English translation

March 23, 2023

Annual Report

(January 1, 2022 through December 31, 2022)

1. Current Status of the Corporate Group

(1) Business conditions and operating results

From the fiscal year ended December 31, 2022, the Group began preparing consolidated financial statements in connection with the commencement of operations at its wholly-owned U.S.-based subsidiary, SymBio Pharma USA, Inc. (President: Carolyn Yanavich), which serves as a strategic base for our global operations as a specialty pharmaceutical company. As reference, we have provided year-on-year comparisons with the non-consolidated financial statements in the same period last year, since there have been no substantial changes in our business composition.

(i) Business results

In December 2020, the Group began selling TREAKISYM® (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate) through its own sales organization. This was a critical step of the Group to attain profitability in FY 2021, which was a top priority for the fiscal year.

The Group has assigned medical representatives nationwide to establish a highly productive salesforce that can identify local needs and plan detailed proposals. We also deployed hematology experts in each region of operation to provide scientific information. To achieve nationwide distribution, we have entered into distribution agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. with both companies as exclusive distributors. We are also working with S.D. Collabo Co., Ltd. and have established two logistics centers, one in Eastern Japan and the other in Western Japan.

In February 2022, the Group obtained approval for a partial change to the marketing authorization of the ready-to-dilute (RTD) liquid formulation of TREAKISYM® to add rapid infusion (RI) administration. Compared to the freeze-dried (FD) formulation, the RTD formulation of TREAKISYM® reduces the time required for the complicated dissolution process. RI administration further reduces the infusion time to 10 minutes, benefitting both patients and healthcare providers. The reduction in infusion volume also lowers the volume of saline solution and, accordingly, the amount of salt (sodium chloride) used.

Conversion to the RI administration proceeded smoothly, with over 80% of medical institutions switching to RI administration as of the end of December 2022.

As a result, net sales totaled 10,008,338 thousand yen (+21.2% year on year). Despite sales activities being constrained by delays in treatment and continued restrictions on facility visits due to the spread of COVID-19, net sales rose due to the approval for the use of TREAKISYM® in the bendamustine-rituximab (BR) therapy and in polatuzumab vedotin plus bendamustine-rituximab (Pola+BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL).

Selling, general and administrative expenses totaled 5,636,278 thousand yen (+1.1% year on year). This amount includes research and development expenses of 2,554,799 thousand yen (+47.2% year on year).

As a result, in FY 2022, operating profit was 1,963,625 thousand yen (versus 1,016,001 thousand yen in FY 2021) and ordinary profit was 1,999,878 thousand yen (versus 1,001,133 thousand yen in FY 2021). Profit attributable to owners of parent amounted to 1,179,238 thousand yen (versus 2,032,203 thousand yen in the same period of FY 2021, due in part to the recording of 1,275,759 thousand yen in deferred tax assets). As cumulative total sales of the RTD formulation of TREAKISYM® reached 11,000,000 thousand yen in FY 2022, the Group booked 550,000 thousand yen in sales milestone payments to Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.; hereinafter "Eagle") under cost of sales.

In February 2022, generic versions of TREAKISYM® were approved for manufacturing and marketing in Japan. Given the potential infringement of Eagle's patents related to TREAKISYM® in Japan which are exclusively licensed to the Company, the Company in coordination with Eagle notified four generic makers of potential patent infringement and requested they take appropriate measures to avoid such infringement. In December 2022, Eagle and the Company commenced the litigation seeking an injunction against the manufacture and sale of Pfizer's and Towa's generic version of TREAKISYM® and compensation for damages arising from the infringement.

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

(ii) Research and development activities

During the fiscal year under review, we conducted the following research and development activities in each of our development pipelines.

(a) Anticancer agents: SyB L-0501 (FD formulation), SyB L-1701 (RTD formulation), and SyB L-1702 (RI administration) (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM®)

For the RI administration, the Group completed clinical studies on safety and a partial change application was approved in February 2022, enabling the use of RI injection for all approved indications of the RTD formulation in-licensed from Eagle.

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

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

For rigosertib in-licensed from Onconova Therapeutics, Inc. and TREAKISYM®, the Group is searching for new indications as well as new applications for the drugs used in combination with each other or with other existing drugs, through joint research and the offering of academia-industry collaborative courses with the University of Tokyo.

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

In the development of the intravenous and oral formulations of antiviral drug brincidofovir (SyB V-1901; hereinafter “BCV IV” and “BCV Oral”) , in-licensed from Onconova with a view to global rollout, the Group has been carrying out joint research with top research institutions of each specialized field in Japan and overseas in light of the drugs’ broad effectiveness against dsDNA viruses.

The Group has decided to prioritize the global development of BCV IV primarily in Japan, the U.S., and Europe, targeting disseminated AdV infections occurring after hematopoietic stem cell transplantation, a niche area with a high unmet medical need. In March 2021, the Group filed an Investigational New Drug (IND) application with the FDA to conduct a Phase II clinical trial primarily in pediatric patients suffering from AdV infections (also including adults). This development program was granted Fast Track designation by the FDA in April 2021, and the investigational drug was administered to the first patient in August 2021. As of December 31, 2022, 20 patients were enrolled.

BK virus (BKV) infection after kidney transplantation is a disease with serious consequences for the recipient, the donor, the medical practitioner, and the society, due to the risk of impaired renal function and loss of the transplanted kidney (graft loss). The Group submitted a clinical trial notification for a global Phase II study in patients infected with BKV after kidney transplantation to the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan in May 2022 and filed another notification with the Therapeutic Goods Administration (TGA) of Australia in August 2022, and the investigational drug was administered to the first patient in December 2022.

The Group is also looking to develop BCV to treat multiple sclerosis, an intractable disease that has recently been proven to be associated with Epstein-Barr virus (EBV). In August 2022, the Group entered into a collaboration agreement with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) in the U.S., for the transfer of materials for evaluation of BCV’s potential antiviral effect on EBV.

Among double-stranded DNA viruses (dsDNA), polyomaviruses are known to cause serious diseases through their infection. As existing antiviral drugs show little efficacy, the development of an effective treatment is eagerly awaited. In November 2022, the Group entered into Material Transfer Agreement with Penn State College of Medicine whereby the Group will provide BCV for use in a non-clinical study to evaluate the efficacy of BCV in a mouse model of polyomavirus infection.

Some double-stranded DNA viruses, such as HSV1 and VZV, are directed against cranial nerve tissues and are known to cause serious diseases, including Alzheimer's disease, in various cranial nerve areas due to infection caused by their reactivation. In December 2022, the Group entered into a Sponsored Research Agreement with Tufts University to conduct joint research on BCV. This joint research is a nonclinical study that will evaluate the efficacy of BCV in a herpes simplex virus (HSV) infection model using a 3D (three-dimensional) brain model established by Tufts University.

In addition to having its strong antiviral effect, BCV also is expected to have an antitumor effect, and the Group is exploring new indications such as EBV-positive lymphoma, refractory brain tumors, and other cancers via research collaborations with the National Cancer Centre Singapore (NCCS) and University of California San Francisco (UCSF) Brain Tumor Center. In December 2022, the results of collaborative research with NCCS on the therapeutic efficacy of BCV in the treatment of NK/T-cell lymphoma for which no effective treatment is currently available were presented by Dr. Jason Yongsheng Chan at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans.

In September 2022, Chimerix Inc. announced that it has completed the closing of the sale of BCV to Emergent BioSolutions Inc. (head office: Maryland, U.S.). The Group's exclusive worldwide development, manufacturing, and marketing rights to BCV for all indications except orthopox virus infections (including smallpox and monkeypox) will not be affected.

(iii) Business outside Japan

The Group appointed Dr. Carolyn Yanavich, President and Chief Operating Officer of SymBio Pharma USA, Inc., as Chief Development Officer of the Group to further expand our global development structure and make SymBio Pharma USA, Inc. as the driving force behind the international clinical trials, spearheading and accelerating the global development plan for BCV.

(iv) Licensing of new drug candidates

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

(v) Capital investment

The total amount of capital expenditures during the fiscal year under review was 47,559 thousand yen, mainly consisting of office investments and the purchase of appliances, network devices, and business software.

