English translation

March 28, 2019

Annual Report

(January 1, 2018 through December 31, 2018)

1. Business Performance of SymBio Pharmaceuticals Limited

(1) Business conditions and operating results

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

(i) Domestic

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

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

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

The Company markets TREAKISYM® in Japan through its business partner, Eisai. The Company obtained manufacturing and marketing approval for first-line treatment of low-

grade non-Hodgkin's lymphoma (low-grade NHL) and mantle cell lymphoma (MCL) in December 2016, for recurrent/refractory low-grade NHL (Note 1) and MCL in October 2010, and for chronic lymphocytic leukemia (CLL) in August 2016.

Following this indication expansion, TREAKISYM® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment, at medical clinics and hospitals. Further, the combination treatment (BR therapy) of TREAKISYM® and rituximab was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 edited and published by the Japanese Society of Hematology in July 2018, becoming recommended as a choice for standard treatment. With this development, TREAKISYM® has been effectively establishing its foothold as the standard treatment for malignant lymphoma. In-market sales at NHI price basis for the fiscal year under review posted an increase of 11.6% year on year.

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

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

Further, the Company acquired approval for the partial revision to the manufacturing and marketing authorization in July 2018. As a result, TREAKISYM® can now be used in combination with not only rituximab but also obinutuzumab (Note 3) (launched in August

2018) for the treatment of CD20 positive follicular lymphoma (FL), a common histologic type of low-grade NHL, allowing the Company to provide patients with a new treatment therapy. In September 2018, the Company applied for the approval of partial revision to the manufacturing and marketing authorization of TREAKISYM® regarding its use as a pre-treatment for regenerative medicine products.

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

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

(Note 2) RTD and RI are pre-dissolved liquid formulations that differ from currently available freeze-dried ("FD") powder injection. RTD (ready-to-dilute) will significantly reduce the preparation time and labor cost for healthcare providers, and RI (rapid infusion) will reduce infusion duration to 10 minutes from the current 60 minutes, providing significant benefit and value to both patients and healthcare providers.

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

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

U.S. licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) ("Onconova") is conducting a global Phase III clinical trial (with trial sites in more than 20 countries) of the intravenous formulation of rigosertib for higher-risk myelodysplastic

syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents. The Company is responsible for clinical development in Japan and in December 2015 began the trial. Forty patients were enrolled as of December 31, 2018, and patient enrollment is proceeding. Based on the results of the interim analysis completed in January 2018, the independent Data Monitoring Committee (DMC) recommended that Onconova continues the trial with patient enrollment increased in accordance with statistical criteria in an adaptive design previously agreed upon with the U.S. Food and Drug Administration (FDA). Based on the results of the trial, the Company is planning to apply for approval in Japan at the same time as in the U.S. and Europe.

As for the oral formulation of rigosertib, Onconova has completed Phase I/II clinical trials in the U.S. for the target indication of first-line HR-MDS (in combination with azacitidine (Note 4)) and has been conducting a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS. The Company started a domestic Phase I clinical trial in June 2017 to confirm the tolerability and safety of the oral formulation of rigosertib for Japanese patients. The first patient was enrolled in October 2017 and patient enrollment is proceeding favorably. After completion of this trial, the Company plans to promptly conduct a Phase I clinical trial for combination therapy with azacitidine and to take part in a global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with higher-risk MDS, which Onconova currently plans to conduct. The Company also plans and prepares to apply for approval of the oral formulation of rigosertib in Japan in timing alignment with the U.S. and Europe. With respect to the development for the indication of transfusion-dependent lower-risk MDS, the Company will continue to consider participating from Japan in view of the status of development by Onconova.

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

[Patient-controlled pain management drug: SyB P-1501]

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly owned subsidiary of US-based The Medicines Company (head office: New

Jersey, U.S.) for an exclusive license to develop and commercialize SyB P-1501 in Japan. The Company, acting in the best interest of patients, resolved to temporarily suspend new patient enrollment for SyB P-1501 from April 21, 2017 due to its concern as to the continuity of The Medicines Company's business regarding the product.

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

Arbitration proceedings against The Medicines Company are still ongoing.

[New drug candidates]

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

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

(ii) Markets outside Japan

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

(iii) Business results

As a result of the above, net sales totaled 3,835,530 thousand yen for the fiscal year under review, primarily reflecting product sales of TREAKISYM®. Product sales showed a year-on-year increase of 10.6%. Accordingly, net sales rose 11.4% year on year.

