

March 24, 2021

**Annual Report**  
(January 1, 2020 through December 31, 2020)

**1. Business Performance of SymBio Pharmaceuticals Limited**

**(1) Business conditions and operating results**

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

(i) Domestic business

[Establishment of the Company's own sales organization]

With its business partnership agreement with Eisai Co., Ltd. ("Eisai") set to expire in December 2020, SymBio began preparing to establish its own sales organization for the sale of TREAKISYM® in Japan in October 2018.

In the fiscal year ended December 31, 2020 (hereafter "FY 2020"), the Company identified needs of each region and formulated detailed proposals to address these needs. In efforts to establish a salesforce with enhanced productivity, the Company assigned 53 medical representatives across the nation and nine hematology experts to each region of operation.

Further, to establish a nationwide distribution system, in September 2020 the Company concluded basic agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. for the distribution of pharmaceutical products, and after the partnership agreement with Eisai expired, began transactions with these two companies as its sole wholesalers. For a nationwide logistics system, the Company began collaborating with S.D. Collabo Co., Ltd and set up two logistics centers—one in Eastern and the other in Western Japan.

Through these efforts, the Company established its own sales organization, and following the expiration of its partnership agreement with Eisai, transitioned the sale of TREAKISYM® to its own sales system in December 2020.

Achieving profitability in FY 2021 and sustaining earnings growth thereafter are important issues for the Company, and with the transition to its own sales organization, its prospects for future growth have become solid.

[Stable supply of products]

SymBio imports lyophilized powder formulation of TREAKISYM® from Astellas Deutschland GmbH ("Astellas Deutschland"), a subsidiary of Astellas Pharma Inc. In the first half of FY 2020, some batches imported from Astellas Deutschland were found to contain impurities and had appearance defects, causing TREAKISYM® inventories at Eisai to trend at a lower level year-on-year. However, in the second half of the fiscal year, the Company conducted secondary packaging and

quality tests for a number of imported batches, bringing the Company's inventory of the product back to its normal level.

The Company obtained manufacturing and marketing approval for the ready-to-dilute (RTD) liquid formulation of TREAKISYM<sup>®</sup>, for which it entered an exclusive license agreement with Eagle Pharmaceuticals Inc. (head office: New Jersey, U.S.) in September 2020. In the fourth quarter of FY 2020, we began importing and delivering to wholesalers the RTD formulation scheduled for market launch in January 2021.

[Stable supply of products]

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In the fourth quarter of FY 2020, the Company obtained manufacturing and marketing approval for the ready-to-dilute (RTD) liquid formulation of TREAKISYM<sup>®</sup>, for which it entered an exclusive license agreement with Eagle Pharmaceuticals Inc. (head office: New Jersey, U.S.) in September 2020, and began importing and delivering to wholesalers the RTD formulation scheduled for market launch in January 2021.

- (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<sup>®</sup>, 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-CD20 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<sup>®</sup> intravenous infusion (generic name: tisagenlecleucel, marketed by Novartis Pharma K.K.): Kymriah<sup>®</sup> 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<sup>®</sup> for use in the treatment of CD19 positive relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive DLBCL in March 2019. Kymriah<sup>®</sup> intravenous infusion was included in NHI price listings in May 2019.
- (Note 5) Chimeric antigen receptor T-cell (CAR-T) therapy is a type of tumor-specific T-cell infusion therapy that introduces genes that code chimeric antigen receptors (CARs) into T-cells, amplifies these cells and then infuses them. These chimeric antigen receptors are produced by combining the intracellular domains of T-cell receptors with the antigen binding sites of antibodies capable of recognizing

membrane antigens attached to tumor cells. In clinical trials using CARs to target CD19 that expresses on B-cells, CD19-targeting CARs were introduced into T-cells that were later administered to patients with B-cell tumors. These modified cells produced clear clinical effects.

- (Note 6) Developed by Roche using Seattle Genetics' antibody-drug conjugate (ADC) technology, polatuzumab vedotin is a first-in-class anti-CD79b ADC (targeting CD79b) built by conjugating humanized monoclonal antibody targeting CD79b to a tubulin polymerization inhibitor. CD79b protein is specifically expressed on the surface of many B-cells, and is expected to be a promising target in new drug development. Polatuzumab vedotin selectively binds to CD79b while minimally affecting normal cells, and destroys B-cells with the chemotherapeutic agent it contains.
- (Note 7) Ready-to-dilute (RTD) and rapid infusion (RI) are pre-dissolved liquid formulations that differ from currently available lyophilized (freeze-dried) powder injection. RTD will significantly reduce the preparation time and labor cost for healthcare providers, and RI will reduce infusion duration to 10 minutes from the current 60 minutes, providing significant benefit and value to both patients and healthcare providers.

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

U.S. licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S., "Onconova") is conducting 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 additional analysis of the INSPIRE study in the future development of rigosertib.

As for the oral formulation of rigosertib, Onconova completed a Phase I/II clinical trial of the investigational drug (in combination with azacitidine (Note 8)) in the U.S. in first-line HR-MDS patients, and the results suggested that the oral formulation of rigosertib and azacitidine used in combination were safe and effective. In June 2017, the Company initiated a Phase I clinical trial 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 TREAKISYM® and rigosertib, the Company intends to conduct joint research with the Institute of Medical Science, the University of Tokyo, 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.

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

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

On September 30, 2019, the Company concluded an exclusive global licensing agreement for intravenous and oral formulation of antiviral drug brincidofovir (Note 9) (SyB V-1901; “BCV IV” and “BCV Oral,” respectively) with Chimerix Inc. (head office: North Carolina, U.S., “Chimerix”). Under this agreement, the Company acquired exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding smallpox.

As a result of the review at the Global Advisory Board meeting convened in February 2020, the Company decided to prioritize the global development of BCV IV targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, an area with high unmet medical needs as there currently exists no effective treatment, primarily in Japan, the U.S., and Europe. Leveraging its knowledge of the efficacy and safety of BCV obtained from clinical trials, 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 of the drug to viral infections after kidney or other organ transplantation. Through these efforts, the Company aims to expand the market for BCV and maximize its business value. Currently, the Company is preparing to start clinical trials of BCV IV targeting AdV infections in children scheduled for FY 2021.

