress	5,836	4,330
Total intangible assets	301,841	259,104
Investments and other assets		
Shares of subsidiaries and associates	0	0
Deferred tax assets	—	1,275,759
Lease and guarantee deposits	80,871	86,660
Total investments and other assets	80,871	1,362,419
Total non-current assets	459,415	1,705,159
Total assets	6,274,707	8,452,997
Liabilities		
Current liabilities		
Accounts payable–trade	665,460	69,683
Unearned revenue	192,705	—
Accounts payable–other	645,813	515,075
Income taxes payable	81,928	383,599
Consumption taxes payable	—	516,036
Provision for sales returns	—	4,342
Other	29,431	29,373
Total current liabilities	1,615,339	1, 518,111
Non-current liabilities		
Provision for product changeover	—	186,437
Provision for retirement benefits	2,050	2,776
Total non-current liabilities	2,050	189,213
Total liabilities	1,617,389	1,707,324

(Unit: thousands of yen)

	FY 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Net assets		
Shareholders' equity		
Capital stock	17,044,943	17,157,628
Capital surplus		
Legal capital surplus	17,014,943	17,127,628
Other capital surplus	4,541	4,873
Total capital surplus	17,019,485	17,132,501
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(30,009,713)	(27,977,510)
Total retained earnings	(30,009,713)	(27,977,510)
Treasury shares	(17,538)	(86,045)
Total shareholders' equity	4,037,177	6,226,573
Share acquisition rights	620,140	519,099
Total net assets	4,657,318	6,745,672
Total liabilities and net assets	6,274,707	8,452,997

(2) Statement of income

(Unit: thousands of yen)

	FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Net sales		
Net sales of goods	2,977,051	8,256,924
Rights income	10,000	—
Total net sales	2,987,051	8,256,924
Cost of sales		
Beginning merchandise inventory	—	944,442
Cost of purchased goods	3,163,251	2,145,244
Purchase allowance and returns	98,611	—
Total	3,064,640	3,089,686
Ending merchandise inventory	*1, 944,442	*1, 637,214
Cost of goods sold	2,120,198	2,452,471
Gross profit	866,853	5,804,452
Provision for sales returns	—	4,342
Net gross profit	866,853	5,800,110
Selling, general and administrative expenses	*2, *3 5,373,073	*2, *3 4,784,109
Operating profit (loss)	(4,506,220)	1,016,001
Non-operating income		
Interest income	137	57
Interest on tax refund	120	68
Dividend income of insurance	2,324	2,579
Commission income	—	14,757
Other	2	0
Total non-operating income	2,585	17,462
Non-operating expenses		
Commission expenses	43,958	9,499
Share issuance costs	27,021	1,950
Foreign exchange losses	41,287	20,186
Other	—	693
Total non-operating expenses	112,268	32,330
Ordinary profit (loss)	(4,615,903)	1,001,133
Extraordinary income		
Gain on reversal of share acquisition rights	4,341	198
Settlement received	525,145	—
Total extraordinary income	529,486	198
Profit (loss) before income taxes	(4,086,416)	1,001,331
Income taxes–current	3,800	244,887
Income taxes–deferred	—	(1,275,759)
Total income taxes	3,800	(1,030,871)
Profit (loss)	(4,090,216)	2,032,203

(3) Statement of changes in equity

FY 2020 (from January 1, 2020 to December 31, 2020)

(Unit: thousands of yen)

	Shareholders' equity						
	Capital stock	Capital surplus			Retained earnings		Treasury shares
		Legal capital surplus	Other capital surplus	Total capital surplus	Other retained earnings: Retained earnings brought forward	Total retained earnings	
Balance at beginning of current period	14,870,639	14,840,639	2,498	14,843,137	(25,919,496)	(25,919,496)	(15,077)
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	2,174,304	2,174,304		2,174,304			
Profit (loss)					(4,090,216)	(4,090,216)	
Purchase of treasury shares							(6,387)
Disposal of treasury shares			2,043	2,043			3,926
Net changes of items other than shareholders' equity							
Total changes of items during period	2,174,304	2,174,304	2,043	2,176,347	(4,090,216)	(4,090,216)	(2,461)
Balance at end of current period	17,044,943	17,014,943	4,541	17,019,485	(30,009,713)	(30,009,713)	(17,538)