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

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

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

(iv) Capital investment

The total amount of capital expenditures during the fiscal year under review was 57,459 thousand yen, mainly consisting of office investments and the purchase of appliances, network devices and business software.

(2) Status of fund procurement

In order to secure the funds necessary for its research and development activities, the establishment of its own salesforce, and the in-licensing of new drug candidates, the Company made a resolution at the Board of Directors meeting held on April 9, 2018 to issue the 45th through 47th warrants (with Exercise Price Revision Clauses) to the EVO FUND. As of the end of the fiscal year under review, a payment of 2,611,800 thousand yen had been completed in connection with the issue of these warrants.

As for the 42nd warrant issued to SBI SECURITIES Co., Ltd. on August 25, 2017, all rights

have been exercised and paid for in full as of January 2018.

In addition, exercise of all rights and associated payments related to the 39th warrant issued to Whiz Healthcare Japan 2.0 Investment Limited Partnership on April 22, 2016 were completed as of December 2018.

(3) Status of assets and profit and loss

(Unit: thousands of yen)

Classification \ Fiscal year	FY 2015 The 11th Term	FY 2016 The 12th Term	FY 2017 The 13th Term	FY 2018 The 14th Term (current)
Net sales	1,933,241	2,368,112	3,444,206	3,835,530
Operating profit (loss)	(2,551,662)	(2,127,049)	(3,947,061)	(2,656,072)
Ordinary profit (loss)	(2,630,386)	(2,316,806)	(3,976,784)	(2,748,730)
Profit (loss)	(2,632,095)	(2,313,233)	(3,977,862)	(2,752,533)
Loss per share (yen)	(81.26)	(58.82)	(79.78)	(41.38)
Total assets	4,984,289	6,878,384	4,252,284	6,239,423
Net assets	4,431,811	5,484,870	3,239,402	4,901,799
Net assets per share (yen)	127.56	108.61	50.00	53.06

(4) Issues to be addressed by the Company

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

(i) Further expansion of the pipeline

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

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

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

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

TREAKISYM® is approved for manufacturing and marketing in Japan for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, chronic lymphocytic leukemia, and first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. The Company has completed a Phase II clinical trial for recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), and a Phase III clinical trial is currently underway. In addition, the Company intends to maximize business value of TREAKISYM® by promoting the product life cycle management of the product, and pursue the development of TREAKISYM® liquid

formulation (RTD and RI liquid formulations) in-licensed from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.). In addition to the intravenous formulation, the Company is also exploring the development of an oral formulation of TREAKISYM® with a focus on the treatment of solid tumors and autoimmune diseases, further expanding the business potential. To this end, the Company has commenced a Phase I clinical trial for progressive solid tumors with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of TREAKISYM®, and narrowing down the types of target tumors.

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

The Company is focused on maximizing the business value of TREAKISYM® and rigosertib by promoting product life cycle management through further indication expansion.

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

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

Providing specialized technical information will enable the Company to more accurately understand the needs of the market and respond more swiftly, allowing it to contribute to the benefit of patients while aiming to maximize the business value of TREAKISYM®. Furthermore, the Company strives to build a consistent sales organization with a high level of specialization in the field of hematological diseases. Through this effort, the Company aims to achieve high business efficiency, ensure

sustainable earnings growth, and maximize shareholder gains once the intravenous and oral formulations of rigosertib, which are currently under development to treat myelodysplastic syndromes (MDS), join TREAKISYM® in the product lineup.

(iv) Global expansion for further growth

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

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

Under these circumstances, the Company will promote global expansion aiming for further growth. The Company will carry out the search, evaluation, and negotiation activities for new drug candidates, in order to acquire global rights on such candidates, utilizing its experience fostered through its business in Asia.

(v) Securing personnel

The Company places the highest priority on personnel as the Company's principal management resource. We cannot make superior achievements in exploring and developing new drugs without talent. We have been continually recruiting talented people; especially after being listed, we have recruited the best and brightest people in order to strengthen the management organization. Going forward, we plan to continue to further strengthen our human resources by providing on-the-job training and employee development programs.

(vi) Financial issue

It is necessary for the Company to raise funds required for business activities such as R&D expenditures as the pipeline development progresses and the number of drug candidates increases.

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

(5) Major business activities (as of December 31, 2018)

The Company regards underserved therapeutic areas that lack the development of new drugs, despite significant unmet medical needs, as business opportunities. We engage in the development of new drugs with a primary focus on the treatment of rare diseases, mainly in the areas of oncology and hematology; search and evaluation, development and manufacturing to sales are the main activities of our business.