BCV Oral demonstrated highly active antiviral effects in clinical trials conducted in Europe and the U.S. by Chimerix. 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 December 2020, Chimerix announced that the U.S. Food and Drug Administration (FDA) accepted its filing of a New Drug Application (NDA) for BCV as a medical countermeasure for smallpox. The FDA granted BCV a priority review designation and based on the Prescription Drug User Fee Act (PDUFA), set the PDUFA date for April 7, 2021.

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

(Note 10) Double-stranded DNA (dsDNA) viruses include herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as CMV, AdV, HHV-6, BK virus, HSV1/2, VZV, HPV, JCV, and small pox virus.

[Patient-controlled analgesia SyB P-1501]

On October 11, 2017, SymBio initiated an arbitration against The Medicines Company (head office: New Jersey, U.S., “MDCO”)—from whom the Company in-licensed SyB P-1501 (IONSYS in the

U.S.) in October 2015—under the rules of the International Chamber of Commerce, seeking damages of 82 million US dollars arising from MDCO’s decision to discontinue and withdraw IONSYS from the U.S. and European markets and failure to provide adequate assurances of MDCO’s performance under the license agreement. On September 1, 2020, the Company announced that the arbitral tribunal did not agree with the Company’s claim that MDCO failed to provide adequate assurances of performance under the license agreement and denied the Company’s claim for damages. However, the arbitral tribunal awarded the Company 4,950,000 US dollars representing 50% of its legal fees and expenses that it sought to recover in the arbitration.

(ii) Business outside Japan

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

(iii) Licensing of new drug candidates

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

(iv) Business results

As a result of the above, net sales totaled 2,987,051 thousand yen for FY 2020, primarily reflecting product sales of TREAKISYM<sup>®</sup>, and overall net sales increased 5.3% year on year.

Selling, general and administrative expenses totaled 5,373,073 thousand yen (+4.0% year on year). This included research and development (“R&D”) expenses of 2,266,556 thousand yen (-7.2% year on year), reflecting expenses associated with clinical trials for the intravenous formulation of TREAKISYM<sup>®</sup> and the intravenous formulation of rigosertib, as well as other selling, general and administrative expenses of 3,106,517 thousand yen (+14.0% year on year), reflecting upfront spending for establishing the internal sales organization.

As a result, an operating loss of 4,540,035 thousand yen was recognized for FY 2020 (an operating loss of 4,301,615 thousand yen in the previous fiscal year). In addition, non-operating income was 2,585 thousand yen, primarily consisting of dividend income of insurance of 2,324 thousand yen. Meanwhile, non-operating expenses were 112,268 thousand yen and primarily comprised commission expenses of 43,958 thousand yen, foreign exchange losses of 41,287 thousand yen, and share issuance cost of 27,021 thousand yen. Consequently, ordinary loss totaled 4,615,903 thousand yen (an ordinary loss of 4,376,655 thousand yen in the previous fiscal year) and bottom-line loss in FY 2020 totaled 4,090,216 thousand yen (a loss of 4,376,258 thousand yen in the previous fiscal year), partially offset by the recording of settlement received of 525,124 thousand yen.

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.

(v) Capital investment

The total amount of capital expenditures during the fiscal year under review was 148,932 thousand yen, mainly consisting of office investments and the purchase of appliances, network devices, and business software.

**(2) Status of fund procurement**

The company procured 4,255,230 thousand yen as a result of the exercise of share acquisition rights associated with the 47th, 50th, and 51st warrants (with Exercise Price Revision Clauses) in the fiscal year under review.

**(3) Status of assets and profit and loss**

(Unit: thousands of yen)

Fiscal year Classification	FY 2017 The 13th Term	FY 2018 The 14th Term	FY 2019 The 15th Term	FY 2020 The 16th Term (current)
Net sales	3,444,206	3,835,530	2,837,753	2,987,051
Operating profit (loss)	(3,947,061)	(2,656,072)	(4,301,615)	(4,506,220)
Ordinary profit (loss)	(3,976,784)	(2,748,730)	(4,376,655)	(4,615,903)
Profit (loss)	(3,977,862)	(2,752,533)	(4,376,258)	(4,090,216)
Loss per share (yen)	(79.78)	(165.54)	(189.03)	(124.13)
Total assets	4,252,284	6,239,423	5,273,955	6,274,707
Net assets	3,239,402	4,901,799	4,400,116	4,657,318
Net assets per share (yen)	50.00	212.23	143.07	105.76

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

**(4) Issues to be addressed by the Company**

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

(i) Further expansion of the pipeline

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

The Company is conducting or planning development of anticancer agents, including SyB L-0501, SyB L-1101, SyB C-1101, SyB L-1701, and SyB L-1702, and an 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 enterprise value, the Company believes that 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<sup>®</sup> is approved for manufacturing and marketing in Japan for the indications of relapsed/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<sup>®</sup> also achieved primary endpoints in the Phase III clinical trial for the target indication of relapsed/refractory diffuse large B-cell lymphoma (r/r DLBCL), and the Company applied for approval to partially revise the manufacturing and marketing authorization in May 2020 for the additional indication. In addition, the Company in-licensed RTD and RI liquid formulations of TREAKISYM<sup>®</sup> from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) in efforts to maximize the business value of TREAKISYM<sup>®</sup> by promoting the product 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 formulation, the Company is conducting clinical trials with the primary purpose of confirming the formulation's safety.

The development of intravenous and oral formulations of rigosertib for the indication of myelodysplastic syndromes (MDS) is underway. Few useful therapeutic agents are currently available for MDS, so it is an area with a very high unmet medical need. With respect to the global Phase III clinical trial (INSPIRE study) of the intravenous formulation conducted by Onconova, Onconova announced that the primary endpoint—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. Further, the oral formulation of rigosertib has been shown to be effective and safe when administered in combination with azacitidine in the Phase I/II clinical trial in first-line higher risk MDS patients conducted in the U.S. by Onconova. The Company commenced a Phase I clinical trial in Japan to confirm the safety of high-dose monotherapy and tolerance in Japanese patients in June 2017, and completed patient enrollment in June 2019.

With the aim of maximizing the business value of TREAKISYM<sup>®</sup> and rigosertib, the Company intends to conduct joint research with the Institute of Medical Science, University of Tokyo, 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 also decided to prioritize the global development of antiviral drug brincidofovir primarily in Japan, the US, and Europe targeting adenovirus infections occurring after hematopoietic stem cell transplantation, an area with a high unmet medical need. We will aim to maximize earnings through managing the lifecycle of our products as we transform into a specialty pharmaceutical company with the capacity to further expand in the global markets.