(2) Fundraising status

In the consolidated fiscal year under review, the Group raised 662,000 thousand yen through the issue of new shares with the CVI Investments, Inc. as the allottee, and 13,760 thousand yen through the issue of the 58th share acquisition rights (total issue price: 13,760 thousand yen, total value of shares to be issued when the share acquisition rights are exercised in full: 1,570,000 thousand yen).

(3) Status of assets and profit and loss

(Unit: thousands of yen)

Fiscal year / Classification	FY 2019 The 15th Term	FY 2020 The 16th Term	FY 2021 The 17th Term	FY 2022 The 18th Term (Consolidated fiscal year)
Net sales	−	−	−	10,008,338
Operating profit (loss)	−	−	−	1,963,625
Ordinary profit (loss)	−	−	−	1,999,878
Profit (loss) attributable to owners of parent	−	−	−	1,179,238
Profit (Loss) per share (yen)	−	−	−	30.20
Total assets	−	−	−	10,433,347
Net assets	−	−	−	8,506,092
Net assets per share (yen)	−	−	−	204.83

(Note) Figures for the 17th and prior terms have been omitted as the Company began preparing consolidated financial statements from the 18th term (the consolidated fiscal year under review).

(4) Issues to be addressed by the Group

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

TREAKISYM® is approved for manufacturing and marketing in Japan for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, chronic lymphocytic leukemia, and first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. TREAKISYM® 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 efforts to maximize the business value of TREAKISYM® 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 injection, the Company filed a partial change application in May 2021, and obtained approval in February 2022.

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, 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 and BK virus infections occurring after kidney transplantation, areas with a high unmet medical need, ahead of any other indications. It has also begun to explore the potential of the drug in treating 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. Further, by accumulating data from joint research with the National Institutes of Health and Tufts University, both in the US, we will investigate the effectiveness of brincidofovir in treating various dsDNA virus infections in humans and expand its indication to multiple viral infections. In doing so, we aim to maximize the market and business value of brincidofovir.

(iii) Countermeasures to generic drugs

In February 2022, four pharmaceutical companies obtained approval to manufacture and market generic versions of the RTD formulation of TREAKISYM®. Given the potential infringement of the licensor Eagle Pharmaceuticals, Inc.'s patent and the exclusive patent license granted to SymBio, the Company, after discussing with Eagle, notified the four companies of potential patent infringement in writing and requested they take appropriate actions. In December 2022, the Company and Eagle jointly filed a lawsuit against Pfizer Japan Inc. and Towa Pharmaceutical Co., Ltd., seeking an injunction against the manufacture and sale of the generic versions of TREAKISYM® and claiming damages based on patent infringement.

(iv) Global expansion for further growth

In addition to Japan, the Group identifies China, South Korea, Taiwan, and Singapore as strategic regions and has moved forward with business development in Asia. However, with expanding medical expenditures due to the aging population in Japan, and the advent of the "era of generic drugs comprising 80% of all drugs dispensed" as a governmental policy of Japan, the business environment for innovative drug developers is expected to remain extremely challenging. Such a policy may also be implemented by other Asian countries.

Under these circumstances, the Group 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 Group 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 Group 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, 2022)

The Group 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, 2022)

Name	Location
Main office	Minato-ku, Tokyo

(ii) Employees (as of December 31, 2022)

Classification	Number of employees	Increase or decrease from previous fiscal year-end	Average age (years)	Average number of years of service
Male	92	—	52.7	4.3
Female	30	—	49.6	5.3
Total or average	122	—	52.0	4.5

(Notes) 1. Number of employees refers to full time employees.
2. The above number of employees does not include 30 temporary staff (including two at consolidated subsidiary).
3. No comparatives with the previous fiscal year-end have been provided as the Company began preparing consolidated financial statements from the 18th term (the consolidated fiscal year under review).

(7) Status of significant subsidiaries

Company name	Capital	Voting rights ratio	Main business
SymBio Pharma USA, Inc.	USD1.00	100.0%	Pharmaceutical R&D

(8) Main lenders and amount of borrowings (as of December 31, 2022)

Not applicable.

2. Matters Related to Stock (as of December 31, 2022)

(1) Total number of authorized shares

Common stock: 41,750,000 shares

(2) Total number of shares outstanding

Common stock: 39,518,338 shares (excluding 85,268 shares of treasury stock)

(3) Number of shareholders

40,016

(4) Major shareholders (10 largest)

Name of shareholder	Number of shares held	Shareholding ratio
Fuminori Yoshida	1,109,700	2.8%
ML PRO SEGREGATION ACCOUNT	1,001,000	2.5%
Sukenori Ito	430,000	1.1%
Daisuke Gomi	300,000	0.8%
Matsui Securities Co., Ltd.	250,200	0.6%
SMBC Nikko Securities Inc.	221,700	0.6%
Toshitaka Kashihara	220,025	0.6%
Nomura Securities Co., Ltd. self-deposit account	178,600	0.5%
Daiwa Securities Co., Ltd.	155,250	0.4%
JPMorgan Securities Japan Co., Ltd.	136,193	0.3%

(Note) 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, 2022)

	The 30th warrant by resolution of the Board of Directors meeting on May 14, 2013	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	1,160 units	3,050 units	3,150 units
Number of shares to be issued upon the exercise of share acquisition rights (Note 4)	29,000 shares	76,250 shares	78,750 shares
Amount paid for share acquisition rights	None	19,800 yen per unit	19,400 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right (Note 1)	3,196 yen per share	1 yen per share	1 yen per share
Period in which exercise of share acquisition rights is possible	From: May 15, 2015 To: May 14, 2023	From: March 30, 2021 To: March 29, 2028	From: March 30, 2022 To: March 29, 2029
Status of possession by Directors (excluding Audit & Supervisory Committee members and Outside Directors) (Note 4)	645 units (1 holder) 16,125 shares	—	—
Status of possession by Outside Directors (excluding Audit & Supervisory Committee Members)	—	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	The 54th warrant by resolution of the Board of Directors meeting on March 24, 2021	The 56th warrant by resolution of the Board of Directors meeting on March 29, 2022
Number of share acquisition rights	4,600 units	1,630 units	3,200 units
Number of shares to be issued upon the exercise of share acquisition rights (Note 4)	115,000 shares	40,750 shares	80,000 shares
Amount paid for share acquisition rights (Note 2) (Note 4)	8,100 yen per unit	29,225 yen per unit	17,200 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right (Note 1)	1 yen per share	1 yen per share	1 yen per share
Period in which exercise of share acquisition rights is possible	From: March 27, 2023 To: March 26, 2030	From: March 25, 2024 To: March 24, 2031	From: March 30, 2025 To: March 29, 2032
Status of possession by Directors (excluding Audit & Supervisory Committee Members and Outside Directors) (Note 4)	2,800 units (1 holder) 70,000 shares	1,000 units (1 holder) 25,000 shares	2,000 units (1 holder) 50,000 shares
Status of possession by Outside Directors (excluding Audit& Supervisory Committee Members) (Note 4)	800 units (2 holders) 20,000 shares	450 units (3 holders) 11,250 shares	450 units (3 holders) 11,250 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 Directors serving as Audit & Supervisory Committee 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, 2022)

	The 57th warrant by resolution of the Board of Directors meeting on March 29, 2022
Number of share acquisition rights	6,455 units
Number of shares to be issued upon the exercise of share acquisition rights	161,375 shares
Amount paid for share acquisition rights (Note 2)	17,200 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 20, 2025 To: March 29, 2032
Status of allotment to the Company's employees (Note 1)	5,881 units (105 holders) 147,025 shares

(Notes) 1. Of the share acquisition rights mentioned above, 574 units (14,350 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 (as of December 31, 2022)

The details of the issue of share acquisition rights via third-party allotment were determined as below by resolution of the Board of Directors at a meeting held on May 16, 2022.