	Shareholders' equity: Total shareholders' equity	Share acquisition rights	Total net assets
Balance at beginning of current period	3,779,202	620,913	4,400,116
Changes of items during period			
Issuance of new shares (exercise of share acquisition rights)	4,348,608		4,348,608
Profit (loss)	(4,090,216)		(4,090,216)
Purchase of treasury shares	(6,387)		(6,387)
Disposal of treasury shares	5,969		5,969
Net changes of items other than shareholders' equity		(772)	(772)
Total changes of items during period	257,974	(772)	257,201
Balance at end of current period	4,037,177	620,140	4,657,318

FY 2021 (from January 1, 2021 to December 31, 2021)

(Unit: thousands of yen)

		Shareholders' equity					
		Capital surplus			Retained earnings		
	Capital stock	Legal capital surplus	Other capital surplus	Total capital surplus	Other retained earnings Retained earnings brought forward	Total retained earnings	Treasury shares
Balance at beginning of current period	17,044,943	17,014,943	4,541	17,019,485	(30,009,713)	(30,009,713)	(17,538)
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	112,684	112,684		112,684			
Profit (loss)					2,032,203	2,032,203	
Purchase of treasury shares							(68,825)
Disposal of treasury shares			331	331			318
Net changes of items other than shareholders' equity							
Total changes of items during period	112,684	112,684	331	113,015	2,032,203	2,032,203	(68,507)
Balance at end of current period	17,157,628	17,127,628	4,873	17,132,501	(27,977,510)	(27,977,510)	(86,045)

	Shareholders' equity Total shareholders' equity	Share acquisition rights	Total net assets
Balance at beginning of current period	4,037,177	620,140	4,657,318
Changes of items during period			
Issuance of new shares (exercise of share acquisition rights)	225,368		225,368
Profit (loss)	2,032,203		2,032,203
Purchase of treasury shares	(68,825)		(68,825)
Disposal of treasury shares	649		649
Net changes of items other than shareholders' equity		(101,041)	(101,041)
Total changes of items during period	2,189,396	(101,041)	2,088,354
Balance at end of current period	6,226,573	519,099	6,745,672

(4) Statement of cash flows

(Unit: yen in thousands)

	FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Cash flows from operating activities		
Profit (loss) before income taxes	(4,086,416)	1,001,331
Depreciation	63,835	93,959
Amortization of guarantee deposits	952	1,223
Share-based remuneration expenses	102,378	124,270
Increase (decrease) in provision for retirement benefits	431	726
Increase (decrease) in provision for sales returns	—	4,342
Increase (decrease) in provision for product changeover	—	186,437
Interest income	(137)	(57)
Settlement received	(525,145)	—
Foreign exchange losses (gains)	1,501	(14,209)
Commission expenses	43,958	9,499
Share issuance cost	27,021	1,950
Gain on reversal of share acquisition rights	(4,341)	(198)
Loss on retirement of non-current assets	37	693
Decrease (increase) in trade receivables	142,286	(1,740,521)
Decrease (increase) in inventories	(944,442)	559,235
Decrease (increase) in prepaid expenses	10,398	(64,366)
Decrease (increase) in advances paid	41,791	—
Increase/decrease in consumption taxes payable/consumption taxes refund receivable	(39,436)	830,797
Decrease (increase) in other current assets	(203,578)	9,825
Increase (decrease) in notes and accounts payable–trade	544,546	(595,776)
Increase (decrease) in accounts payable–other	29,132	(125,188)
Increase (decrease) in other current liabilities	190,341	(132,180)
Others	—	1,489
Subtotal	(4,604,882)	153,285
Interest and dividends received	153	57
Settlement package received	525,145	—
Commitment fee paid	(41,000)	(9,499)
Income taxes paid	(1,900)	(3,800)
Net cash provided by (used in) operating activities	(4,122,483)	140,042
Cash flows from investing activities		
Purchase of property, plant and equipment	(15,667)	(25,454)
Purchase of intangible assets	(133,264)	(38,383)
Payments of leasehold and guarantee deposits	(11,377)	(7,011)
Net cash provided by (used in) investing activities	(160,309)	(70,849)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	4,244,690	254
Proceeds from issuance of share acquisition rights	10,540	—
Payments for issuance of shares	(27,290)	(4,001)
Purchase of treasury shares	(6,387)	(68,825)
Proceeds from disposal of treasury shares	538	649
Net cash provided by (used in) financing activities	4,222,090	(71,922)
Effect of exchange rate change on cash and cash equivalents	(1,501)	14,209
Net increase (decrease) in cash and cash equivalents	(62,203)	11,480
Cash and cash equivalents at beginning of period	3,910,830	3,848,626
Cash and cash equivalents at end of period	*1 3,848,626	*1 3,860,106