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

With the business partnership agreement with its sales agent, Eisai, set to expire 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®. Furthermore, the Company strives to build a uniformed sales organization with a high level of specialization in the field of hematological diseases. Through this effort, the Company aims to achieve high business efficiency, ensure sustainable earnings growth, and maximize shareholder gains once the intravenous and oral formulations of rigosertib, which are currently under development to treat myelodysplastic syndromes (MDS), join TREAKISYM® in the product lineup.

With regard to antiviral drug brincidofovir, we will not only pursue domestic sales, but also consider global business development in all parts of the world, including Europe and the United States.

(iv) Global expansion for further growth

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

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 in Japan is expected to remain extremely challenging for innovative drug developers. Such a policy may also be adopted by other Asian countries.

Under these circumstances, the Company will promote global expansion for further growth. Utilizing its experience fostered through its business in Asia, the Company will search for, evaluate, and negotiate for new drug candidates, whose rights can be acquired on a global scale, after the in-licensing of antiviral drug brincidofovir.

(v) Securing personnel

The Company places the highest priority on personnel as the Company’s principal management resource. Without talent, we would be unable to achieve superior results in terms of exploring, developing, and providing information concerning new drugs, and unable to develop and commercialize these new drugs on a global scale. We continually recruit talents. Especially after being listed, we have recruited the best and brightest people in order to strengthen the management organization. Going forward, we plan to further strengthen our human resources by providing on-the-job training and employee development programs.

(vi) Financial

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.

**(5) Major business activities** (as of December 31, 2020)

The Company regards underserved therapeutic areas that lack the development of new drugs, despite significant unmet medical needs, as business opportunities. We develop new drugs with a primary focus on the treatment of rare diseases, mainly in the areas of oncology, hematology, and multiple viral infections, and conduct integrated business activities that encompass search for new drug candidates, development, manufacturing, and sales.

**(6) Main office and employees**

(i) Main office (as of December 31, 2020)

Name	Location
Main office	Minato-ku, Tokyo

(ii) Employees (as of December 31, 2020)

Classification	Number of employees	Increase or decrease from previous fiscal year end	Average age (years)	Average number of years of service
Male	95	15 (increase)	49.8	3.2
Female	32	5 (increase)	46.1	4.4
Total or average	127	20 (increase)	48.8	3.5

(Notes) 1. Number of employees refers to full time employees.

2. The above number of employees does not include 48 temporary staff.

**(7) Status of parent company and significant subsidiaries**

Not applicable.

**(8) Status of main lenders** (as of December 31, 2020)

Not applicable.

**2. Matters Related to Stock** (as of December 31, 2020)

**(1) Total number of authorized shares**

Common stock: 41,750,000 shares

**(2) Total number of shares outstanding**

Common stock: 38,172,813 shares (excluding 30,143 shares of treasury stock)

**(3) Number of shareholders**

33,913

**(4) Major shareholders (10 largest)**

Name of shareholder	Number of shares held	Shareholding ratio
Kyoichi Kageyama	1,020,000	2.7%
Fuminori Yoshida	900,000	2.4%
SBI Securities Co Ltd.	744,310	1.9%
Cephalon, Inc.	647,250	1.7%
Arata Takahashi	534,000	1.4%
Norihiro Kuroda	447,500	1.2%
Matsui Securities Co., Ltd.	310,600	0.8%
Fumishige Ehira	270,200	0.7%
Hitoshi Imamura	239,300	0.6%
Eisai Co., Ltd.	208,350	0.5%

(Notes) Shareholding ratio (%) indicates the percentage of shares outstanding held. Shares outstanding is equal to the number of shares issued minus treasury shares.

### 3. Matters Related to Share Acquisition Rights

#### (1) Share acquisition rights held by the Company's Officers that were issued as compensation for services (as of December 31, 2020)

	The 24th warrant by resolution of the Ordinary General Meeting of Shareholders on March 30, 2011	The 26th warrant by resolution of the Board of Directors meeting on April 17, 2012	The 30th warrant by resolution of the Board of Directors meeting on May 14, 2013
Number of share acquisition rights	1,920 units	3,625 units	1,160 units
Number of shares to be issued upon the exercise of share acquisition rights <sup>(Note 4)</sup>	48,000 shares	90,625 shares	29,000 shares
Amount paid for share acquisition rights	None	None	None
Value of property to be contributed upon the exercise of each share acquisition right <sup>(Note 1)</sup>	2,728 yen per share	2,220 yen per share	3,196 yen per share
Period in which exercise of share acquisition rights is possible	From: March 31, 2013 To: March 30, 2021	From: April 18, 2014 To: April 17, 2022	From: May 15, 2015 To: May 14, 2023
Status of possession by Directors (excluding Outside Directors) <sup>(Note 4)</sup>	1,200 units (1 holder) 30,000 shares	2,600 units (1 holder) 65,000 shares	645 units (1 holder) 16,125 shares
Status of possession by Outside Directors	—	—	—

	The 40th warrant by resolution of the Board of Directors meeting on March 29, 2017	The 43rd warrant by resolution of the Board of Directors meeting on March 29, 2018	The 48th warrant by resolution of the Board of Directors meeting on March 28, 2019
Number of share acquisition rights	2,800 units	3,050 units	3,150 units
Number of shares to be issued upon the exercise of share acquisition rights <sup>(Note 4)</sup>	70,000 shares	76,250 shares	78,750 shares
Amount paid for share acquisition rights <sup>(Note 2) (Note 4)</sup>	20,300 yen per unit	19,800 yen per unit	19,400 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right <sup>(Note 1)</sup>	1 yen per share	1 yen per share	1 yen per share
Period in which exercise of share acquisition rights is possible	From: March 30, 2020 To: March 29, 2027	From: March 30, 2021 To: March 29, 2028	From: March 30, 2022 To: March 29, 2029
Status of possession by Directors (excluding Outside Directors) <sup>(Note 4)</sup>	1,450 units (1 holder) 36,250 shares	1,450 units (1 holder) 36,250 shares	1,400 units (1 holder) 35,000 shares
Status of possession by Outside Directors <sup>(Note 4)</sup>	—	250 units (1 holder) 6,250 shares	500 units (2 holders) 12,500 shares

	The 52nd warrant by resolution of the Board of Directors meeting on March 26, 2020
Number of share acquisition rights	4,600 units
Number of shares to be issued upon the exercise of share acquisition rights	115,000 shares
Amount paid for share acquisition rights <sup>(Note 2)</sup>	8,100 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right	1 yen per share
Period in which exercise of share acquisition rights is possible	From: March 27, 2023 To: March 26, 2030
Status of possession by Directors (excluding Outside Directors)	3,800 units (2 holders) 95,000 shares
Status of possession by Outside Directors	800 units (2 holders) 20,000 shares

(Notes) 1. New shares were issued through the public offering on December 4, 2013, and third-party allotment on December 25, 2013, at the paid-in amount less than the value of property to be contributed upon the exercise of each share acquisition right. Therefore, the stated value of property to be contributed upon the exercise of each share acquisition right excluding those issued for the 32nd warrant and thereafter is adjusted in accordance with the adjustment provision.