	The 58th warrant by resolution of the Board of Directors meeting on May 16, 2022
Allotee	CVI INVESTMENT, Inc.
Number of share acquisition rights	20,000 units
Number of shares to be issued upon the exercise of share acquisition rights	2,000,000 shares
Amount paid for share acquisition rights	688 yen per unit
Value of property to be contributed upon the exercise of each share acquisition right	785 yen per share
Period in which exercise of share acquisition rights is possible	From: June 2, 2022 To: June 1, 2027

4. The Company's Officers (as of December 31, 2022)

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

Company position	Name	Responsibility and significant concurrent position
Representative Director	Fuminori Yoshida	Representative Director, President and CEO
Director	Shigetoshi Matsumoto	Senior Advisor, Protiviti LLC Audit Practice Counselor, Japan Audit & Supervisory Board Members Association
Director	Bruce David Cheson	Scientific Advisor, Lymphoma Research Foundation Doctor, Cancer and Blood Disorders Center
Director	Eiji Ebinuma	Partner, Tanabe & Partners Outside Director, Rakuten Bank, Ltd. Audit & Supervisory Board Member, Toko Electrical Construction Co.
Director (full-time Audit & Supervisory Committee Member)	Kiyoshi Watanabe	
Director (Audit & Supervisory Committee Member)	Kesao Endo	Representative, Endo C.P.A. Firm Outside Director, Careerlink Co., Ltd. Representative Partner, ABS Audit Corp.
Director (Audit & Supervisory Committee Member)	Yasuhiro Tamo	Partner, Nomura & Partners

(Notes) 1. On March 29, 2022, the Company transitioned to a company with Audit & Supervisory Committee. As a result of the transition, the terms of office of full-time Audit & Supervisory Board Member Kiyoshi Watanabe and Audit & Supervisory Board Members Kesao Endo and Yasuhiro Tamo had expired, and Kiyoshi Watanabe was appointed Director (full-time Audit & Supervisory Committee Member) and Kesao Endo and Yasuhiro Tamo were appointed Directors (Audit & Supervisory Committee Members).

2. Shigetoshi Matsumoto, Bruce David Cheson, Eiji Ebinuma, Kiyoshi Watanabe, Kesao Endo, and Yasuhiro Tamo are Outside Directors.
3. The Company has designated Outside Directors Shigetoshi Matsumoto, Eiji Ebinuma, Kiyoshi Watanabe, and Kesao Endo as independent officers pursuant to the provisions of the Tokyo Stock Exchange (TSE) and registered them as such with the TSE.
4. Director (Audit & Supervisory Committee Member) Kesao Endo possesses deep insight in finance and accounting, which he gained through his profession as a certified public accountant.
5. Change in Directors during the fiscal year under review is as follows:
   Director Hirotaka Ito resigned on May 31, 2022. At the time of his resignation, he was Director, Vice President, and COO.
6. The Company has appointed Outside Director Kiyoshi Watanabe as full-time Audit & Supervisory Committee Member to enable gathering of information from Directors (excluding Audit & Supervisory Committee Members) and information sharing at important meetings, as well as sufficient cooperation between the Internal Audit Division and Audit & Supervisory Committee, with the aim of strengthening the Committee's audit and supervisory functions.
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
   Corporate Officer Koji Fukushima
   Corporate Officer Kozo Yoshida
   Corporate Officer Yoshiharu Torikai
   Corporate Officer Kei Bamba

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

The Company has entered into a liability limitation agreement with all Directors excluding those engaged in business execution based on the provisions of Article 427, Paragraph 1 of the Companies Act. Under the terms of the agreement, in the event that a Director has caused loss to the Company due to negligence of his or her duties, and if the Director performed his or her duties in good faith and without gross negligence, the Director's liability will be limited to the higher of 1,000,000 yen or the minimum liability amount set forth in Article 425, Paragraph 1 of the Companies Act.

(3) Summary of the contents of the indemnification contract

The Company has entered into an indemnification contract with Fuminori Yoshida, Shigetoshi Matsumoto, Bruce David Cheson, Kiyoshi Watanabe, Kesao Endo, and Yasuhiro Tamo as stipulated in Article 430-2, Paragraph 1 of the Companies Act. In addition to expenses related to shareholder lawsuits that may arise due to misconduct, the indemnification contract covers a wide range of expenses that individual directors and the Company may incur, including the costs of dealing with criminal proceedings and public investigations outside Japan. An indemnification contract was also concluded for Director Hirotaka Ito, who resigned on May 31, 2022.

(4) Directors and Officers Liability Insurance Policies

The Company has obtained Directors and Officers Liability Insurance Policies covering the Directors and Corporate Officers 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 Corporate Officers. However, the insurance policies exclude coverage for claims arising out of fraudulent or dishonest acts conducted knowing that they were in violation of the laws and regulations. By establishing such exclusions, we have taken steps to ensure the appropriateness of the execution of duties by officers is not compromised.

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

(5) Compensation of members of the Board of Directors

(i) Matters related to the policy for determining the details of individual compensation for Directors

The Company's basic policy is to set the compensation for Directors after the transition to a Company with Audit & Supervisory Committee at an appropriate level in consideration of their responsibilities. The amount of compensation for Directors does not include the share of salary as an employee for Directors who are concurrently serving as employees.

The Audit & Supervisory Committee has the authority to make decisions on the policy concerning the determination of the amount of compensation, or the calculation method thereof, for Directors serving as Audit & Supervisory Committee Members. The contents of such authority and the scope of discretion shall be determined by the Audit & Supervisory Committee with the consent of all of its members, within the limit of the total amount determined at the General Meeting of Shareholders.

1. Basic policy

The compensation system for Directors (excluding those serving as Audit & Supervisory Committee Members) shall be linked to shareholders' profit to function sufficiently as an incentive for the sustainable enhancement of corporate value. Furthermore, the compensation of individual Directors (excluding those serving as Audit & Supervisory Committee Members) shall be determined at an appropriate level based on the responsibilities of each position, and compensation shall consist of basic compensation as fixed compensation and stock-based compensation.

2. Policy on determination of the amount of basic compensation (monetary compensation) of individual Directors (excluding those serving as Audit & Supervisory Board Members; including policies on determining the timing or conditions for granting compensation)

The basic compensation for Directors (excluding those serving as Audit & Supervisory Committee Members) of the Company shall be a monthly fixed compensation, and shall be determined based on a comprehensive consideration of the role, responsibilities, years of service taking into account the level of compensation at other companies, the Company's business performance, and the level of employee salaries. In making the decision, the Company confirms that the decision is in line with the above policy, based on the report of the Nomination and Compensation Committee, which is composed of a majority of Outside Directors, with an Outside Director serving as the chairperson. The decision is then delegated to the Representative Director by a resolution of the Board of Directors. In addition, the Company ensures reasonableness by delegating the decision to the Representative Director within the scope of the report that has been appropriately reviewed by the Nomination and Compensation Committee.

3. Policy on determining the ratio of performance-linked compensation and other compensation of Directors (excluding those serving as Audit & Supervisory Committee Members)

Performance-linked compensation may be linked to the Medium-Term Management Plan to raise awareness of the need to improve business performance, and compensation may be paid in a way that links business performance to compensation, or stock options may be granted. The ratio of performance-linked compensation to other compensation shall be considered by the Nomination and Compensation Committee. The Board of Directors shall delegate the President and Representative Director to respect the content of the report of the Nomination and Compensation Committee and to determine the content of compensation for each individual Director (excluding those serving as Audit & Supervisory Committee Members). The ratio of compensation for Directors who engage in business execution is considered based on the level of compensation benchmarked to companies of a similar scale as the Company or companies in related industries and business categories.

4. Matters concerning the determination of the content of individual compensation of Directors (excluding those serving as Audit & Supervisory Committee Members)

The amount of compensation and stock options for each individual shall be reviewed by the Nomination and Compensation Committee. The Board of Directors shall delegate the Representative Director, President and CEO to make decisions while respecting the content of the report of the Nomination and Compensation Committee. Based on the delegation by the resolution of the Board of Directors, Representative Director, President and CEO Fuminori Yoshida decides the amount, timing, and method of payment of compensation to each Director for the current fiscal year. The above authority was delegated to Fuminori Yoshida, as the Company deems it appropriate for the Representative Director, President and CEO to make decisions on the contents of compensation in order to make decisions that take into account the evaluation of each Director's business performance while taking a comprehensive view of the Company's performance.

(ii) Reasons for the Board of Directors' determination that the contents of the compensation of Directors (excluding those serving as Audit & Supervisory Committee Members) for the fiscal year under review is in line with the said policy

In determining the compensation for each individual Director (excluding those serving as Audit & Supervisory Committee Members), the Board of Directors has determined that the contents of the decision are in line with the above policy, given that the Representative Director makes the decision in line with the said policy.