(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 and associates

Shares of subsidiaries and associates 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

Merchandise and finished goods are stated at cost determined by the first-in, first-out method, while semi-finished goods are stated at cost determined by the weighted-average method. The amount on the balance sheet is calculated by reducing book value when the contribution of inventories to profitability declines.

4. Depreciation and amortization of non-current assets

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

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

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

Buildings	3 to 18 years
Tools, furniture and fixtures	4 to 20 years

(2) Intangible assets (excluding lease assets)

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

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

(3) Lease assets

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

5. Deferred assets

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

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

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

7. Basis for reserves and provisions

Provision for retirement benefits

The provision for retirement benefits is provided based on an estimated amount for retirement benefit obligations as of the end of the fiscal year under review.

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.

Provision for sales returns

The provision for sales return is provided to prepare for losses from returned products sold, an amount equivalent to losses based on the estimated amount of future returns is recorded.

Provision for product changeover

The provision for product changeover is provided to prepare for expenses to be incurred in connection with the changeover from FD to RTD formulation, the estimated amount of such expenses is recorded.

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

(Change in accounting methods)

(Change in inventory valuation methods)

The Company previously valued its inventory using the weighted-average method, but from the first quarter of FY 2021, it has adopted the first-in, first-out method for merchandise and finished goods and the weighted-average method for semi-finished goods. The transition to in-house sales has enabled the Company to better monitor and understand the flow of inventory, prompting it to reexamine its definition of and valuation methods for inventory to allow for more appropriate inventory valuation and profit/loss calculation.

As a result, the Company adopted the first-in, first-out method for merchandise and finished goods and the weighted-average method for semi-finished goods to better reflect the flow of its inventory. The Company determined that these methods were rational from the perspective of ensuring appropriate inventory valuation and profit/loss calculation, and that these methods better reflected the Company's business conditions.

The Company has not retrospectively applied the revised valuation methods to previous results as the impact of the change was negligible.

(Change in presentation)

(Balance sheet)

The transition to in-house sales has enabled the Company to better understand and monitor the flow of its inventory, prompting it to revise its definition of merchandise and finished goods, as well as of semi-finished goods, to allow for more appropriate inventory valuation and profit/loss calculation.

As a result, the Company replaced merchandise and finished goods of 944,442 thousand yen at the previous fiscal year-end recorded under the current assets section of the balance sheet with semi-finished goods of 672,891 thousand yen and merchandise and finished goods of 271,550 thousand yen.

(Accounting Standards Not Yet Applied, etc.)

- "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020, Accounting Standards Board of Japan)
- "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30, March 26, 2021, Accounting Standards Board of Japan)

(1) Overview

The International Accounting Standards Board (IASB) and the Financial Accounting Standards Board (FASB) in

the United States jointly developed comprehensive accounting standards for revenue recognition, and in May 2014 published “Revenue from Contracts with Customers” (IFRS 15 at IASB, Topic 606 at FASB). Given that IFRS 15 will be applied to fiscal years with dates on or after January 1, 2018 and Topic 606 will be applied to fiscal years with dates after December 15, 2017, the Accounting Standards Board of Japan (ASBJ) has developed comprehensive accounting standards for revenue recognition and published them along with the Implementation Guidance.

The basic policy of the ASBJ in developing accounting standards for revenue recognition is thought to be setting accounting standards, with the incorporation of the basic principles of IFRS 15 as a starting point, from a standpoint of comparability between financial statements, which is one of the benefits of ensuring consistency with IFRS 15, and to add alternative accounting treatments without losing comparability if there is an item that should be taken into account in practices, etc. that have been conducted in Japan.

(2) Planned date of application

To be applied at the beginning of the fiscal year ending December 31, 2022.

(3) Effect of application of the accounting standards, etc.