2. The person who receives the allotment of share acquisition rights shall offset the amount to be paid for the relevant share acquisition rights against cash compensation equivalent to the amount.

3. There are no share acquisition rights held by Audit & Supervisory Board Members.

4. The Company conducted a 1-for-4 consolidation of common shares on July 1, 2019. Number of shares to be issued upon the exercise of share acquisition rights and exercise price have been adjusted accordingly.

**(2) Share acquisition rights distributed to the Company's employees as compensation for services during the fiscal year under review (as of December 31, 2020)**

	The 53rd warrant by resolution of the Board of Directors meeting on March 26, 2020
Number of share acquisition rights	15,000 units
Number of shares to be issued upon the exercise of share acquisition rights	375,000 shares
Amount paid for share acquisition rights <sup>(Note 2)</sup>	8,100 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right	1 yen per share
Period in which exercise of share acquisition rights is possible	From: March 27, 2023 To: March 26, 2030
Status of allotment to the Company's employees <sup>(Note 1)</sup>	11,910 units (107 holders) 297,750 shares

(Notes) 1. Of the share acquisition rights mentioned above, 3,090 units (77,250 shares) have been forfeited due to the retirement or resignation of employees.

2. The person who receives the allotment of share acquisition rights shall offset the amount to be paid for the relevant share acquisition rights against cash compensation equivalent to the amount.

**(3) Other important matters concerning share acquisition rights**

Not applicable.

#### 4. The Company's Officers (as of December 31, 2020)

##### (1) Names of Directors and Audit & Supervisory Board Members

Company position	Name	Responsibility and significant concurrent position
Representative Director	Fuminori Yoshida	Chief Executive Officer
Director	Shigeo Kimura	Director, Managing Senior Executive Officer, and Head of the Japan Business Unit
Director	Shigetoshi Matsumoto	
Director	Bruce David Cheson	Scientific Advisory Board, Lymphoma Research Foundation
Full-time Audit & Supervisory Board Member	Kiyoshi Watanabe	
Audit & Supervisory Board Member	Kesao Endo	Representative, Endo C.P.A Firm Outside Director, Careerlink Co., Ltd. Representative Partner, ABS Audit Corp.
Audit & Supervisory Board Member	Eiji Ebinuma	Partner, Tanabe & Partners Law Firm Outside Director, Rakuten Bank, Ltd. Audit & Supervisory Board Member, Toko Electrical Construction Co., Ltd.

- (Notes) 1. Of the Directors, Shigetoshi Matsumoto, Bruce David Cheson, and Rockford Douglas Norby are Outside Directors.
2. Kiyoshi Watanabe, Kesao Endo, and Eiji Ebinuma are outside members of the Audit & Supervisory Board.
3. Shigetoshi Matsumoto, Kiyoshi Watanabe, and Kesao Endo have been designated as independent officers pursuant to the provisions of the Tokyo Stock Exchange and registered as such with the Tokyo Stock Exchange.
4. Kesao Endo possesses deep insight in finance and accounting, which he gained through his profession as a certified public accountant.
5. Eiji Ebinuma is an attorney with specialized knowledge and extensive experience in law.
6. Changes in Directors and Audit & Supervisory Board Members during the fiscal year under review are as follows:
- Director Kenji Murata resigned on January 31, 2020. Mr. Murata had held the post of Director, Corporate Officer, and CFO.
  - Director Rockford Douglas Norby passed away on April 13, 2020, and has therefore resigned. During his term in office, Mr. Norby also held a significant concurrent position as an Outside Director at Krystal Biotech, Inc.
7. The Company has adopted the Corporate Officer System. The Corporate Officers who do not hold concurrent positions as Directors are as follows:
- Corporate Officer Takaaki Fukushima

##### (2) Summary of the contents of the liability limitation agreement

The Company has executed an agreement with each Director (excluding those who engage in business execution) and each member of the Audit & Supervisory Board with respect to the liability in Article 423, Paragraph 1 of the Companies Act, setting forth that director liability will be limited to the higher of 1,000,000 yen or the maximum liability amount set forth in laws and regulations in cases where the Director or member of the Audit & Supervisory Board has performed their duties in good faith and without gross negligence.

### (3) Directors and Officers Liability Insurance Policies

The Company has obtained Directors and Officers Liability Insurance Policies covering the Directors and Audit & Supervisory Board Members of the Company and its subsidiaries.

The aforementioned insurance is payable as indemnification for losses suffered by the insureds as a result of a legal action brought for alleged wrongful acts in their capacity as directors and officers.

Costs of premiums paid on the aforementioned insurance are borne entirely by the Company.

### (4) Compensation of members of the Board of Directors and the Audit & Supervisory Board

Company Board	Number of Directors or Audit & Supervisory Board Members Paid	Total Amount of Compensation (thousands of yen)
Board of Directors	6 (Outside: 3)	97,512 (Outside: 19,227)
Audit & Supervisory Board	3 (Outside: 3)	21,592 (Outside: 21,592)
Total	9 (Outside: 6)	119,105 (Outside: 40,820)

- (Notes) 1. Salary in the event of a Director doubling as an employee is not included in the above compensation for Directors.
2. The maximum amount of compensation for Directors was resolved as an annual amount of 130 million yen at the Extraordinary General Meeting of Shareholders held on August 3, 2005. In addition to the aforementioned compensation, it was resolved that compensation for Directors in the form of share acquisition rights as stock options be granted up to a maximum annual amount of 80 million yen at the 8th Ordinary General Meeting of Shareholders held on March 28, 2013. (Of 80 million yen, 30 million yen was granted for Outside Directors, which was resolved at the 11th Ordinary General Meeting of Shareholders held on March 30, 2016.)
3. The maximum amount of compensation for Audit & Supervisory Board Members was resolved as an annual amount of 30 million yen at the Extraordinary General Meeting of Shareholders held on June 30, 2011.
4. The number of Directors or Audit & Supervisory Board Members compensated as stated above includes one (1) Director who resigned on January 31, 2020, and one (1) Director who passed away, and thereby resigned on April 13, 2020.
5. The total compensation paid includes expenses (for five (5) Directors, a total of 35,383 thousand yen) in connection with share acquisition rights as stock options for the fiscal year under review.