(6) Main office and employees

(i) Main office (as of December 31, 2018)

Name	Location
Main office	Minato-ku, Tokyo

(ii) Employees (as of December 31, 2018)

Classification	Number of employees	Increase or decrease from previous fiscal year end	Average age (years)	Average number of years of service
Male	65	9 (increase)	49.9	3.6
Female	25	3 (increase)	46.3	4.4
Total or average	90	12 (increase)	48.9	3.8

(Notes) 1. Number of employees refers to full time employees.
2. The above number of employees does not include 12 temporary staff.

(7) Status of parent company and significant subsidiaries

Not applicable.

(8) Status of main lenders (as of December 31, 2018)

Not applicable.

2. Matters Related to Stock (as of December 31, 2018)

(1) Total number of authorized shares

Common stock: 167,000,000 shares

(2) Total number of shares outstanding

Common stock: 82,398,849 shares (excluding 75 shares of treasury stock)

(3) Number of shareholders

31,858

(4) Major shareholders (10 largest)

Name of shareholder	Number of shares held	Shareholding ratio
Fuminori Yoshida	3,451,000	4.2%
Cephalon, Inc.	2,589,000	3.1%
Matsui Securities Co., Ltd.	1,238,100	1.5%
Japan Securities Finance Co., Ltd.	1,224,700	1.5%
Eisai Co., Ltd.	833,400	1.0%
J.P. Morgan Securities Plc	695,158	0.8%
Waseda No.1 Investment LP	684,000	0.8%
Aizawa Securities Co., Ltd.	606,200	0.7%
BNY GCM CLIENT ACCOUNT JPRD AC ISG (FE-AC)	599,876	0.7%
BNP PARIBAS LONDON BRANCH FOR PRIME BROKERAGE CLEARANCE ACC FOR THIRD PARTY	599,876	0.7%

(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, 2018)

	The 20th warrant by resolution of the Ordinary General Meeting of Shareholders on March 30, 2010	The 22nd warrant by resolution of the Ordinary General Meeting of Shareholders on March 30, 2010	The 24th warrant by resolution of the Ordinary General Meeting of Shareholders on March 30, 2011
Number of share acquisition rights	3,445 units	1,530 units	1,920 units
Number of shares to be issued upon the exercise of share acquisition rights	344,500 shares	153,000 shares	192,000 shares
Amount paid for share acquisition rights	None	None	None
Value of property to be contributed upon the exercise of each share acquisition right (Note 1)	585 yen per share	585 yen per share	682 yen per share
Period in which exercise of share acquisition rights is possible	From: April 1, 2012 To: March 31, 2020	From: April 1, 2012 To: March 31, 2020	From: March 31, 2013 To: March 30, 2021
Status of possession by Directors (excluding Outside Directors)	1,800 units (1 holder) 180,000 shares	—	1,200 units (1 holder) 120,000 shares
Status of possession by Outside Directors	300 units (1 holder) 30,000 shares	200 units (1 holder) 20,000 shares	150 units (1 holder) 15,000 shares

	The 26th warrant by resolution of the Board of Directors meeting on April 17, 2012	The 30th warrant by resolution of the Board of Directors meeting on May 14, 2013	The 32nd warrant by resolution of the Board of Directors meeting on April 15, 2014
Number of share acquisition rights	3,625 units	1,160 units	2,520 units
Number of shares to be issued upon the exercise of share acquisition rights	362,500 shares	116,000 shares	252,000 shares
Amount paid for share acquisition rights	None	None	22,900 yen per unit (Note 2)
Value of property to be contributed upon the exercise of each share acquisition right (Note 1)	555 yen per share	799 yen per share	1 yen per share
Period in which exercise of share acquisition rights is possible	From: April 18, 2014 To: April 17, 2022	From: May 15, 2015 To: May 14, 2023	From: April 16, 2017 To: April 15, 2024
Status of possession by Directors (excluding Outside Directors)	2,600 units (1 holder) 260,000 shares	645 units (1 holder) 64,500 shares	—
Status of possession by Outside Directors	324 units (1 holder) 32,400 shares	205 units (2 holders) 20,500 shares	350 units (2 holders) 35,000 shares