Application of the “Accounting Standard for Fair Value Measurement,” etc. will have a negligible impact on financial statements

- “Accounting Standard for Fair Value Measurement” (ASBJ Statement No. 30, July 4, 2019, Accounting Standards Board of Japan)
- “Implementation Guidance on Accounting Standard for Fair Value Measurement” (ASBJ Guidance No. 31, July 4, 2019, Accounting Standards Board of Japan)
- “Accounting Standard for Measurement of Inventories” (ASBJ Statement No. 9, July 4, 2019, Accounting Standards Board of Japan)
- “Accounting Standard for Financial Instruments” (ASBJ Statement No. 10, July 4, 2019, Accounting Standards Board of Japan)
- “Implementation Guidance on Disclosures about Fair Value of Financial Instruments” (ASBJ Guidance No. 19, March 31, 2020, Accounting Standards Board of Japan)

(1) Overview

In light of virtually identical and detailed guidance issued by the International Accounting Standards Board (IASB) and the U.S. Financial Accounting Standards Board (FASB), specifically “Fair Value Measurement” (IFRS 13) under international financial reporting standards and Accounting Standards Codification – “Fair Value Measurement (Topic 820)” under U.S. accounting standards, the Accounting Standards Board of Japan (ASBJ) has taken steps to bringing Japan standards into conformity with international accounting standards, particularly with respect to guidance and disclosure regarding the fair value of financial instruments. This decision resulted in announcement of the Accounting Standard for Fair Value Measurement.

As a basic policy in development of the accounting standard regarding measurement of fair value, ASBJ opted essentially to adopt IFRS 13 in its entirety, with a view to improving the comparability of financial statements between Japanese and foreign companies by utilizing a unified measurement approach. Additionally, in consideration of actual practice in Japan to date, ASBJ has defined other procedures with respect to individual item

categories within a scope that will not significantly harm comparability between financial statements.

(2) Planned date of application

To be applied at the beginning of the fiscal year ending December 31, 2022.

(3) Effect of application of the accounting standards, etc.

Application of the "Accounting Standard for Fair Value Measurement," etc. will have a negligible impact on 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 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Total amounts of bank overdraft limit and loan commitment line	3,150,000	3,150,000
Balance of borrowing outstanding	—	—
Unused balance	3,150,000	3,150,000

(Statement of income)

* 1 The amount of inventories at the end of each fiscal year is book value after the write-down due to decreased profitability, and the following valuation loss is included in the cost of sales.

(Unit: thousands of yen)

FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
187,840	275,633

* 2 The selling expenses ratio is roughly 24.2% and 34.4% for FY 2020 and FY 2021, respectively, and the general and administrative expenses ratio is roughly 75.8% and 65.6% for FY 2020 and FY 2021, respectively.

Major expense items and amounts are as follows:

(Unit: thousands of yen)

	FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Remuneration for directors (and other officers)	119,105	119,643
Salaries and allowance	410,547	453,632
Retirement benefit expenses	753	853
Research and development expenses	2,266,556	1,736,126
Depreciation	40,171	68,737
Fee expenses	405,325	38,318
Promotion expenses	1,301,048	1,642,559

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

(Unit: thousands of yen)

FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
2,266,556	1,736,126

(Statement of changes in equity)

FY 2020 (from January 1, 2020 to December 31, 2020)

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	26,437,681	11,765,275	—	38,202,956
Total	26,437,681	11,765,275	—	38,202,956
Treasury shares				
Common stock	22,593	13,900	6,350	30,143
Total	22,593	13,900	6,350	30,143

(Notes) 1. Increase of 11,765,275 issued shares of common stock is due to the exercise of share acquisition rights.
2. Increase of 13,900 issued shares of common stock is due to the purchase of fractional shares.
3. Of the decrease of 6,350 common treasury shares, 5,200 were due to exercise of share acquisition rights, and 1,150 were sold to owners of fractional shares.

2. Share acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2018 (thousands of yen)
			At beginning of current period	Increase	Decrease	At end of current period	
SymBio Pharmaceuticals Limited	The 47th warrant	Common stock	1,675,000	—	1,675,000	—	—
	The 50th warrant	Common stock	—	7,000,000	7,000,000	—	—
	The 51th warrant	Common stock	—	3,000,000	3,000,000	—	—
	Share acquisition rights as stock options	—	—	—	—	—	620,140
Total			1,675,000	10,000,000	11,675,000	—	620,140

(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 47th warrant: 1,675,000 shares

Increase due to issuance of the 50th warrant: 7,000,000 shares

Decrease due to exercise of the 50th warrant: 7,000,000 shares

Increase due to issuance of the 51st warrant: 3,000,000 shares

Decrease due to exercise of the 51st warrant: 3,000,000 shares

3. Dividends

None to be reported.