(iii) Matters concerning the resolution of the General Meeting of Shareholders regarding compensation

At the 17th Ordinary General Meeting of Shareholders held on March 29, 2022, it was resolved that the maximum annual amount of compensation for Directors (excluding those serving as Audit & Supervisory Committee Members) shall be 130 million yen (40 million yen for Outside Directors; does not include employee salaries for Directors concurrently serving as employees). The number of Directors (excluding those serving as Audit & Supervisory Committee Members) at the conclusion of the said General Meeting of Shareholders was five (5), including three (3) Outside Directors.

Separate from the monetary compensation, it was resolved at the said General Meeting of Shareholders that the maximum annual amount of stock options granted to Directors (excluding those serving as Audit & Supervisory Committee Members) shall be 90 million yen (30 million yen for Outside Directors), and that the maximum number of stock acquisition rights granted within a year from the date of the General Meeting of Shareholders of each fiscal year shall be 3,200 units (does not include employee salaries for Directors concurrently serving as employees). The number of Directors (excluding those serving as Audit & Supervisory Committee Members) at the conclusion of the said General Meeting of Shareholders was five (5), including three (3) Outside Directors. Note that prior to the transition to a company with Audit & Supervisory Committee, it was resolved that the maximum annual amount of stock options granted to Directors shall be 80 million yen at the 8th Ordinary General Meeting of Shareholders held on March 28, 2013 (30 million for Outside Directors, approved at the 11th Ordinary General Meeting of Shareholders held on March 30, 2016). Further, it was resolved that no more than 3,200 units of share acquisition rights shall be granted per year to Directors at the 16th Ordinary General Meeting of Shareholders held on March 24, 2021. The number of Directors at the conclusion of the said General Meeting of Shareholders was seven (7), including five (5) Outside Directors.

At the 17th Ordinary General Meeting of Shareholders held on March 29, 2022, it was resolved that the maximum annual amount of monetary compensation for Directors serving as Audit & Supervisory Committee Members shall be 30 million yen, and that the specific amount and timing of payments shall be determined by discussions among Directors serving as Audit & Supervisory Committee Members. The number of Directors serving as Audit & Supervisory Committee Members at the conclusion of the said General Meeting of Shareholders was three (3). Note that prior to the transition to a company with Audit & Supervisory Committee, it was resolved that the maximum annual amount of compensation for Audit & Supervisory Board Members shall be 30 million yen at the Extraordinary General Meeting of Shareholders held on June 30, 2011. The number of Audit & Supervisory Board Members at the conclusion of the said General Meeting of Shareholders was four (4).

(iv) Total amount of compensation for Directors and Audit & Supervisory Board Members

Classification	Total amount of compensation (thousand yen)	Total amount of compensation by type (thousand yen)			Number of eligible officers
		Base compensation	Performance-linked compensation	Non-monetary compensation	
Directors, excluding Audit & Supervisory Committee Members (Outside Directors)	98,112 (29,364)	60,646 (20,019)	— (—)	37,466 (9,345)	5 (3)

Directors serving as Audit & Supervisory Committee Members (Outside Directors)	18,909 (18,909)	18,909 (18,909)	— (—)	— (—)	3 (3)
Audit & Supervisory Board Members (outside members)	5,398 (5,398)	5,398 (5,398)	— (—)	— (—)	3 (3)

(Notes) 1. The amount of compensation for Directors does not include the share of salary as an employee for Directors who are concurrently serving as employees.
2. On March 29, 2022, the Company transitioned to a company with Audit & Supervisory Committee with the approval of the proposal to partially amend the Articles of Incorporation at the 17th Ordinary General Meeting of Shareholders held on the same day.
3. Compensation for the Audit & Supervisory Board Members above is the amount paid prior to the transition to a company with Audit & Supervisory Committee.
4. The number of Directors or Audit & Supervisory Board Members compensated as stated above includes one (1) Director who resigned on May 31, 2022.
5. The contents of non-monetary compensation are the amount of expenses recorded during the fiscal year under review related to stock acquisition rights granted as stock options.

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

(i) 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	Status of attendance at the Audit & Supervisory Committee meetings	Opinions at the Board of Directors meetings, the Audit & Supervisory Board meetings, and the Audit & Supervisory Committee meetings
Director	Shigetoshi Matsumoto	17 out of 17 (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	17 out of 17 (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	Eiji Ebinuma	17 out of 17 (100%)	—	—	Mr. Ebinuma expressed opinions from an objective perspective independent from the Company's management engaged in business operations, using his knowledge and experience at financial institutions and as an attorney at law, mainly in the area of labor law, and his extensive knowledge as an Outside Director.

Director (full-time Audit & Supervisory Committee Member)	Kiyoshi Watanabe	17 out of 17 (100%)	4 out of 4 (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.
Director (Audit & Supervisory Committee Member)	Kesao Endo	17 out of 17 (100%)	4 out of 4 (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.
Director (Audit & Supervisory Committee Member)	Yasuhiro Tamo	17 out of 17 (100%)	4 out of 4 (100%)	14 out of 14 (100%)	Mr. Tamo expressed opinions from an objective perspective independent from the Company's management engaged in business operations, based on his knowledge and experience as an attorney at law, mainly in the area of corporate law.

(Notes) 1. On March 29, 2022, the Company transitioned to a company with Audit & Supervisory Committee with the approval of the proposal to partially amend the Articles of Incorporation at the 17th Ordinary General Meeting of Shareholders held on the same day.

2. Changes in Directors and Audit & Supervisory Board Members during the fiscal year under review were as follows. The terms of office of full-time Audit & Supervisory Board Member Kiyoshi Watanabe and Audit & Supervisory Board Members Kesao Endo and Yasuhiro Tamo expired, and Kiyoshi Watanabe was appointed Director (full-time Audit & Supervisory Committee Member) and Kesao Endo and Yasuhiro Tamo were appointed Directors (Audit & Supervisory Committee Members).

(ii) Summary of duties performed in roles expected to be fulfilled by Outside Directors

1. Shigetoshi Matsumoto and Eiji Ebinuma have been involved as members of the Nomination and Compensation Committee from an objective and neutral standpoint in the selection of candidates for the Company's Board of Directors and the determination of compensation for Directors.
2. Bruce David Cheson has contributed to the enhancement of the Company's group-wide governance and supervisory functions from a global perspective, and to the monitoring and supervision of the management of the Company from an independent standpoint.
3. Kiyoshi Watanabe has contributed to the enhancement and reinforcement of the Company's corporate governance and to the monitoring and supervision of the Company's management from an independent standpoint, leveraging his track record at financial institutions and his broad experience and deep insight in management.
4. Kesao Endo has monitored and supervised the Company's management and contributed to strengthening its supervisory function over business execution from an independent standpoint, drawing on his expertise and abundant experience as a certified public accountant.
5. Yasuhiro Tamo has monitored and supervised the Company's management and contributed to strengthening the supervisory function of business execution from an independent standpoint, based on his knowledge and extensive experience as an attorney at law, mainly in the area of corporate law.

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) Summary of the contents of the compensation agreement
Not applicable.

(4) Amount of compensation

	Amount paid
Amount of compensation paid to the accounting auditor concerning the fiscal year under review	33,500 thousand yen
Total amount of monetary and other property benefits to be paid by the Company and its subsidiary	33,500 thousand yen

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

(5) 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 Committee 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 Committee shall dismiss the accounting auditor with the consent of all members of the Audit & Supervisory Committee. If this is the case, an Audit & Supervisory Committee Member selected by the Audit & Supervisory Committee 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 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 for the Group 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 at the Company to ensure the Group's complete observance of laws and ordinances, the Articles of Incorporation, and other internal regulations through exhaustive supervision.

(iii) Establishment of internal audit office, etc.

The Company has established an internal audit office as an independent unit under the direct supervision of the President and appoints internal auditors to its subsidiary as necessary. Through regular audits and related activities, 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 of the Group, 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 for the Group.

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

The Group 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 Group 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 and their associates

The Group resolutely opposes anti-social forces and their associates 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 Committee Members

Audit & Supervisory Committee Members may request that the Representative Director and President appoint an employee to act as an assistant to Audit & Supervisory Committee 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 Committee Members from Directors (excluding those serving as Audit &Supervisory Committee Members) and the effectiveness of the Audit & Supervisory Committee Members' instructions to employees

(i) Assistants to Audit & Supervisory Committee Members shall not receive instructions concerning their supporting duties from anyone other than Audit & Supervisory Committee Members.