**(5) Matters Concerning Outside Directors and outside members of the Audit & Supervisory Board**

Status of main activities during the fiscal year under review

Position	Name	Status of attendance at the Board of Directors meetings	Status of attendance at the Audit & Supervisory Board meetings	Opinions at the Board of Directors meetings and the Audit & Supervisory Board meetings
Director	Shigetoshi Matsumoto	13 out of 13 (100%)	—	Mr. Matsumoto expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his extensive knowledge and experience with the business practices of companies in the same industry and with auditing work.
Director	Bruce David Cheson	13 out of 13 (100%)	—	Dr. Cheson expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his extensive knowledge and experience as a physician.
Director	Rockford Douglas Norby	3 out of 4 (75%)	—	Dr. Norby expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his extensive experience and knowledge regarding healthcare companies.
Full-time Audit & Supervisory Board Member	Kiyoshi Watanabe	13 out of 13 (100%)	14 out of 14 (100%)	Mr. Watanabe actively expressed opinions from an objective and fair perspective based on his extensive experience and knowledge as an audit & supervisory board member at listed companies in order to achieve highly effective managerial supervision.
Audit & Supervisory Board Member	Kesao Endo	13 out of 13 (100%)	14 out of 14 (100%)	Mr. Endo actively expressed opinions from a neutral perspective based on the specialized knowledge and extensive experience he accumulated as a certified public accountant in order to achieve highly effective managerial supervision.
Audit & Supervisory Board Member	Eiji Ebinuma	13 out of 13 (100%)	14 out of 14 (100%)	Mr. Ebinuma actively expressed opinions from a neutral perspective based on the specialized knowledge and extensive experience he accumulated as an attorney in order to achieve highly effective managerial supervision.

(Note) With regard to Director Rockford Douglas Norby, his attendance at the meetings is calculated from the Board of Directors meetings and the Audit & Supervisory Board meetings held up until his retirement in April, 2020.

## 5. Status of Accounting Auditor

### (1) Name of accounting auditor

Ernst & Young ShinNihon LLC

### (2) Summary of the contents of the liability limitation agreement

Not applicable.

### (3) Amount of compensation

	Amount paid
Amount of compensation paid to the accounting auditor concerning the fiscal year under review	27,000 thousand yen
Total amount of monetary and other property benefits to be paid by the Company	27,000 thousand yen

(Notes) 1. Reasons for the Audit & Supervisory Board's approval of the amount of compensation to be paid to the accounting auditor

The Audit & Supervisory Board verified the contents of the audit planning by the accounting auditor, performance of its duties in previous years, and status of planning and actual performance, and as a result of a careful review on the adequacy of the amount of compensation for the fiscal year under review, has approved the amount of compensation to be paid to the accounting auditor, pursuant to the provisions of Article 399, Paragraph 1 of the Companies Act.

2. The amounts of compensation for audits paid in accordance with the Companies Act, and the audits conducted in accordance with the Financial Instruments and Exchange Act, are not distinguished in the contract agreement between the Company and the accounting auditor. It is not possible to distinguish between compensation paid for these two types of audits; therefore the total amount thereof is stated.

### (4) Policies for dismissal or non-reappointment of the accounting auditor

When it is deemed necessary to dismiss (or not reappoint) the accounting auditor for reasons relating to the accounting auditor's execution of duties, the Audit & Supervisory Board shall determine the contents of a proposal to be presented to a General Meeting of Shareholders in respect of the dismissal (or non-reappointment). In addition, when the accounting auditor falls under any of the items of Article 340, Paragraph 1 of the Companies Act, the Audit & Supervisory Board shall dismiss the accounting auditor with the consent of all members of the Audit & Supervisory Board. If this is the case, an Audit & Supervisory Board Member selected by the Audit & Supervisory Board shall report the dismissal of the accounting auditor and the reasons for such dismissal at the first General Meeting of Shareholders convened after the dismissal.

## **6. System to Ensure the Appropriateness of Operations**

### **(1) The corporate system to ensure that Directors, officers, and employees comply with laws and ordinances, as well as the Articles of Incorporation, in the process of performing their duties**

#### **(i) Dissemination and thorough implementation of management philosophy**

In order to implement its management philosophy, the Company has established a Corporate Action Charter and standards of conduct to which all Company members are expected to adhere. The Company informs all executives and staff regarding these policies and asks for each member's understanding regarding the spirit of these regulations and for thorough compliance with the same. All business activities of the Company are based on the premise of compliance with laws and ordinances and the maintenance of corporate ethical standards (below, "compliance").

#### **(ii) Establishment of internal control committee**

The Company develops internal control systems and employs other measures to support thorough compliance, risk management, and financial reporting. In addition, an internal control committee has been established to ensure complete observance of laws and ordinances, the Articles of Incorporation, and other internal regulations through exhaustive supervision.

#### **(iii) Establishment of internal audit office**

The Company has established an internal audit office as an independent unit which conducts regular audits and related activities under the direct authorization by the Representative Director and President. Through such audits, objective assessments are made as to the effectiveness and efficiency of business, the reliability of various financial reports, safeguarding of assets, compliance status of operations, and the appropriateness and effectiveness of corporate risk management policies. When necessary, the Company ensures the efficacy of internal controls by accepting advice and proposals concerning recommended improvements to the maintenance and operation of systems.

#### **(iv) Establishment of compliance reporting and consultation hot-lines**

The Company has established compliance reporting and consultation hot-lines both internal to and outside the Company, and has designated compliance liaisons to respond to reports and requests for consultation from employees, and to identify and resolve any compliance issues at the earliest stage possible.

#### **(v) Systems for securing reliable financial reporting**

The Company establishes internal control systems and oversees their appropriate operation in order to ensure reliable financial reporting.