FY 2021 (from January 1, 2021 to December 31, 2021)

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	38,202,956	254,250	—	38,457,206
Total	38,202,956	254,250	—	38,457,206
Treasury shares				
Common stock	30,143	53,025	550	82,618
Total	30,143	53,025	550	82,618

(Notes) 1. Increase of 254,250 issued shares of common stock is due to the exercise of share acquisition rights.
2. Increase of 53,025 issued shares of common stock is due to the purchase of fractional shares.
3. The decrease of 550 common treasury shares is due to sales to owners of fractional shares.

2. Share acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2018 (thousands of yen)
			At beginning of current period	Increase	Decrease	At end of current period	
SymBio Pharmaceuticals Limited	Share acquisition rights as stock options	—	—	—	—	—	519,099
Total			—	—	—	—	519,099

(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.”

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 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Cash and deposits	3,848,626	3,860,106
Cash and cash equivalents	3,848,626	3,860,106

(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 60 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 department in charge of these matters 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.

(5) Concentration of credit risk

As of the end of the fiscal year under review, 100% of 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 2020 (as of December 31, 2020)

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Differences
(1) Cash and deposits	3,848,626	3,848,626	—
(2) Accounts receivable–trade	406,988	406,988	—
(3) Consumption taxes receivable	314,761	314,761	—
Assets, total	4,570,376	4,570,376	—
(1) Accounts payable–trade	665,460	665,460	—
(2) Accounts payable–other	645,813	645,813	—
(3) Income taxes payable	81,928	81,928	—
(4) Accrued consumption taxes	—	—	—
Liabilities, total	1,393,202	1,393,202	—
Derivative transactions, total (*)	—	—	—

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

FY 2021 (as of December 31, 2021)

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Differences
(1) Cash and deposits	3,860,106	3,860,106	—
(2) Accounts receivable–trade	2,147,510	2,147,510	—
(3) Consumption taxes receivable	—	—	—
Assets, total	6,007,617	6,007,617	—
(1) Accounts payable–trade	69,683	69,683	—
(2) Accounts payable–other	515,075	515,075	—
(3) Income taxes payable	383,599	383,599	—
(4) Accrued consumption taxes	516,036	516,036	—
Liabilities, total	1,484,394	1,484,394	—
Derivative transactions, total (*)	—	—	—

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

shown in parentheses.

(Notes)

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

Assets

(1) Cash and deposits, (2) Accounts receivable–trade, and (3) Consumption taxes receivable

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, (3) Income taxes payable, and (4) Accrued consumption taxes

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

Derivative transactions

None to be reported.

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

(Unit: thousands of yen)

	FY 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Lease and guarantee deposits	80,871	86,660

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

FY 2020 (as of December 31, 2020)

(Unit: thousands of yen)

	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Deposits	3,848,535	—	—	—
Accounts receivable–trade	406,988	—	—	—
Consumption taxes receivable	314,761	—	—	—
Total	4,570,285	—	—	—

FY 2021 (as of December 31, 2021)

(Unit: thousands of yen)

	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Deposits	3,860,106	—	—	—
Accounts receivable–trade	2,147,510	—	—	—
Consumption taxes receivable	—	—	—	—
Total	6,007,617	—	—	—

(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 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Provision for retirement benefits at beginning of period	1,619	2,050
Retirement benefit expenses	530	726
Paid amount of retirement benefits	(99)	—
Provision for retirement benefits at end of period	2,050	2,776

(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 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Retirement benefit obligations under non-contributory plan	2,050	2,776
Net defined benefit liability or asset on the balance sheet	2,050	2,776
Provision for retirement benefits	2,050	2,776
Net defined benefit liability or asset on the balance sheet	2,050	2,776

(3) Retirement benefit expenses

Retirement benefit expenses calculated under the simplified method FY 2020: 530 thousand yen
FY 2021: 726 thousand yen

3. Defined contribution pension plan

The amount of the Company's contribution to the defined contribution pension plan for FY 2020 and FY 2021 were 2,518 thousand yen and 2,546 thousand yen, respectively.