	The 35th warrant by resolution of the Board of Directors meeting on March 26, 2015	The 37th warrant by resolution of the Board of Directors meeting on March 30, 2016	The 40th warrant by resolution of the Board of Directors meeting on March 29, 2017
Number of share acquisition rights	2,042 units	2,365 units	2,800 units
Number of shares to be issued upon the exercise of share acquisition rights	204,200 shares	236,500 shares	280,000 shares
Amount paid for share acquisition rights	30,600 yen per unit (Note 2)	27,200 yen per unit (Note 2)	20,300 yen per unit (Note 2)
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, 2018 To: March 26, 2025	From: March 31, 2019 To: March 30, 2026	From: March 30, 2020 To: March 29, 2027
Status of possession by Directors (excluding Outside Directors)	—	1,490 units (1 holder) 149,000 shares	1,950 units (2 holders) 195,000 shares
Status of possession by Outside Directors	253 units (2 holders) 25,300 shares	545 units (3 holders) 54,500 shares	450 units (2 holders) 45,000 shares

	The 43rd warrant by resolution of the Board of Directors meeting on March 29, 2018
Number of share acquisition rights	3,050 units
Number of shares to be issued upon the exercise of share acquisition rights	305,000 shares
Amount paid for stock share rights	19,800 yen per unit (Note 2)
Value of property to be contributed upon the exercise of each share acquisition right (Note 1)	1 yen per share
Period in which exercise of share acquisition rights is possible	From: March 30, 2021 To: March 29, 2028
Status of possession by Directors (excluding Outside Directors)	1,950 units (2 holders) 195,000 shares
Status of possession by Outside Directors	1,100 units (4 holders) 110,000 shares

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

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

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

(2) Share acquisition rights distributed to the Company's employees as compensation for services during the fiscal year under review (as of December 31, 2018)

	The 44th warrant by resolution of the Board of Directors meeting on March 29, 2018
Number of share acquisition rights	4,648 units
Number of shares to be issued upon the exercise of share acquisition rights	464,800 shares
Amount paid for share acquisition rights	19,800 yen per unit (Note 2)
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 30, 2021 To: March 29, 2028
Status of allotment to the Company's employees	4,043 units (83 holders) 404,300 shares

(Notes) 1. Of the share acquisition rights mentioned above, 605 units (60,500 shares) have been forfeited due to the retirement 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, 2018)

Details of the share acquisition rights issued by resolution of the Board of Directors meeting held on April 9, 2018 are as follows:

	The 45th warrant by resolution of the Board of Directors meeting on April 9, 2018	The 46th warrant by resolution of the Board of Directors meeting on April 9, 2018	The 47th warrant by resolution of the Board of Directors meeting on April 9, 2018
Number of share acquisition rights	20,000,000 units	15,000,000 units	15,000,000 units
Number of shares to be issued upon the exercise of share acquisition rights	20,000,000 shares	15,000,000 shares	15,000,000 shares
Amount paid for share acquisition rights	10,800,000 yen	6,600,000 yen	5,700,000 yen
Value of property to be contributed upon the exercise of each share acquisition right	207 yen per unit (Note 2)	209 yen per unit (Note 2)	211 yen per unit (Note 2)
Period in which exercise of share acquisition rights is possible	From: April 26, 2018 To: April 26, 2021	From: April 26, 2018 To: April 26, 2021	From: April 26, 2018 To: April 26,2021

(Notes) 1. All share acquisition rights issued in the 45th warrant have been exercised as of October 1, 2018.

2. Figures are calculated using the initial exercise price.

4. The Company's Officers (as of December 31, 2018)

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

Company position	Name	Responsibility and significant concurrent position
Representative Director	Fuminori Yoshida	Chief Executive Officer
Representative Director	Kazuo Asakawa	Corporate Officer, Executive Vice President (CCO) and Head of the Japan Business Unit
Director	Shigetoshi Matsumoto	
Director	George Morstyn	CEO of G&R Morstyn Pty Ltd.
Director	Milton Grannatt	Director, Arkay Therapeutics Director, Myostin Therapeutics
Director	Robin Campbell	Chairman of the Board of Aptitude Medical Systems Inc. Director, Chairman of the Compensation Committee, Member of the Audit Committee of Pfenex Inc.
Full-time Audit & Supervisory Board Member	Kiyoshi Watanabe	
Audit & Supervisory Board Member	Saneaki Ichijo	Lawyer at Anderson Mori & Tomotsune
Audit & Supervisory Board Member	Kesao Endo	Representative of the Endo C.P.A. Firm Outside Director at Careerlink Co., Ltd. Representative partner at the ABS Audit Corporation