(ii) Matters such as personnel evaluation and transfer and disciplinary actions concerning employees that assist Audit & Supervisory Committee Members shall be subject to the prior consent of the Audit & Supervisory Committee.

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

(i) Any Director or employee shall promptly inform the Audit & Supervisory Committee 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 Committee 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. In addition, they are permitted to view key decision-making documents related to these meetings.

(iii) Audit & Supervisory Committee 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 Committee 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 Committee.

(9) Matters related to the treatment of expenses or obligations associated with the execution of duties of Audit & Supervisory Committee Members (limited to the execution of duties of Audit & Supervisory Committee), 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 Committee Members under Article 399-2 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 Committee Members.

(ii) The Company authorizes and shoulders expenses incurred when Audit & Supervisory Committee 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.

(10) System to ensure appropriate operations of the corporate organization consisting of the Company and its subsidiary

The Company will take the following measures to properly manage and operate the Group.

(i) We will apply SymBio Charter of Corporate Conduct to our subsidiary, and strive to ensure thorough awareness of the Charter, along with the Codes of Conduct of subsidiary created based on the Charter.

(ii) The Company will build and operate an appropriate internal control system related to the following, to enable appropriate management and business execution of the Group.

1) System for reporting matters related to the execution of duties of subsidiary Directors to the Company

2) Regulations and other systems for risk management and loss control of the subsidiary

3) System to ensure that Directors of subsidiary are executing their duties efficiently

4) System to ensure that Directors and employees of subsidiary are executing their duties in compliance with laws and regulations and the Articles of Incorporation

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 (including Directors serving as Audit & Supervisory Committee Members) participate in resolutions from an independent standpoint and monitor and supervise the management. Each Audit & Supervisory Committee Member carries out management audits as well.

(3) Full-time Audit & Supervisory Committee 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.

Consolidated Balance Sheet

(As of December 31, 2022)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	9,312,706	Current liabilities	1,923,870
Cash and deposits	6,282,554	Accounts payable–trade	46,633
Accounts receivable–trade	2,084,915	Accounts payable–other	1,163,721
Merchandise and finished goods	293,757	Income taxes payable	401,066
Semi-finished goods	175,170	Provision for product changeover	16,331
Supplies	452	Other	296,118
Advance payments	252,745	Non-current liabilities	3,385
Prepaid expenses	209,886	Provision for retirement benefits	3,385
Other	13,224	Total liabilities	1,927,255
Non-current assets	1,120,641	(Net assets)	
Property, plant and equipment	69,009	Shareholders’ equity	8,094,176
Buildings	64,931	Capital stock	17,548,459
Tools, furniture and fixtures	73,159	Capital surplus	17,523,357
Accumulated depreciation	(69,080)	Retained earnings	(26,889,486)
Intangible assets	222,204	Treasury shares	(88,154)
Software	222,204	Accumulated other comprehensive income	243
Investments and other assets	829,427	Foreign currency translation adjustment	243
Deferred tax assets	744,728	Share acquisition rights	411,672
Leasehold and guarantee deposits	84,698		
		Total net assets	8,506,092
Total assets	10,433,347	Total liabilities and net assets	10,433,347

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

Consolidated Statement of Income

(From January 1, 2022 to December 31, 2022)

(Unit: thousands of yen)

Item	Amount	
I. Net sales		10,008,338
II. Cost of goods sold		2,408,434
Gross profit		7,599,904
III. Selling, general and administrative expenses		5,636,278
Operating profit		1,963,625
IV. Non-operating income		
Interest income	98	
Foreign exchange gains	136,179	
Other	2,925	139,204
V. Non-operating expenses		
Commission fee	56,543	
Share issuance cost	45,867	
Other	540	102,951
Ordinary profit		1,999,878
VI. Extraordinary income		
Gain on reversal of share acquisition rights	106,401	106,401
Profit before income taxes		2,106,279
Income taxes–current	396,010	
Income taxes–deferred	531,030	927,041
Profit		1,179,238
Profit attributable to non-controlling interests		—
Profit attributable to owners of parent		1,179,238

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

Consolidated Statement of Changes in Equity

(From January 1, 2022 to December 31, 2022)

(Unit: thousands of yen)

	Shareholders' equity				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total Shareholders' equity
Balance as of January 1, 2022	17,157,628	17,132,501	(27,975,902)	(86,045)	6,228,181
Cumulative effect of changes in accounting policies			(92,822)		(92,822)
Restated balance	17,157,628	17,132,501	(28,068,725)	(86,045)	6,135,358
Changes during period					
Issuance of new shares	331,000	331,000			662,000
Issuance of new shares (exercise of share acquisition rights)	59,831	59,831			119,662
Profit attributable to owners of parent			1,179,238		1,179,238
Purchase of treasury shares				(2,165)	(2,165)
Disposal of treasury shares		24		56	81
Net changes of items other than shareholders' equity					
Total changes during period	390,831	390,856	1,179,238	(2,108)	1,958,817
Balance as of December 31, 2022	17,548,459	17,523,357	(26,889,486)	(88,154)	8,094,176

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance as of January 1, 2022	44	44	519,099	6,747,325
Cumulative effect of changes in accounting policies				(92,822)
Restated balance	44	44	519,099	6,654,502
Changes during period				
Issuance of new shares				662,000
Issuance of new shares (exercise of share acquisition rights)				119,662
Profit attributable to owners of parent				1,179,238
Purchase of treasury shares				(2,165)
Disposal of treasury shares				81
Net changes of items other than shareholders' equity	198	198	(107,426)	(107,228)
Total changes during period	198	198	(107,426)	1,851,589
Balance as of December 31, 2022	243	243	411,672	8,506,092

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

Notes to Consolidated Financial Statements

(Basis of consolidated financial statements)

(Scope of consolidation)

Number of consolidated subsidiaries and the name of key consolidated subsidiary

Number of consolidated subsidiaries	One
Name of consolidated subsidiary	SymBio Pharma USA, Inc.

Effective from the fiscal year under review, the Company included SymBio Pharma USA, Inc., previously a non-consolidated subsidiary, in the scope of consolidation due to the subsidiary's increased significance.

(Application of equity method accounting)

None to be reported.

(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	Merchandise and finished goods are stated at cost determined by the first-in, first-out method, and semi-finished goods are stated at cost determined by the weighted average cost method. The amount on the balance sheet is calculated by reducing book value when the contribution of inventories to profitability declines. Inventory items are classified into separate categories for the purpose of detailed monitoring of inventory movements and appropriate valuation.

(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) Basis for reserves and provisions

Provision for product changeover	An estimated amount of expenses is recorded to prepare for expenses to be incurred accompanying the changeover from the FD formulation to RTD formulation of TREAKISYM®.

(4) Recognition of significant revenues and expenses

The Group recognizes revenue from the sale of merchandise and finished goods at the time of delivery to the customer, as this is when the control of the merchandise and finished goods is transferred to the customer and performance obligations are satisfied. Revenue from the sale of merchandise and finished goods is estimated within the range in which it is highly probable that there will not be a significant reversal of the consideration promised in the contract with the customer less sales rebates in accordance with the terms of the sales contract. The amount of consideration expected to be refunded to the customer is recorded as a refund liability. The refund liability is estimated based on the terms of the contract and past records.

(5) Other significant matters for preparation of consolidated financial statements

(i) Fiscal year of the consolidated subsidiary

The closing date of the consolidated subsidiary is the same as the consolidated closing date.

(ii) Accounting method for deferred assets

Share issuance costs and bond issuance costs are recorded in full as expenses when incurred.

(iii) Accounting method for retirement benefits

A simplified method is applied in calculating the retirement benefit liabilities and retirement benefit expenses, using the amount of benefits that would be payable if all employees voluntarily retired at the end of the fiscal year as retirement benefit liabilities.

(iv) Standard for translation of foreign-currency denominated assets or liabilities into Japanese yen

Monetary assets and liabilities denominated in foreign currencies are translated into Japanese yen at the spot exchange rate prevailing on the closing date, and the difference arising from such translation is recorded as profit or loss.