(Stock options)

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

(Unit: thousands of yen)

	FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Selling, general and administrative expenses	102,378	124,270

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

(Unit: thousands of yen)

	FY 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Gain on reversal of share acquisition rights	4,341	198

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

The following information is based on stock options that were available in the fiscal year ended December 31, 2021. The number of stock options is converted into the number of shares.

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

(1) Description of stock options

	The 24th Warrant	The 25th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 5	Employees of the Company 59
Class and number of shares to be issued upon the exercise of the stock options	Common stock 48,000 shares	Common stock 48,750 shares
Grant date	March 31, 2011	March 31, 2011
Vesting conditions	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. 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 31, 2013 to March 30, 2021	From March 31, 2013 to March 30, 2021

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

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

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

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

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

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

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

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

	The 52th Warrant	The 53rd Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 4	Employees of the Company 119
Class and number of shares to be issued upon the exercise of the stock options	Common stock 115,000 shares	Common stock 375,000 shares
Grant date	April 24, 2020	April 24, 2020
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 27, 2023 to March 26, 2030	From March 27, 2023 to March 26, 2030

	The 54th Warrant	The 55th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 5	Employees of the Company 134
Class and number of shares to be issued upon the exercise of the stock options	Common stock 40,750 shares	Common stock 114,125 shares
Grant date	April 23, 2021	April 23, 2021
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 25, 2024 to March 24, 2031	From March 25, 2024 to March 24, 2031

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

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

The 26th and the 27th warrants

(a) Those who were granted the share acquisition rights may exercise the rights within the limit of one-fourth (1/4) from April 18, 2014 to April 17, 2015.

(b) Those who were granted the share acquisition rights may exercise the rights within the limit of one-half (1/2) from April 18, 2015 to April 17, 2016.

(c) Those who were granted the share acquisition rights may exercise the rights within the limit of three-fourths (3/4) from April 18, 2016 to April 17, 2017.

(d) Those who were granted the share acquisition rights may exercise all the rights from April 18, 2017 to April 17, 2022.

The 30th and the 31st warrants

(a) Those who were granted the share acquisition rights may exercise the rights within the limit of one-fourth (1/4) from May 15, 2015 to May 14, 2016.

(b) Those who were granted the share acquisition rights may exercise the rights within the limit of one-half (1/2) from May 15, 2016 to May 14, 2017.

(c) Those who were granted the share acquisition rights may exercise the rights within the limit of three-fourths (3/4) from May 15, 2017 to May 14, 2018.

(d) Those who were granted the share acquisition rights may exercise all the rights from May 15, 2018 to May 14, 2023.

(3) The Person Granted shall exercise the rights starting from the date of resolution by the below-mentioned shareholders' meeting or the Board of Directors' meeting until one day before the effective date of the Organizational Restructuring as followed, regardless of the conditions of the exercise period originally stipulated, when the Organizational Restructuring is approved by the resolution of the Company's shareholders' meeting (including the case where resolution of a shareholders' meeting is deemed to exist pursuant to the provision of Article 319 of the Companies Act) or the Board of Directors' meeting (limited to the case where no shareholders' meeting is required for the said Organizational Restructuring) before the exercise period of the share acquisition rights comes into effect: an absorption-type merger or an incorporation-type merger where the Company becomes a dissolving company and an absorption-type split or an incorporation-type company split where the Company becomes a split company, or a share exchange or a share transfer where the Company becomes a wholly-owned subsidiary (collectively, "Organizational Restructuring" as mentioned above).

(4) The share acquisition rights shall not be offered for pledge or disposed of in any other way.

(5) A person to whom these stock options are granted ("Person Granted") must have the status as the Company's director, Audit & Supervisory Board member, or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case where:

(a) The Person Granted is a director or Audit & Supervisory Board member of the Company or its affiliates and retires due to the expiry of her/his term.

(b) The Person Granted is an employee of the Company or its affiliates and retires due to compulsory retirement.

(c) The Person Granted is a director, Audit & Supervisory Board member, or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition.