### **(2) Corporate system for maintenance and control of information regarding the performance of duties by Directors**

The Company appoints an individual to be responsible for the general management of corporate documents and to appropriately maintain and otherwise control all important documents containing information as to the performance by Directors of their duties in addition to legally required records of proceedings of Shareholders meetings and Board of Directors meetings, as provided in laws and ordinances as well as in the Company's own "Rules for the Management of Documents."

**(3) Corporate system for control of risk of loss, including in-house rules for such control**

The Company practices risk control under its basic risk control policy and related rules. The Internal Control Committee is responsible for the supervision and promotion of risk management. Additionally, the Company will swiftly respond to emergency situation by establishing an emergency response headquarters managed by the Representative Director and President.

**(4) Corporate system to ensure the efficient performance of duties by Directors**

- (i) Directors and employees perform their duties in appropriate and efficient accordance with the “Rules for the Board of Directors” and “Rules for the Internal Approvals,” as well as other related regulations.
- (ii) The Company regularly holds Executive Management Committee meetings pursuant to the “Rules for the Executive Management Committee” and reviews key proposals for the purpose of supporting careful and timely decision-making from the Representative Director and President.
- (iii) The Company develops mid- to long-term business plans and operates and expands its business in accordance with these plans. In addition, the Company establishes numerical targets within its business plans for each fiscal year and, through monthly closings, manages progress toward these targets while making relevant reports to Directors.

**(5) Basic policy against anti-social forces**

The Company resolutely opposes anti-social forces that pose a threat to the order or safety of society and forbids their participation in any and all business activities.

**(6) Assistant to Audit & Supervisory Board Members**

Audit & Supervisory Board Members may request that the Representative Director and President appoint an employee to act as an assistant to Audit & Supervisory Board Members. Upon receiving such a request, the Representative Director and President shall make an appropriate appointment.

**(7) Ensuring the independence of assistants to Audit & Supervisory Board Members from Directors and the effectiveness of the Audit & Supervisory Board Members’ instructions to employees**

- (i) Assistants to Audit & Supervisory Board Members shall not receive instructions concerning their supporting duties from anyone other than Audit & Supervisory Board Members.
- (ii) Matters such as personnel evaluation and transfer and disciplinary actions concerning employees that assist Audit & Supervisory Board Members shall be subject to the prior consent of the Audit & Supervisory Board.

**(8) Corporate system for Directors and employees to report to the Audit & Supervisory Board; corporate system for other reports to the Audit & Supervisory Board; and corporate system to ensure the efficient performance of audits by the Audit & Supervisory Board**

- (i) Any Director or employee shall promptly inform the Audit & Supervisory Board if and when he/she becomes aware of any circumstance that threatens to cause any significant damage to, or could adversely affect, the Company.
- (ii) Audit & Supervisory Board Members may participate in all matters that they consider important in

terms of gaining a better understanding of decision-making processes, conditions, and statuses of the Company's businesses. Accordingly, they may attend Board of Directors meetings, Executive Management Committee meetings, and other important meetings and are also permitted to view key decision-making documents related to these meetings.

- (iii) Audit & Supervisory Board Members may individually interview Directors and employees in key positions of responsibility to obtain information regarding the management conditions of the Company's businesses.
- (iv) Audit & Supervisory Board Members will regularly exchange opinions with the Representative Director and President and the accounting auditor.
- (v) The Company will not apply any sort of unfavorable treatment or unjust punishment to individuals who make reports to the Audit & Supervisory Board.

**(9) Matters related to the treatment of expenses or obligations associated with the execution of duties of Audit & Supervisory Board Members, including the procedures for prepayment or reimbursement of such expenses**

- (i) The Company will respond without delay to claims for the prepayment of expenses made by Audit & Supervisory Board Members under Article 388 of the Companies Act, accepting responsibility for associated expenses and processing related obligations, except in cases in which these have been determined unnecessary for the execution of the duties of Audit & Supervisory Board Members.
- (ii) The Company authorizes and shoulders expenses incurred when Audit & Supervisory Board Members seek opinions or advice from external experts, including attorneys and certified public accountants, if it is found necessary for the execution of their duties.

## **7. Summary of the Status of System to Ensure the Appropriateness of Operations**

- (1) The Company is striving to foster a culture of compliance across the organization and ensure appropriate operation of internal control systems through its communications with Directors and employees, and through publication of information such as the basic policies regarding internal control systems, corporate compliance conduct principles, basic risk control policies, and the whistleblowing system manual on the Company's intranet bulletin board.
- (2) At the Board of Directors meetings of the Company, Outside Directors participate in resolutions from an independent standpoint and monitor and supervise the management. Each Audit & Supervisory Board Member carries out management audits as well.
- (3) Full-time Audit & Supervisory Board Members attend important meetings such as the Board of Directors meetings as well as Executive Management Committee meetings, and exchange views with representative directors monthly.

## Balance Sheet

(As of December 31, 2020)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
<b>Current assets</b>	<b>5,815,292</b>	<b>Current liabilities</b>	<b>1,615,339</b>
Cash and deposits	3,848,626	Accounts payable–trade	665,460
Accounts receivable–trade	406,988	Unearned revenue	192,705
Merchandise and finished goods	944,442	Accounts payable–other	645,813
Supplies	482	Income taxes payable	81,928
Advance payments–trade	43,494	Other	29,431
Prepaid expenses	80,645	<b>Non-current liabilities</b>	<b>2,050</b>
Consumption taxes receivable	314,761	Provision for retirement benefits	2,050
Other	175,852	<b>Total liabilities</b>	<b>1,617,389</b>
<b>Non-current assets</b>	<b>459,415</b>	(Net assets)	
Property, plant and equipment	76,701	<b>Shareholders' equity</b>	<b>4,037,177</b>
Buildings	59,123	Capital stock	17,044,943
Tools, furniture and fixtures	90,043	Capital surplus	17,019,485
Accumulated depreciation	(72,464)	Legal capital surplus	17,014,943
Intangible assets	301,841	Other capital surplus	4,541
Software	296,005	Retained earnings	(30,009,713)
Software in progress	5,836	Other retained earnings	(30,009,713)
Investments and other assets	80,871	Retained earnings brought forward	(30,009,713)
Shares of subsidiaries and associates	0	Treasury shares	(17,538)
Leasehold and guarantee deposits	80,871	Share acquisition rights	620,140
		<b>Total net assets</b>	<b>4,657,318</b>
<b>Total assets</b>	<b>6,274,707</b>	<b>Total liabilities and net assets</b>	<b>6,274,707</b>