(Notes) 1. Of the Directors, Shigetoshi Matsumoto, George Morstyn, Milton Grannatt, and Robin Campbell are Outside Directors.
2. Kiyoshi Watanabe, Saneaki Ichijo, and Kesao Endo are outside members of the Audit & Supervisory Board.
3. Shigetoshi Matsumoto, Kiyoshi Watanabe, and Kesao Endo have been designated as independent officers pursuant to the provisions of the Tokyo Stock Exchange and registered as such with the Tokyo Stock Exchange.
4. Kesao Endo possesses deep insight in finance and accounting, which he gained through his profession as a certified public accountant.
5. Changes in Directors and Audit & Supervisory Board Members during the fiscal year under review are as follows:
   - Directors Sumio Ariyoshi and Naoko Iino resigned upon expiration of their terms of office at the closing of the 13th Ordinary General Meeting of Shareholders held on March 29, 2018.
   - Audit & Supervisory Board Member Shigetoshi Matsumoto resigned at the closing of the 13th Ordinary General Meeting of Shareholders held on March 29, 2018.
   - Shigetoshi Matsumoto and Robin Campbell were newly appointed as Directors at the 13th Ordinary General Meeting of Shareholders held on March 29, 2018.
   - Kesao Endo was newly appointed as an Audit & Supervisory Board Member at the 13th Ordinary General Meeting of Shareholders held on March 29, 2018.

6. The Company has adopted the Corporate Officer System. The Corporate Officers who do not hold concurrent positions as Directors are as follows:
   Corporate Officer Kenji Murata
   Corporate Officer Nobuo Ishida

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

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

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

Company Board	Number of Directors or Audit & Supervisory Board Members Paid	Total Amount of Compensation (thousands of yen)
Board of Directors	8 (Outside: 6)	144,150 (Outside: 43,455)
Audit & Supervisory Board	4 (Outside: 4)	19,821 (Outside: 19,821)
Total	12 (Outside: 10)	163,971 (Outside: 63,277)

(Notes) 1. Salary in the event of a Director doubling as an employee is not included in the above compensation for Directors.
2. The maximum amount of compensation for Directors was resolved as an annual amount of 130 million yen at the Extraordinary General Meeting of Shareholders held on August 3, 2005. In addition to the aforementioned compensation, it was resolved that compensation for Directors in the form of share acquisition rights as stock options be granted up to a maximum annual amount of 80 million yen at the 9th Ordinary General Meeting of Shareholders held on March 27, 2014. (Of 80 million yen, 30 million yen was granted for Outside Directors, which was resolved at the 11th Ordinary General Meeting of Shareholders held on March 30, 2016.)
3. The maximum amount of compensation for Audit & Supervisory Board Members was resolved as an annual amount of 30 million yen at the Extraordinary General Meeting of Shareholders held on June 30, 2011.
4. The number of Directors or Audit & Supervisory Board Members paid as stated above includes two (2) Directors and one (1) Audit & Supervisory Board Member who resigned at the closing of the 13th Ordinary General Meeting of Shareholders held on March 29, 2018.
5. The total compensation paid includes expenses (for eight (8) Directors, a total of 61,144 thousand yen) in connection with share acquisition rights as stock options for the fiscal year under review.

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

Status of main activities during the fiscal year under review

Position	Name	Status of attendance at the Board of Directors meetings	Status of attendance at the Audit & Supervisory Board meetings	Opinions at the Board of Directors meetings and the Audit & Supervisory Board meetings
Director	Shigetoshi Matsumoto	11 out of 11 (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	George Morstyn	16 out of 16 (100%)	—	Dr. Morstyn 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	Milton Grannatt	16 out of 16 (100%)	—	Dr. Grannatt expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his extensive experience and knowledge regarding healthcare companies.
Director	Robin Campbell	11 out of 11 (100%)	—	Dr. Campbell expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his extensive experience and knowledge regarding healthcare companies.
Full-time Audit & Supervisory Board Member	Kiyoshi Watanabe	16 out of 16 (100%)	17 out of 17 (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 surveillance.

Position	Name	Status of attendance at the Board of Directors meetings	Status of attendance at the Audit & Supervisory Board meetings	Opinions at the Board of Directors meetings and the Audit & Supervisory Board meetings
Audit & Supervisory Board Member	Saneaki Ichijo	16 out of 16 (100%)	17 out of 17 (100%)	Mr. Ichijo actively expressed opinions from a neutral perspective based on the specialized knowledge and extensive experience he accumulated as an attorney in order to achieve highly effective managerial surveillance.
Audit & Supervisory Board Member	Kesao Endo	11 out of 11 (100%)	11 out of 11 (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 surveillance.