(6) In the event that:

(a) The Person Granted dies before the exercise period comes into effect, the beneficiary/ies shall exercise the rights of up to one-half (1/2) within six (6) months from the date of inheritance, or

(b) The Person Granted dies during the exercise period, the beneficiary/ies shall exercise all the rights within six (6) months from the date of inheritance. However, in the event that the beneficiary/ies dies, the rights shall be discarded and shall not be exercised by his/her beneficiary/ies.

(7) The Person Granted must have the status as a director or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case where:

(a) The Person Granted is a director of the Company or its affiliates and retires due to the expiry of her/his term.

(b) The Person Granted is an employee of the Company or its affiliates and retires due to compulsory retirement.

(c) The Person Granted is a director or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition.

(8) In the event that the Person Granted dies, the beneficiary/ies shall be able to succeed and exercise the share acquisition rights as prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted. However, in the event that the beneficiary/ies dies, the rights shall be discarded and shall not be exercised by his/her beneficiary/ies.

(2) Changes in the size of stock options

(a) Number of stock options

(Unit: number of shares)

	The 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	48,000	19,125	90,625	43,375
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	48,000	19,125	—	—
At the end of the year	—	—	90,625	43,375

(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	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	29,000	11,925	17,250	15,175
Vested	—	—	—	—
Exercised	—	—	17,250	5,550
Expired	—	—	—	—
At the end of the year	29,000	11,925	—	9,625

(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	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	14,050	20,500	17,750	31,325
Vested	—	—	—	—
Exercised	11,475	8,125	17,750	18,875
Expired	—	—	—	—
At the end of the year	2,575	12,375	—	12,450

(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	—	—	42,500	62,325
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	42,500	62,325
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	65,000	42,800	33,750	14,000
Vested	—	—	42,500	62,325
Exercised	60,000	20,650	57,500	37,075
Expired	—	—	—	250
At the end of the year	5,000	22,150	18,750	39,000

(Unit: number of shares)

	The 48th Warrant	The 49th Warrant	The 52nd Warrant	The 53rd Warrant
Grant date	April 22, 2019	April 22, 2019	April 24, 2020	April 24, 2020
Non-vested shares:				
At the beginning of the year	47,500	122,375	115,000	297,750
Granted	—	—	—	—
Expired	—	16,500	—	27,250
Vested	—	—	25,000	—
At the end of the year	47,500	105,875	90,000	270,500
Vested shares:				
At the beginning of the year	6,250	2,250	—	—
Vested	—	—	25,000	—
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	6,250	2,250	25,000	—

(Unit: number of shares)

	The 54th Warrant	The 55th Warrant
Grant date	April 23, 2021	April 23, 2021
Non-vested shares:		
At the beginning of the year	—	—
Granted	40,750	114,125
Expired	4,500	4,750
Vested	—	—
At the end of the year	36,250	109,375
Vested shares:		
At the beginning of the year	—	—
Vested	—	—
Exercised	—	—
Expired	—	—
At the end of the year	—	—

(b) Per share prices

	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)	2,728	2,728	2,220	2,220
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen) (Note 2)	0	0	(a) 716 (b) 748 (c) 780 (d) 808	(a) 716 (b) 748 (c) 780 (d) 808

	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)	3,196	3,196	1	1
Average stock price at the time of exercise (yen)	—	—	1,129	1,177
Fair value price at grant date (yen) (Note 2)	(a) 2,344 (b) 2,408 (c) 2,468 (d) 2,524	(a) 2,344 (b) 2,408 (c) 2,468 (d) 2,524	916	916

	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)	1,126	1,157	1,127	1,162
Fair value price at grant date (yen)	1,224	1,224	1,088	1,088

	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)	1,119	1,187	1,135	1,393
Fair value price at grant date (yen)	812	812	792	792

	The 48th Warrant	The 49th Warrant	The 52nd Warrant	The 53rd Warrant
Grant date	April 22, 2019	April 22, 2019	April 24, 2020	April 24, 2020
Exercise price (yen)	1	1	1	1
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	776	776	324	324

	The 54th Warrant	The 55th Warrant
Grant date	April 23, 2021	April 23, 2021
Exercise price (yen)	1	1
Average stock price at the time of exercise (yen)	—	—
Fair value price at grant date (yen)	1,169	1,169

(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 54th Warrant	The 55th Warrant
Volatility of stock price (Note 1)	71.90%	71.90%
Estimated remaining period (Note 2)	2.92 years	2.92 years
Estimated dividend (Note 3)	0 yen per share	0 yen per share
Risk-free interest rate (Note 4)	(0.14)%	(0.14)%

(Notes) 1. The volatility was calculated based on the actual stock prices from May 22, 2018 to April 23, 2021.