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

## Statement of Income

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

(Unit: thousands of yen)

Item	Amount	
<b>I. Net sales</b>		<b>2,987,051</b>
<b>II. Cost of goods sold</b>		<b>2,120,198</b>
<b>Gross profit</b>		<b>866,853</b>
<b>III. Selling, general and administrative expenses</b>		<b>5,373,073</b>
<b>Operating loss</b>		<b>(4,506,220)</b>
<b>IV. Non-operating income</b>		
Interest income	137	
Dividend income of insurance	2,324	
Interest on tax refund	120	
Other	2	2,585
<b>V. Non-operating expenses</b>		
Commission fee	43,958	
Share issuance cost	27,021	
Foreign exchange losses	41,287	112,268
<b>Ordinary loss</b>		<b>(4,615,903)</b>
<b>VI. Extraordinary income</b>		
Gain on reversal of share acquisition rights	4,341	
Settlement received	525,145	529,486
<b>Loss before income taxes</b>		<b>(4,086,416)</b>
Income taxes-current	3,800	3,800
<b>Net loss</b>		<b>(4,090,216)</b>

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

## Statement of Changes in Equity

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

(Unit: thousands of yen)

	Shareholders' equity				
	Capital stock	Capital surplus			Retained earnings
		Legal capital surplus	Other capital surplus	Total capital surplus	Other retained earnings
					Retained earnings brought forward
Balance as of January 1, 2020	14,870,639	14,840,639	2,498	14,843,137	(25,919,496)
Changes of items during period					
Issuance of new shares (exercise of share acquisition rights)	2,174,304	2,174,304		2,174,304	
Net loss					(4,090,216)
Purchase of treasury shares					
Disposal of treasury shares			2,043	2,043	
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)
Balance as of December 31, 2020	17,044,943	17,014,943	4,541	17,019,485	(30,009,713)

	Shareholders' equity		Share Acquisition rights	Total net assets
	Treasury shares	Total shareholders' equity		
Balance as of January 1, 2020	(15,077)	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
Net loss		(4,090,216)		(4,090,216)
Purchase of treasury shares	(6,387)	(6,387)		(6,387)
Disposal of treasury shares	3,926	5,969		5,969
Net changes of items other than shareholders' equity			(772)	(772)
Total changes of items during period	(2,461)	257,974	(772)	257,201
Balance as of December 31, 2020	(17,538)	4,037,177	620,140	4,657,318

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

## Notes to Non-Consolidated Financial Statements

### (Significant accounting policies)

#### (1) Valuation basis and method of marketable and investment securities

Marketable and investment securities

Shares of subsidiaries and affiliates

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

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.

Derivative transactions

Derivative financial instruments are stated at fair value.

Inventories

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

#### (2) Depreciation and amortization of non-current assets

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

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.

Lease assets

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

(3) Deferred assets

Share issuance costs and bond issuance costs	Share issuance costs and bond issuance costs are recorded as expenses in full at the time of expenditure.
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(4) Basis for translating assets and liabilities denominated in foreign currencies into Japanese yen

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

(5) 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 at the end of 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.
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(6) Accounting for consumption tax

Transactions are recorded at amounts exclusive of consumption tax.

**(Changes in presentation methods)**

(Balance sheet items)

Advance payments—trade, which were 2,177 thousand yen and included in the Other line of Current assets for FY 2019, have increased in importance, and are therefore presented as a separate line item for FY 2020.

**(Additional information)**

(Overdraft and commitment line contracts)

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 the fiscal year under review is as follows:

	(Unit: thousands of yen)
Total amounts of bank overdraft limit and loan commitment line	3,150,000
Balance of borrowing outstanding	—
Unused balance	3,150,000

(Impact of COVID-19)

The outbreak of COVID-19 has made the outlook for the business environment more unpredictable. The pandemic has led to changes in patient behavior and rescheduling of treatments, in addition to which a number of hospitals continue to have visitor restrictions in place. Such impacts are considered in our asset

impairment indicator assessment and are reflected in the estimates report.

**(Balance sheet)**

Monetary assets receivable from subsidiaries are as follows.

Short-term monetary assets receivable: 1,807 thousand yen

**(Statement of income)**

(1) Inventories at fiscal year-end are stated after writing down based on the decrease in profitability.

The following amount is included within cost of sales as loss on valuation of inventories.

Cost of sales: 69,199 thousand yen

A certain batch of TREAKISYM® 100mg was determined to be unsalable due to its poor quality, which resulted in an inventory valuation loss.

(2) R&D costs included in general and administrative expenses: 2,266,556 thousand yen

**(Statement of changes in equity)**

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

(Notes) 1. Increase of 11,765,275 shares issued in common stock is due to the exercise of share acquisition rights.

2. Increase of 13,900 treasury shares in common stock is due to the purchase of shares less than one unit.

3. Of the decrease of 6,350 treasury shares in common stock, 5,200 shares to the exercise of share acquisition rights, and 1,150 shares to the sale of shares less than one unit.

(2) Number of shares to be issued upon exercise of share acquisition rights issued at the end of the fiscal year under review

Common stock 465,900 shares

(Note) Excludes share acquisition rights for which the commencement date of the exercise period has not yet arrived.

**(Tax effect accounting)**

Significant components of deferred tax assets and liabilities

Deferred tax assets:	(Unit: thousands of yen)
Excess depreciation for lump-sum depreciable assets	1,903
Excess amortization for deferred assets	571,893
Research and development expenses disallowed	2,311,778
Accounts payable—other disallowed	1,653
Provision for retirement benefits disallowed	627
Enterprise taxes payable disallowed	25,411
Asset retirement obligations disallowed	1,749
Share-based compensation expenses disallowed	128,054
Loss carried forward	4,935,118
Subtotal of deferred tax assets	<u>7,978,186</u>
Valuation allowances for loss carried forward	(4,935,118)
Valuation allowances for deductible temporary differences	<u>(3,043,068)</u>
Subtotal of valuation allowances	<u>(7,978,186)</u>
Total deferred tax assets	<u>—</u>

**(Financial instruments)**

(1) Financial instruments

(i) 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.