(Note) With regard to Directors Shigetoshi Matsumoto and Robin Campbell and Audit & Supervisory Board Member Kesao Endo, their status of attendance at the meetings is calculated from the Board of Directors meetings and the Audit & Supervisory Board meetings held after their appointments on March 29, 2018.

5. Status of Accounting Auditor

(1) Name of accounting auditor

Ernst & Young ShinNihon LLC

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

Not applicable.

(3) Amount of compensation

	Amount paid
Amount of compensation paid to the accounting auditor concerning the fiscal year under review	15,500 thousand yen
Total amount of monetary and other property benefits to be paid by the Company	15,500 thousand yen

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

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

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

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

6. System to Ensure the Appropriateness of Operations

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

(i) Dissemination and thorough implementation of management philosophy

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

(ii) Establishment of internal control committee

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

(iii) Establishment of internal audit office

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

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

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

(v) Systems for securing reliable financial reporting

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

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

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

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

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

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

(i) Directors, officers, 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 precise and timely decision-making from the Representative Director and President.

(iii) The Company develops mid- to long-term business plans and operates and expands its business in accordance with these plans. In addition, the Company establishes numerical targets within its business plans for each fiscal year and, through monthly closings, manages progress toward these targets while making relevant reports to Directors.

(5) Basic policy against anti-social forces

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

(6) Assistant to Audit & Supervisory Board Members

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

appropriate appointment.

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

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

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

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

(i) Any Director or employee shall promptly inform the Audit & Supervisory Board if and when he/she becomes aware of any circumstance that threatens to cause any significant damage to, or could adversely affect, the Company.

(ii) Audit & Supervisory Board Members may participate in all matters that they judge to be important in terms of gaining a better understanding of decision-making processes, conditions, and statuses of the Company's businesses. Accordingly, they may attend Board of Directors meetings, Executive Management Committee meetings, and other important meetings and are also permitted to view key decision-making documents related to these meetings.

(iii) Audit & Supervisory Board Members may individually interview Directors and employees in key positions of responsibility to obtain information regarding the management conditions of the Company's businesses.

(iv) Audit & Supervisory Board Members will regularly exchange opinions with the Representative Director and President and the accounting auditor.

(v) The Company will not apply any sort of unfavorable treatment or unjust punishment to individuals who make reports to the Audit & Supervisory Board.

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

(i) The Company will respond without delay to claims for the prepayment of expenses made

by Audit & Supervisory Board Members under Article 388 of the Companies Act, accepting responsibility for associated expenses and processing related obligations, except in cases in which these have been determined unnecessary for the execution of the duties of Audit & Supervisory Board Members.

(ii) The Company authorizes and shoulders expenses incurred when Audit & Supervisory Board Members seek opinions or advice from external experts, including attorneys and certified public accountants, if it is found necessary for the execution of their duties.

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

(1) The Company is striving to instill a culture of compliance across the organization through its communications with Directors and employees, and through publication of information such as the corporate compliance conduct principles and the whistleblowing system manual on the Company's intranet bulletin board.

(2) The Board of Directors of the Company is composed of six (6) Directors (including four (4) Outside Directors). Outside Directors participate in resolutions from an independent standpoint and monitor and supervise the management. Each Audit & Supervisory Board Member carries out management audits as well.

(3) Full-time Audit & Supervisory Board Members attend important meetings such as the Board of Directors meetings as well as Executive Management Committee meetings, and exchange views with representative directors monthly.

Balance Sheet

(As of December 31, 2018)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	**6,038,490**	**Current liabilities**	**1,336,342**
Cash and deposits	4,821,355	Accounts payable–trade	726,100
Accounts receivable–trade	411,720	Accounts payable–other	503,637
Merchandise and finished goods	533,824	Income taxes payable	71,249
Supplies	589	Forward exchange contracts	16,427
Prepaid expenses	83,372	Other	18,926
Advances paid	31,147	**Non-current liabilities**	**1,281**
Consumption taxes receivable	124,855	Provision for retirement benefits	1,281
Other	31,624		
Non-current assets	**200,932**	**Total liabilities**	**1,337,623**
Property, plant and equipment	56,951	(Net assets)	
Buildings	46,198	**Shareholders' equity**	**4,371,902**
Tools, furniture and fixtures	59,541	Capital stock	12,972,579
Accumulated depreciation	(48,788)	Capital surplus	12,942,579
Intangible assets	71,376	Legal capital surplus	12,942,579
Software	50,946	Retained earnings	(21,543,238)
Software in progress	20,430	Other retained earnings	(21,543,238)
Investments and other assets	72,604	Retained earnings brought forward	(21,543,238)
Shares of subsidiaries	0	Treasury shares	(17)
Long-term prepaid expenses	1,225	**Share acquisition rights**	**529,897**
Lease and guarantee deposits	71,378	**Total net assets**	**4,901,799**
Total assets	**6,239,423**	**Total liabilities and net assets**	**6,239,423**