(Notes on changes in accounting policy)

(Application of Accounting Standard for Revenue Recognition)

The Group has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29; March 31, 2020; hereinafter "Revenue Recognition Standard") from the beginning of the fiscal year under review. As a result of the application of this standard, revenue will be recognized in the amount expected to be received in exchange for the promised goods or services at the time control of the promised goods or services is transferred to the customer.

Under the previous accounting standard, for transactions where the total amount of consideration the Group is entitled to in exchange for the transfer of promised goods or services, i.e., the transaction price, is likely to be reduced after a contract is signed with the customer, the Group revised the transaction price once the amount to be reduced was fixed. However, under the new accounting standard, the Group makes a reasonable estimate of the variable amount and subtracts it from the transaction price at the time the goods or services are transferred to the customer. Further, under the previous accounting standard, the Group accounted for expected sales returns by recording provisions for sales returns in the amount equivalent to gross profit; however, in accordance with the provisions regarding variable consideration, the Group no longer recognizes revenue at the time of sale and records refund liabilities as "other" under the current liabilities section of the balance sheet.

The Group has followed the transitional treatment prescribed in the provision of Paragraph 84 of the Revenue Recognition Standard and has applied the new accounting standard from the opening balance of retained earnings of the fiscal year under review, whereby the cumulative effect of retrospective application of the new accounting standard prior to the beginning of the fiscal year under review is added to or deducted from the beginning balance of retained earnings.

As a result, in the consolidated statements of income for the fiscal year under review, net sales increased by 62,962-thousand-yen, operating profit and ordinary profit increased by 62,962 thousand yen, respectively, and profit before income taxes increased by 62,962 thousand yen. In addition, the balance of retained earnings at the beginning of the period decreased by 92,822 thousand yen.

Net assets per share, net income per share and diluted net income per share decreased by 2.38 yen, increased by 1.61 yen and increased by 1.59 yen, respectively, during the current fiscal year.

(Application of Accounting Standard for Fair Value Measurement)

The Group has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30; July 4, 2019; hereinafter "Fair Value Measurement Standard") from the beginning of the fiscal year under review.

In applying the Fair Value Measurement Standard, the Group has followed the transitional treatment prescribed in the provision of Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the "Accounting

Standard for Financial Instruments" (ASBJ Statement No. 10; July 4, 2019) and will apply accounting the Fair Value Measurement Standard prospectively.

The adoption of this accounting standard has no effect on the consolidated financial statements.

(Note to Significant Accounting Estimates)

(1) Amount recorded in the consolidated financial statements for the fiscal year under review

Deferred tax assets recorded in the fiscal year under review: 744,728 thousand yen

(2) Information regarding significant accounting estimates on the identified item

(i) Calculation method

Based on the company classification stipulated in the "Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No. 26, February 16, 2018), the Company recorded deferred tax assets for the deductible temporary differences and losses carryforward at the end of the fiscal year under review, to the extent that they can be used to reduce future tax burden. When recording deferred tax assets, taxable income before adjustment for temporary differences, etc. is estimated based on the business plan.

(ii) Major assumptions

Taxable income based on future profitability is estimated according to the Group's business plan. The estimate is also based on certain assumptions that take into consideration significant uncertainties caused by such factors as the impact of sales volume of existing drugs on net sales and the impact of pipeline development progress on tax adjustment items.

(iii) Impact on the consolidated financial statements for subsequent fiscal years

Any revisions to the assumptions underlying the estimates due to changes in the economic conditions, etc., may have a significant impact on the amount of deferred tax assets to be recorded on the consolidated financial statements for subsequent fiscal years.

(Additional information)

(Overdraft and commitment line contracts)

The Group 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 outlook for the business environment remains uncertain, as COVID-19 infections remain a threat to healthcare facilities and patients, altering patient care behavior and making patients more cautious about treatment. Such impacts are considered in our accounting estimates such as the recoverability of deferred tax assets, etc.

(Consolidated statement of income)

R&D costs included in general and administrative expenses: 2,554,799 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 issued	38,457,206	1,146,400	—	39,603,606

(Notes) Increase of 1,000,000 shares in the total number of outstanding common shares is due to a capital increase and increase of 146,400 shares issued in common stock is due to the exercise of share acquisition rights.

(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 2,175,425 shares

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

(3) Matters related to dividends from surplus paid during the current fiscal year.
None to be reported

(Financial instruments)

(1) Financial instruments

(i) Policies for financial instruments

The Group 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 Group does not enter into derivative transactions for speculative trading purposes but uses them within the scope prescribed in the Group's internal rules.

(ii) Types of financial instruments and related risks

Operating receivables such as accounts receivable–trade 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.

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 Group 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 Group'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 Group 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 Group deposits cash primarily with financial institutions with high credit ratings.

The Group 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 Group's internal rules, the Finance & Accounting department executes and monitors derivative transactions. Transaction performances are reported to the Executive Management Committee on a regular basis.

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 Group 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 consolidated balance sheet, fair values, and their differences as of December 31, 2022 are as follows.

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Difference
Lease and guarantee deposits	84,698	81,183	△3,514
Assets, total	84,698	81,183	△3,514
Derivative transactions (*1)	(11,128)	(11,128)	—

(Note) 1. Receivables and liabilities arising from derivative transactions are presented on a net basis and net liabilities are shown in parentheses.
(Note) 2. Cash and deposits, Accounts receivable–trade, Accounts payable–trade, Accounts payable–other, Income taxes payable and Consumption taxes payable are omitted because they are cash or are settled within a short time and the fair value is almost equal to the book value.
(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
Cash and deposits	6,282,554	—	—	—
Accounts receivable–trade	2,084,915	—	—	—
Total	8,367,470	—	—	—

(Notes) Lease and guarantee deposits are not included because it is not possible to clearly determine the return date necessary to estimate the amortized amount of lease and guarantee deposits.

(3) Fair Value of Financial Instruments by levels

The fair value of financial instruments is classified into the following three levels based on the observability and materiality of the inputs used to calculate fair value.

Level 1: Fair value derived from quoted prices in active markets for identical assets or liabilities.
Level 2: Fair value derived from observable inputs that are not included in Level 1 inputs.
Level 3: Fair value derived from unobservable inputs.

When multiple inputs that have a significant impact on the fair value calculation are used, the fair value is classified at lower level category.

(ⅰ)Financial instruments measured at fair value

(Unit: thousands of yen)

Classification	Fair value			
	Level 1	Level 2	Level 3	Total
Derivative transactions Currency-related transactions	—	(11,128)	—	(11,128)
Liabilities, total	—	(11,128)	—	(11,128)

(Notes) Net receivables and payables, which were derived from derivative transactions, are presented in net amounts, and any item for which the total becomes a net liability is indicated in parentheses.

(ⅱ)Financial instruments other than those measured at fair value

(Unit: thousands of yen)

Classification	Fair value			
	Level 1	Level 2	Level 3	Total

Lease and guarantee deposits	—	81,183	—	81,183
Assets, total	—	81,183	—	81,183

(Notes) Derivative transactions
Fair value calculations are based on quoted prices provided by counterparty financial institutions and are classified as Level 2 fair value.

Lease and guarantee deposits
Based on a reasonably estimated expected return period, the fair value is calculated based on the present value of the future cash flows discounted by the Japanese government bond yields corresponding to the period until redemption, and is classified as Level 2 fair value.

(Revenue recognition)

(1) Information about breakdown of revenue from contracts with customers

(Unit: thousands of yen)

	Current Consolidated Fiscal Year (From January 1, 2022 to December 31, 2022)
Sales of Merchandise and finished goods	10,008,338
Revenue from contracts with customers	10,008,338
Sales to external customers	10,008,338

(2) Underlying information in understanding revenue
Underlying information in understanding revenue is as stated in (Basis of consolidated financial statements), (Significant accounting policies), (4) Recognition of significant revenues and expenses.

(3) Information for understanding the revenue amount for the fiscal year under review and subsequent fiscal years
(i) Balance of contract assets and contract liabilities
The Group has no balance of contract assets and contract liabilities. In addition, no revenue was recognized in the fiscal year under review from performance obligations satisfied in previous fiscal years.
(ii) Transaction price allocated to remaining performance obligations
The Group does not have any material transactions with an initial expected term of contract exceeding one year. Further, there is no material amount of consideration arising from contracts with customers that is not included in the transaction price.