(ii) Types of financial instruments and related risks

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

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

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

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

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

(iii) Risk management for financial instruments

1. 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 department in charge 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.

2. 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.

3. 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.

(iv) 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.

(v) Concentration of credit risk

As of the end of fiscal year under review, 100% 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.

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Difference
(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	—
Liabilities, total	1,393,202	1,393,202	—
Derivative transactions (*)	—	—	—

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

(Note) 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, and (3) Income taxes payable

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

Derivative transactions

Forward exchange contracts

The fair value of forward exchange contracts is measured based on market quotes obtained from financial institutions.

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

Leasehold and guarantee deposits (carrying value of 80,871 thousand yen) are not included in the above table since no market quote is available and their fair value is extremely difficult to determine.

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

(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	—	—	—

**(Transactions with affiliated parties)**

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: 2.40	—	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.

**(Per-share information)**

(1) Net assets per share	105.76 yen
(2) Net loss per share	(124.13) yen
Average number of shares outstanding during the year	32,950,201 shares

**(Significant subsequent events)**

None to be reported.

## Independent Auditor's Report

February 19, 2021

The Board of Directors  
SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC  
Tokyo, Japan

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Hironao Yazaki  
Designated Engagement Partner  
Certified Public Accountant

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Koichiro Kitaike  
Designated Engagement Partner  
Certified Public Accountant

### Opinion

Pursuant to Article 436, Section 2, Paragraph 1 of the Companies Act, we have audited the accompanying financial statements, which comprise the balance sheet, the statement of income, the statement of changes in equity, the notes to non-consolidated financial statements and the related supplementary schedules of SymBio Pharmaceuticals Limited (the "Company") applicable to the 16th fiscal year from January 1, 2020 to December 31, 2020.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position and results of operations of the Company applicable to the fiscal year ended December 31, 2020, in accordance with accounting principles generally accepted in Japan.

### Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Japan, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### **Responsibilities of Management, the Corporate Auditor and the Board of Corporate Auditors for the Financial Statements**

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern and disclosing, as required by accounting principles generally accepted in Japan, matters related to going concern.

The Corporate Auditor and the Board of Corporate Auditors are responsible for overseeing the Company's financial reporting process.

### **Auditor's Responsibility for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.
- Consider internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances for our risk assessments, while the purpose of the audit of the financial statements is not expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation in accordance with accounting principles generally accepted in

Japan.

We communicate with the Corporate Auditor and the Board of Corporate Auditors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Corporate Auditor and the Board of Corporate Auditors with a statement that we have complied with the ethical requirements regarding independence that are relevant to our audit of the financial statements in Japan, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

**Interest Required to Be Disclosed by the Certified Public Accountants Act of Japan**

Our firm and its designated engagement partners do not have any interest in the Company which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

## **Report of the Audit & Supervisory Board**

We, Audit & Supervisory Board Members, prepare this report of audit with regard to the execution of Directors' duties during the 16th Term of the Company from January 1, 2020 to December 31, 2020, as the unanimous opinion of all the Audit & Supervisory Board Members after careful discussion based on the audit reports prepared by respective Audit & Supervisory Board Members, and report as follows.

### **1. Method and Contents of the Audit by the Audit & Supervisory Board Members and the Audit & Supervisory Board**

The Audit & Supervisory Board formulated the audit policy and plan for the Term reported, and received reports from the respective Audit & Supervisory Board Members with regard to the state of implementation and results of audits as well as received the reporting from Directors and the accounting auditor with regard to the state of execution of their duties, and requested additional explanations as deemed necessary.

The respective Audit & Supervisory Board Members, in conformity with the standards for audits by Audit & Supervisory Board Members that the Audit & Supervisory Board set forth and in accordance with the audit policy and plan for the Term, strove to collect information and improve audit environments by communicating with Directors, the internal audit section, and other employees. We also attended Board of Directors meetings and other important meetings, received the reporting from Directors and employees with regard to the state of execution of their duties, requesting additional explanations as deemed necessary, reviewed documents for important settlements, and researched the situation of operations and assets. Moreover, with regard to the system to ensure that the execution of Directors' duties described in the business report was compliant with laws and ordinances and the Company's Articles of Incorporation and other systems required to secure the appropriateness of operations as a stock company maintained based on the contents of resolution by the Board of Directors with regard to the maintenance of systems stipulated by the Ordinance for Enforcement of Article 100, Paragraph 1 and 3 of the Companies Act (hereinafter the "Internal Control System"), we received reporting on the status of their establishment and operation from Directors and employees, requested additional explanation as deemed necessary, and expressed our opinion. Based on the method described above, we reviewed the business report and supplementary schedules with regard to the Term reported.

In addition, we monitored and inspected the independent position of the accounting auditor and the execution of appropriate audits by the accounting auditor, and also received the reporting from the accounting auditor with regard to the state of execution of its duties, requesting additional explanation as deemed necessary. Furthermore, we received the notification from the accounting auditor that "the system to ensure that its duties are executed as appropriate (the items listed by the respective paragraphs of Article 131 of the Ordinance on the Accounting of Companies)" is maintained in accordance with "the standards for quality control of audits (Business Accounting Council, October 28, 2005)," requesting additional explanation as deemed necessary. Based on the method described above, we reviewed the financial report (including balance sheet, statement of income, statement of changes in equity, and notes to non-consolidated financial statements) and related supplementary schedules for the Term reported.

2. Results of audit

(1) Results of the audit of the business report

- a. The business report and supplementary schedules fairly present the Company's situation in accordance with laws and ordinances and the Company's Articles of Incorporation.
- b. No misconduct in the execution of Directors' duties or any material facts in violation of laws or ordinances or the Company's Articles of Incorporation was observed.
- c. The contents of resolution by the Board of Directors with regard to the Internal Control System are appropriate. Also, there is no matter to be noted as for the descriptions in the business report regarding such Internal Control System and the execution of Directors' duties.

(2) Results of the audit of the financial statements and related supplementary schedules

Both the method used for and the result of the audit conducted by the accounting auditor, Ernst & Young ShinNihon LLC, are appropriate.

February 19, 2021

Audit & Supervisory Board,  
SymBio Pharmaceuticals Limited

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Kiyoshi Watanabe  
Full-time Audit & Supervisory Board Member (Outside)

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Kesao Endo  
Audit & Supervisory Board Member (Outside)

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Eiji Ebinuma  
Audit & Supervisory Board Member (Outside)

End of Report

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