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

Statement of Income

(From January 1, 2018 to December 31, 2018)

(Unit: thousands of yen)

Item	Amount	
I. Net sales		**3,835,530**
II. Cost of goods sold		**2,662,661**
Gross profit		**1,172,869**
III. Selling, general and administrative expenses		**3,828,941**
Operating loss		**(2,656,072)**
IV. Non-operating income		
Interest on refund	116	
Interest income	525	
Dividend income of insurance	1,501	
Other	54	2,196
V. Non-operating expenses		
Commission fee	11,100	
Share issuance cost	29,650	
Foreign exchange losses	54,103	94,854
Ordinary loss		**(2,748,730)**
VI. Extraordinary income		
Gain on reversal of share acquisition rights	9,826	9,826
VII. Extraordinary losses		
Loss on retirement of non-current assets	9,829	9,829
Loss before income taxes		**(2,748,733)**
Income taxes–current	3,800	3,800
Net loss		**(2,752,533)**

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

Statement of Changes in Equity

(From January 1, 2018 to December 31, 2018)

(Unit: thousands of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
		Legal capital surplus	Other retained earnings		
			Retained earnings brought forward		
Balance as of January 1, 2018	10,761,676	10,731,676	(18,790,705)	(17)	2,702,629
Changes of items during period					
Issuance of new shares (exercise of share acquisition rights)	2,210,903	2,210,903			4,421,806
Net loss			(2,752,533)		(2,752,533)
Net changes of items other than shareholders' equity					
Total changes of items during period	2,210,903	2,210,903	(2,752,533)	—	1,669,273
Balance as of December 31, 2018	12,972,579	12,942,579	(21,543,238)	(17)	4,371,902

	Share acquisition rights	Total net assets
Balance as of January 1, 2018	536,772	3,239,402
Changes of items during period		
Issuance of new shares (exercise of share acquisition rights)		4,421,806
Net loss		(2,752,533)
Net changes of items other than shareholders' equity	(6,875)	(6,875)
Total changes of items during period	(6,875)	1,662,397
Balance as of December 31, 2018	529,897	4,901,799

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

Notes on Financial Statements

(Significant accounting policies)

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

Marketable and investment securities

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

Other marketable and investment securities

Available-for-sale securities with determinable market value	Available-for-sale securities with a determinable market value are stated at fair value based on marketable value on the closing date and other premises. Any valuation differences are included directly in shareholders' equity. Cost of securities sold is calculated by the moving-average method.
Available-for-sale securities without determinable market value	Available-for-sale securities without determinable market value are stated at cost determined by the moving-average method.
Derivative transactions	Derivative financial instruments are stated at fair value.
Inventories	Inventories are stated at cost determined by the weighted-average method. The amount on the balance sheet is calculated by reducing book value when the contribution of inventories to profitability declines.

(2) Depreciation and amortization of non-current assets

Property, plant and equipment (excluding lease assets)	Depreciation of property, plant and equipment is computed by the straight-line method. The useful lives of major property, plant and equipment are summarized as follows: Buildings 3 to 18 years Tools, furniture and fixtures 5 to 15 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

Allowance for doubtful accounts	The allowance for doubtful accounts is provided at an amount determined based on the historical experience of bad debt with respect to ordinary receivables and an estimate of uncollectible amounts determined by reference to specific doubtful receivables from customers which are experiencing financial difficulties. For the fiscal year under review, no allowance for doubtful accounts is provided due to no historical experience of bad debt and no receivable balances that are deemed uncollectible.
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.

(6) Accounting for consumption tax

Transactions are recorded at amounts exclusive of consumption tax.

(Notes on Balance sheet)

Monetary assets receivable from subsidiaries are as follows.