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

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

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

5. Estimate of the number of stock options vested

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

(Asset retirement obligations)

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

(Segment information)

[Segment information]

FY 2020 (from January 1, 2020 to December 31, 2020) and FY 2021 (from January 1, 2021 to December 31, 2021)

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 2020 (from January 1, 2020 to December 31, 2020)

1. Information by product and service

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

2. Information about geographical areas

(1) Net sales

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

(2) Property, plant and equipment

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

3. Information by the major customer

(Unit: thousands of yen)

Name of customer	Net sales	Name of related segment
Eisai Co., Ltd.	2,545,650	Pharmaceutical businesses including research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities
Suzuken Co., Ltd.	125,526	Pharmaceutical businesses including research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities
Toho Pharmaceutical Co., Ltd.	119,510	Pharmaceutical businesses including research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities

FY 2021 (from January 1, 2021 to December 31, 2021)

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
Suzuken Co., Ltd.	5,042,274	Pharmaceutical businesses including research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities
Toho Pharmaceutical Co., Ltd.	3,426,221	Pharmaceutical businesses including 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 2020 (from January 1, 2020 to December 31, 2020) and FY 2021 (from January 1, 2021 to December 31, 2021)

None to be reported.

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

FY 2020 (from January 1, 2020 to December 31, 2020) and FY 2021 (from January 1, 2021 to December 31, 2021)

None to be reported.

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

FY 2020 (from January 1, 2020 to December 31, 2020) and FY 2021 (from January 1, 2021 to December 31, 2021)

None to be reported.

(Affiliated party information)

Transactions with affiliated parties

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

FY 2020 (from January 1, 2020 to December 31, 2020)

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: 2.36	—	Exercise of share acquisition rights	40,565 (37,250 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 March 30, 2016.

FY 2021 (from January 1, 2021 to December 31, 2021)

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: 2.83	—	Exercise of share acquisition rights	58,217 (72,500 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 March 29, 2017 and March 29, 2018.

(Per share information)

FY 2020 (from January 1, 2020 to December 31, 2020)		FY 2021 (from January 1, 2021 to December 31, 2021)	
Net assets per share	105.76 yen	Net assets per share	162.26 yen
Loss per share	(124.13) yen	Net income per share	53.04 yen
Dilutive net income per share	—	Dilutive net income per share	52.32 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 2020 (from January 1, 2020 to December 31, 2020)	FY 2021 (from January 1, 2021 to December 31, 2021)
Net income (Loss) per share		
Net income (Loss) (thousands of yen)	(4,090,216)	2,032,203
Amount not attributable to the shareholders of common stock (thousands of yen)	—	—
Net income (Loss) attributable to the shareholders of common stock (thousands of yen)	(4,090,216)	2,032,203
Average number of shares outstanding during the year (shares)	32,950,201	38,313,220
Dilutive net income per share		
Net income adjustment (thousands of yen)	—	—
Increase in number of common stock	—	526,804
(Warrant)	—	(526,804)
Description of potential dilutive shares not included in the earning-per-share calculation due to anti-dilution, with significant changes from the end of the previous fiscal year	3 types of share acquisition rights (1,209,600 units) in accordance with the Companies Act Article 236, 238, and 239.	—

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

	FY 2020 (as of December 31, 2020)	FY 2021 (as of December 31, 2021)
Net assets (thousands of yen)	4,657,318	6,745,672
Amount to be deducted from net assets (thousands of yen)	620,140	519,099
(Of which, share acquisition rights herein [thousands of yen])	(620,140)	(519,099)
Net assets attributable to the shareholders of common stock (thousands of yen)	4,037,177	6,226,573
Number of shares used in the calculation of net assets per share (shares)	38,172,813	38,374,588

(Significant subsequent events)

None to be reported.

6. Other

(1) Change in officers

For information regarding change in officers, see the “Notice of Appointment of Corporate Officer” released on December 20, 2021 and “Notice of Appointment of Vice President and COO” released on December 24, 2021.

(2) Other

None to be reported.