(Per-share information)

(1) Net assets per share	204.83 yen
(2) Net profit per share	30.20 yen
Average number of shares outstanding during the year	39,046,821 shares

(Significant subsequent events)

None to be reported.

Balance Sheet

(As of December 31, 2022)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	9,289,713	Current liabilities	1,895,944
Cash and deposits	6,259,561	Accounts payable–trade	46,633
Accounts receivable–trade	2,084,915	Deferred income	18,803
Merchandise and finished goods	293,757	Accounts payable–other	1,135,794
Semi-finished goods	175,170	Income taxes payable	401,066
Supplies	452	Provision for product changeover	16,331
Advance payments	252,745	Consumption taxes payable	245,324
Prepaid expenses	209,886	Other	31,990
Other	13,224	Non-current liabilities	3,385
Non-current assets	1,120,641	Provision for retirement benefits	3,385
Property, plant and equipment	69,009	Total liabilities	1,899,329
Buildings	64,931	(Net assets)	
Tools, furniture and fixtures	73,159	Shareholders' equity	8,099,352
Accumulated depreciation	(69,080)	Capital stock	17,548,459
Intangible assets	222,204	Capital surplus	17,523,357
Software	222,204	Legal capital surplus	17,518,459
Investments and other assets	829,427	Other capital surplus	4,898
Shares of subsidiaries and associates	0	Retained earnings	(26,884,309)
Deferred tax assets	744,728	Other retained earnings	(26,884,309)
Leasehold and guarantee deposits	84,698	Retained earnings brought forward	(26,884,309)
		Treasury shares	(88,154)
		Share acquisition rights	411,672
		Total net assets	8,511,025
Total assets	10,410,354	Total liabilities and net assets	10,410,354

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

Statement of Income

(From January 1, 2022 to December 31, 2022)

(Unit: thousands of yen)

Item	Amount	
I. Net sales		10,008,338
II. Cost of goods sold		2,408,434
Gross profit		7,599,904
III. Selling, general and administrative expenses		5,627,706
Operating profit		1,972,197
IV. Non-operating income		
Interest income	98	
Foreign exchange gains	128,933	
Other	2,925	131,957
V. Non-operating expenses		
Commission fee	56,543	
Share issuance cost	45,867	
Other	540	102,951
Ordinary profit		2,001,204
VI. Extraordinary income		
Gain on reversal of share acquisition rights	106,401	106,401
Profit before income taxes		2,107,605
Income taxes–current	390,552	
Income taxes–deferred	531,030	921,582
Profit		1,186,022

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

Statement of Changes in Equity

(From January 1, 2022
to December 31, 2022)

(Unit: thousands of yen)

	Shareholders' equity				
		Capital surplus			Retained earnings
					Other retained earnings
	Capital stock	Legal capital surplus	Other capital surplus	Total capital surplus	Retained earnings brought forward
Balance as of January 1, 2022	17,157,628	17,127,628	4,873	17,132,501	(27,977,510)
Cumulative effect of changes in accounting policies					(92,822)
Restated balance	17,157,628	17,127,628	4,873	17,132,501	(28,070,332)
Changes during period					
Issuance of new shares	331,000	331,000		331,000	
Issuance of new shares (exercise of share acquisition rights)	59,831	59,831		59,831	
Profit					1,186,022
Purchase of treasury shares					
Disposal of treasury shares			24	24	
Net changes of items other than shareholders' equity					
Total changes during period	390,831	390,831	24	390,856	1,186,022
Balance as of December 31, 2022	17,548,459	17,518,459	4,898	17,523,357	(26,884,309)

	Shareholders' equity		Share Acquisition rights	Total net assets
	Treasury shares	Total shareholders' equity		
Balance as of January 1, 2022	(86,045)	6,226,573	519,099	6,745,672
Cumulative effect of changes in accounting policies		(92,822)		(92,822)
Restated balance	(86,045)	6,133,750	519,099	6,652,850
Changes during period				
Issuance of new shares		662,000		662,000
Issuance of new shares (exercise of share acquisition rights)		119,662		119,662
Profit		1,186,022		1,186,022
Purchase of treasury shares	(2,165)	(2,165)		(2,165)
Disposal of treasury shares	56	81		81
Net changes of items other than shareholders' equity			(107,426)	(107,426)
Total changes during period	(2,108)	1,965,601	(107,426)	1,858,175

Balance as of December 31, 2022	(88,154)	8,099,352	411,672	8,511,025

(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	Merchandise and finished goods are stated at cost determined by the first-in, first-out method, and semi-finished goods are stated at cost determined by the weighted average cost method. The amount on the balance sheet is calculated by reducing book value when the contribution of inventories to profitability declines. Inventory items are classified into separate categories for the purpose of detailed monitoring of inventory movements and appropriate valuation.

(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.

(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.
Provision for product changeover	An estimated amount of expenses is recorded to prepare for expenses to be incurred accompanying the changeover from the FD formulation to RTD formulation of TREAKISYM®.

(6) Recognition of revenues and expenses

The Company recognizes revenue from the sale of merchandise and finished goods at the time of delivery to the customer, as this is when the control of the merchandise and finished goods is transferred to the customer and performance obligations are satisfied. Revenue from the sale of merchandise and finished goods is estimated within the range in which it is highly probable that there will not be a significant reversal of the consideration promised in the contract with the customer less sales rebates in accordance with the terms of the sales contract. The amount of consideration expected to be refunded to the customer is recorded as a refund liability. The refund liability is estimated based on the terms of the contract and past performance.

(Notes on changes in accounting policy)

(Application of Accounting Standard for Revenue Recognition)

The Company has applied the “Accounting Standard for Revenue Recognition” (ASBJ Statement No. 29; March 31, 2020; hereinafter “Revenue Recognition Standard”) from the beginning of the fiscal year under review. As a result of the application of this standard, revenue will be recognized in the amount expected to be received in exchange for the promised goods or services at the time control of the promised goods or services is transferred to the customer.

Under the previous accounting standard, for transactions where the total amount of consideration the Company is entitled to in exchange for the transfer of promised goods or services, i.e., the transaction price, is likely to be reduced after a contract is signed with the customer, the Company revised the transaction price once the amount to be reduced was fixed. However, under the new accounting standard, the Company makes a reasonable estimate of the variable amount and subtracts it from the transaction price at the time the goods or services are transferred to the customer. Further, under the previous accounting standard, the Company accounted for expected sales returns by recording provisions for sales returns in the amount equivalent to gross profit; however, in accordance with the provisions regarding variable consideration, the Company no longer recognizes revenue at the time of sale and records refund liabilities as “other” under the current liabilities section of the balance sheet.

The Company has followed the transitional treatment prescribed in the provision of Paragraph 84 of the Revenue Recognition Standard and has applied the new accounting standard from the opening balance of retained earnings of the fiscal year under review, whereby the cumulative effect of retrospective application of the new accounting standard prior to the beginning of the fiscal year under review is added to or deducted from the beginning balance of retained earnings.

As a result, in the statements of income for the fiscal year under review, net sales increased by 62,962-thousand-yen, operating profit and ordinary profit increased by 62,962 thousand yen, respectively, and profit before income taxes increased by 62,962 thousand yen. In addition, the balance of retained earnings at the beginning of the period decreased by 92,822 thousand yen.

Net assets per share, net income per share and diluted net income per share decreased by 2.38 yen, increased by 1.61 yen and increased by 1.59 yen, respectively, during the current fiscal year.

(Application of Accounting Standard for Fair Value Measurement)

The Company has applied the “Accounting Standard for Fair Value Measurement” (ASBJ Statement No. 30; July 4, 2019; hereinafter “Fair Value Measurement Standard”) from the beginning of the fiscal year under review.

In applying the Fair Value Measurement Standard, the Company has followed the transitional treatment prescribed in the provision of Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the “Accounting Standard for Financial Instruments” (ASBJ Statement No. 10; July 4, 2019) and will apply the new accounting standard prescribed by the Fair Value Measurement Standard, prospectively.

The adoption of this accounting standard has no effect on the financial statements.