Short-term monetary assets receivable: 969 thousand yen

(Notes on Statement of income)

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

Cost of sales: 121,317 thousand yen

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

(2) R&D costs included in general and administrative expenses: 1,832,746 thousand yen

(Notes on Statement of changes in equity)

(1) Type and number of shares issued and treasury shares

(Unit: number of shares)

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

(Note) Increase of 28,349,700 shares 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 1,999,100 shares

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

(Notes on Deferred tax accounting)

Significant components of deferred tax assets and liabilities

Deferred tax assets:	(Unit: thousands of yen)
Depreciation for lump-sum depreciable assets	2,631
Amortization for deferred assets	799,994
Research and development expenses	1,286,703
Accounts payable–other	1,755
Provision for retirement benefits	392
Enterprise tax payable	28,516
Asset retirement obligations	1,188
Share-based compensation expenses	130,759
Loss on valuation of inventories	37,438
Loss carried forward	3,487,365
Subtotal	5,776,745
Valuation allowance	(5,776,745)
Total deferred tax assets	—

(Notes on Financial instruments)

(1) Financial instruments

(i) Policies for financial instruments

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

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

(ii) Types of financial instruments and related risks

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

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

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

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

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

(iii) Risk management for financial instruments

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

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

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

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

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

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

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

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

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

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

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

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

(v) Concentration of credit risk

As of the end of fiscal year under review, all operating receivables are from one particular major customer.

(2) Fair value of financial instruments

The carrying value on the balance sheet, fair values, and their differences are as follows.

(Unit: thousands of yen)

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

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

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

Assets

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

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

Liabilities

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

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

Derivative transactions

Forward exchange contracts

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

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

Lease and guarantee deposits (carrying value of 71,378 thousand yen) are not included in the above table since no market quote is available and their fair value is extremely difficult to determine.

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

(Unit: thousands of yen)

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

(Notes on Transactions with affiliated parties)

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

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

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

(Notes on Per-share information)

(1) Net assets per share 53.06 yen

(2) Net loss per share (41.38) yen

Average number of shares outstanding during the year 66,511,113 shares

(Notes on Other notes)

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	1,350,000
Balance of borrowing outstanding	—
Unused balance	1,350,000

(Notes on Significant subsequent events)

None to be reported.

Independent Auditor's Report

February 21, 2019
The Board of Directors
SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC

Hironao Yazaki
Certified Public Accountant
Designated and Engagement Partner

Kazuto Shiratori
Certified Public Accountant
Designated and Engagement Partner

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 on financial statements and the related supplementary schedules of SymBio Pharmaceuticals Limited (the "Company") applicable to the 14th fiscal year from January 1, 2018 through December 31, 2018.

Management's Responsibility for the Financial Statements and the Related Supplementary Schedules

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

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements and the related supplementary schedules based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements and the related supplementary schedules are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements and the related supplementary schedules. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements and the related supplementary schedules, whether due to fraud or error. The purpose of an audit of the financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the financial statements and the related supplementary schedules in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements and the related supplementary schedules.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements and the related supplementary schedules referred to above present fairly, in all material respects, the financial position and results of operations of SymBio Pharmaceuticals Limited applicable to the 14th fiscal year ended December 31, 2018 in conformity with accounting principles generally accepted in Japan.

Conflicts of Interest

We have no interest in the Company which should be disclosed in compliance with the Certified Public Accountants Act.

Report of the Audit & Supervisory Board

We, Audit & Supervisory Board Members, prepare this report of audit with regard to the execution of Directors' duties during the 14th Term of the Company from January 1, 2018 to December 31, 2018, as the unanimous opinion of all the Audit & Supervisory Board Members after careful discussion based on the audit reports prepared by respective Audit & Supervisory Board Members, and report as follows.

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

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

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

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

2. Results of audit

(1) Results of the audit of the business report

a. The business report and supplementary schedules fairly present the Company's situation in accordance with laws and ordinances and the Company's Articles of Incorporation.

b. No misconduct in the execution of Directors' duties or any material facts in violation of laws or ordinances or the Company's Articles of Incorporation was observed.

c. The contents of resolution by the Board of Directors with regard to the Internal Control System are appropriate. Also, there is no matter to be noted as for the descriptions in the business report regarding such Internal Control System and the execution of Directors' duties.

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

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

February 21, 2019

Audit & Supervisory Board,
SymBio Pharmaceuticals Limited

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

Saneaki Ichijo, (seal)
Audit & Supervisory Board Member (Outside)

Kesao Endo, (seal)
Audit & Supervisory Board Member (Outside)

End of Report

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