(Note to Significant Accounting Estimates)

(1) Amount recorded in the consolidated financial statements for the fiscal year under review

Deferred tax assets recorded in the consolidated fiscal year under review: 744,728 thousand yen

(2) Information regarding significant accounting estimates on the identified item

(i) Calculation method

Based on the company classification stipulated in the “Implementation Guidance on Recoverability of Deferred Tax Assets” (ASBJ Guidance No. 26, February 16, 2018), the Company recorded deferred tax assets for the deductible temporary differences and losses carryforward at the end of the fiscal year under review, to the extent that they can be used to reduce future tax burden. When recording deferred tax assets, taxable income before adjustment for temporary differences, etc. is estimated based on the business plan.

(ii) Major assumptions

Taxable income based on future profitability is estimated according to the Group's business plan. The estimate is also based on certain assumptions that take into consideration significant uncertainties caused by such factors as the impact of sales volume of existing drugs on net sales and the impact of pipeline development progress on tax adjustment items.

(iii) Impact on the consolidated financial statements for subsequent fiscal years

Any revisions to the assumptions underlying the estimates due to changes in the economic conditions, etc., may have a significant impact on the amount of deferred tax assets to be recorded on the consolidated financial statements for subsequent fiscal years.

(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 outlook for the business environment remains uncertain, as COVID-19 infections remain a threat to healthcare facilities and patients, altering patient care behavior and making patients more cautious about treatment. Such impacts are considered in our accounting estimates such as the recoverability of deferred tax assets, etc.

(Balance sheet)

Monetary assets receivable from subsidiaries are as follows.

Short-term monetary assets receivable: 6,905 thousand yen

(Statement of income)

(1) R&D costs included in general and administrative expenses: 2,546,227 thousand yen

(2) Transaction volume with subsidiaries and affiliates is as follows.

Transaction volume of operating transactions: 144,764 thousand yen

(Statement of changes in equity)

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	Treasury shares	82,618	2,750	100	85,268

(Notes) 1. Increase of 2,750 treasury shares in common stock is due to the purchase of shares less than one unit.

2. Decrease of 100 treasury shares in common stock is due to the sale of shares less than one unit to shareholders.

(Tax effect accounting)

Significant components of deferred tax assets and liabilities

Deferred tax assets:	(Unit: thousands of yen)
Losses on valuation of inventories disallowed	99,374
Excess depreciation for lump-sum depreciable assets	2,359
Excess amortization for deferred assets	1,112,916
Research and development expenses disallowed	2,273,704
Accounts payable–other disallowed	50,852
Provision for retirement benefits disallowed	1,036
Enterprise taxes payable disallowed	41,189
Provision for product changeover disallowed	5,000
Asset retirement obligations disallowed	2,534
Share-based compensation expenses disallowed	114,101
Loss carried forward	4,036,381
Subtotal of deferred tax assets	7,739,451
Valuation allowances for loss carried forward	(3,805,995)
Valuation allowances for deductible temporary differences	(3,188,726)
Subtotal of valuation allowances	(6,994,722)
Total deferred tax assets	744,728

(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 (%)	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: 2.84		Exercise of share acquisition rights	27,195 (35,000 shares)	—	—

(Note) This information describes the exercise during the fiscal year under review of share acquisition rights granted based on resolutions of the Board of Directors meetings held on March 28, 2019.

(Notes on revenue recognition)

Underlying information for understanding revenue arising from contracts with customers

Underlying information for understanding revenue arising from contracts with customers is as stated in (Significant accounting policies), (6) Recognition of revenues and expenses.

(Per-share information)

(1) Net assets per share	204.95 yen
(2) Net profit per share	30.37 yen
Average number of shares outstanding during the year	39,046,821 shares

(Significant subsequent events)

None to be reported.

Audit report on consolidated financial statements by accounting auditor

Independent Auditor's Report

February 28, 2023

The Board of Directors
SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC
Tokyo, Japan

Tetsuya Tomita
Designated Engagement Partner
Certified Public Accountant

Kinuyo Matsuo
Designated Engagement Partner
Certified Public Accountant

Opinion

Pursuant to Article 444, paragraph 4 of the Companies Act, we have audited the accompanying consolidated financial statements, which comprise the consolidated balance sheet, the consolidated statement of income, the consolidated statement of changes in equity, and notes to the consolidated financial statements of SymBio Pharmaceuticals Limited and its consolidated subsidiaries (the Group) applicable to the fiscal year from January 1, 2022 to December 31,2022.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position and results of operations of the Group applicable to the fiscal year ended December 31, 2022, 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 Consolidated Financial Statements section of our report. We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the consolidated 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.

Other Information

The other information comprises the information included in the Group's business report and its supplementary schedules. Management is responsible for preparation and disclosure of the other information. The Audit and Supervisory Committee is responsible for overseeing the Group's reporting process of the other information.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Responsibilities of Management, the Audit and Supervisory Committee for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated 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 consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Group'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 Audit and Supervisory Committee is responsible for overseeing the Group's financial reporting process.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated 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 these consolidated 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 consolidated 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 consolidated financial statements is not expressing an opinion on the effectiveness of the Group'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 Group'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 consolidated 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 Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation in accordance with accounting principles generally accepted in Japan.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Audit and Supervisory Committee 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 Audit and Supervisory Committee with a statement that we have complied with the ethical requirements regarding independence that are relevant to our audit of the consolidated 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 Group which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

Audit report by accounting auditor

Independent Auditor's Report

February 28, 2023

The Board of Directors
SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC
Tokyo, Japan

Tetsuya Tomita
Designated Engagement Partner
Certified Public Accountant

Kinuyo Matsuo
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 18th fiscal year from January 1, 2022 to December 31, 2022.

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, 2022, 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.

Other Information

The other information comprises the information included in the Group's business report and its supplementary schedules. Management is responsible for preparation and disclosure of the other information. The Audit and Supervisory Committee is responsible for overseeing the Group's reporting process of the other information.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Responsibilities of Management, the Audit and Supervisory Committee 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 Audit and Supervisory Committee is responsible for overseeing the Company's financial reporting process.

Auditor's Responsibilities 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 these 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 Audit and Supervisory Committee 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 Audit and Supervisory Committee 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.

Audit report by Audit & Supervisory Committee

Report of the Audit & Supervisory Committee

We, Audit & Supervisory Committee Members, prepare this report of audit with regard to the execution of Directors' duties during the 18th Term of the Company from January 1, 2022 to December 31, 2022. The methods and results of the audit are as follows.

1. Methods and Contents of the Audit

The Audit & Supervisory Committee regularly received reports from Directors and employees regarding the contents of resolution by the Board of Directors related to matters stipulated in Article 399-13, Paragraph 13, Item 1, B and C of the Companies Act and the status of establishment and operation of the internal control system set up based on the said resolution, and requested additional explanation as necessary. The Committee has expressed its opinion and conducted an audit using the methods outlined below.

(i) We conducted the audit in compliance with the standards for audits by Audit & Supervisory Board Committee set forth by the said Committee, and abided by the audit policy and division of duties. In cooperation with the Company's Internal Control Division, we attended important meetings and received reports from Directors and employees regarding their execution of duties, requesting additional explanation if necessary. We also reviewed documents for important settlements, and investigated the status of operations and assets of the headquarters and key business offices. Regarding the Company's subsidiary, we communicated and exchanged information with Directors, etc. of the subsidiary, and received reports on the subsidiary's business operations as necessary.

(ii) 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 methods described above, we reviewed the business reports and related supplementary schedules, financial reports (including balance sheet, statement of income, statement of changes in equity, and notes to non-consolidated financial statements) and related supplementary schedules, and consolidated financial statements (consolidated balance sheet, consolidated statement of income, consolidated statement of changes in equity, and notes to consolidated financial statements) 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 methods used for and the results of the audit conducted by the accounting auditor, Ernst & Young ShinNihon LLC, are appropriate.

(3) Results of the audit of the consolidated financial statements

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

February 20, 2023

Audit & Supervisory Committee,
SymBio Pharmaceuticals Limited

Kiyoshi Watanabe
Full-time Audit & Supervisory Committee Member

Kesao Endo
Audit & Supervisory Committee Member

Yasuhiro Tamo
Audit & Supervisory Committee Member

(Note) Audit & Supervisory Committee Members Kiyoshi Watanabe, Kesao Endo, and Yasuhiro Tamo are Outside Directors of the Company as stipulated in Article 2, Item 15 and Article 331, Paragraph 6 of the Companies Act.

End of Report

End of Document