

English translation

March 6, 2017

Annual Report
(January 1, 2016 through December 31, 2016)

1. Business Performance of SymBio Pharmaceuticals Limited

(1) Business conditions and operating results

The accelerated decline in birthrate and aging of the population as well as increasing medical expenses due to the advancement of medicine have long been pointed out as major economic and financial challenges facing Japan. Promoting the use of generic drugs, conducting appropriate evaluation of drugs, and rectifying the problem of excessive drug administration and left-over drugs, are the areas which enable further efficiency in medical expenditures.

In such an environment, as a symbolic measure during FY 2016, the authorities declared a policy via an urgent NHI price revision in which new drugs with expected annual sales of over 100 billion yen on the NHI price basis would be subject to price revisions. Fundamental reforms of the NHI price scheme are required for the further revisions of medical fees.

Thus, while the environment surrounding the Japanese pharmaceutical industry has been changing at an unprecedented pace, progress in the Company's business for FY 2016 is as follows.

(i) Domestic

[Anticancer agent: SyB L-0501 (generic name: bendamustine hydrochloride, trade name: TREAKISYM®)]

The Company markets TREAKISYM® in Japan through its business partner, Eisai Co., Ltd. ("Eisai"), for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, the first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia. Although net sales showed a slight decrease of 99.2% year-on-year (NHI price basis), net sales through Eisai were generally as planned.

By pursuing four indications, the Company has already obtained approvals for three indications, and continues to pursue approval for the remaining one additional indication, for patients who need new therapies and for maximizing the product value of these agents.

The Company filed a supplemental New Drug Application (sNDA) in Japan to the Pharmaceuticals and Medical Devices Agency (“PMDA”) in December 2015 for the indication of chronic lymphocytic leukemia, and obtained approval for the additional indication in August 2016. The Company has developed and applied for this indication upon request of the Ministry of Health, Labour and Welfare in Japan as one of the “Unapproved or Off-Label Drugs with High Medical Needs.” This is the second approval after the approval of an sNDA for the indication of recurrent/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma which the Company has already received in October 2010.

Regarding the first-line treatment of low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma, the Company filed an sNDA in Japan in December 2015 and received approval for additional indications in December 2016. In Europe, while the Company received a notice from Astellas Pharma GmbH (Head office: Germany) that they withdrew their application in January 2016, the Company, upon consultation with the PMDA, went ahead with the procedures for obtaining approval for the additional indications in Japan and was able to obtain such approval.

Lastly, regarding the indication of recurrent/refractory intermediate/high-grade non-Hodgkin’s lymphoma, the Company continues to discuss the path forward for approval with the PMDA.

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

Regarding these agents, for which a license agreement was entered into in July 2011, the Company has changed their generic name from “rigosertib” to “rigosertib sodium” in accordance with the notice of decision on its Japanese Accepted Names for Pharmaceuticals (JAN) received in October 2016. For the global Phase III trial of the intravenous formulation of rigosertib sodium conducted by Onconova Therapeutics, Inc. (Head office: Pennsylvania, U.S.; “Onconova”), the U.S. Licensor, the Company is in charge of the clinical development in Japan and started the domestic trial in December 2015. The global Phase III trial is conducted with clinical trial sites in more than ten countries worldwide, for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents (HMAs) or which relapse after treatment under the current standard of care (“primary HMA failure”). The Company completed the first patient enrollment in Japan in July 2016. Enrollments are currently accumulating.

Regarding the oral formulation of rigosertib sodium, the Company started its domestic Phase I clinical trial of the oral formulation of rigosertib sodium in combination with

azacitidine (Note) for the target indication of HR-MDS in December 2015. However, the provision of the investigational drug of this clinical trial by Onconova has been delayed. At present, patient enrollment has not yet been started. As soon as this issue on the provision of the investigational drug is resolved, the Company will resume patient enrollment, complete this clinical trial as planned, and consider its participation in the global Phase III clinical trial to be conducted by Onconova.

(Note) About azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug 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.

[Patient-controlled iontophoretic transdermal system for the short-term management of acute post-operative pain: SyB P-1501]

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly-owned subsidiary of U.S.-based The Medicines Company (Head Office: New Jersey, U.S.) for an exclusive license to develop and commercialize in Japan SyB P-1501. The Company commenced a domestic Phase III clinical trial for SyB P-1501 in June 2016 and completed the first patient enrollment in November 2016. The Company intends to complete the Phase III clinical trial at the earliest possible time, with the aim of obtaining approval by the end of 2019.

[New drug candidates]

The Company continued with search and evaluation activities to acquire license rights of new drug candidates in global terms, aiming to grow into a biopharmaceutical company with both profitability and growth potential, always from a medium-to-long-term perspective. Negotiations for multiple licensing agreements are currently underway.

Meanwhile, 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 strategic base for its overseas business development. By actively acquiring the worldwide rights concerning new drug candidates with SymBio Pharma USA as the base of global business, the Company will accelerate its transformation into a global specialty biopharmaceutical company with the aim of developing and commercializing new drugs in the U.S., Japan, Europe and other major global markets.

(ii) Overseas

SyB L-0501 is also marketed in South Korea, Taiwan and Singapore, and sales in these countries have been strong.

(iii) Business results

As a result of the above, net sales totaled 2,368,112 thousand yen for the fiscal year ended December 31, 2016, primarily reflecting product sales of TREAKISYM® in Japan. Product sales showed a year-on-year increase of 10.6%, and the Company recorded non-recurring revenue including resulting from achieving the sales milestone of SyB L-0501 in Taiwan. Accordingly, overall net sales rose 22.5% year-on-year.

Selling, general and administrative expenses totaled 3,031,242 thousand yen (a year-on-year decrease of 3.3%), including research and development (“R&D”) expenses of 1,667,098 thousand yen (a year-on-year decrease of 18.1%) primarily due to expenses associated with the clinical trial for TREAKISYM®, the intravenous and oral formulations of rigosertib as well as SyB P-1501, and other selling, general and administrative expenses of 1,364,143 thousand yen (a year-on-year increase of 24.0%).

As a result, operating loss of 2,127,049 thousand yen was recognized for the fiscal year ended December 31, 2016 (operating loss of 2,551,662 thousand yen for the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 196,467 thousand yen primarily comprising foreign exchange loss of 158,514 thousand yen, stock issuance costs of 11,658 thousand yen and commission fees of 8,975 thousand yen, and non-operating income totaling 6,710 thousand yen primarily due to interest income of 5,235 thousand yen and dividends income of insurance of 1,221 thousand yen. This resulted in an ordinary loss of 2,316,806 thousand yen (ordinary loss of 2,630,386 thousand yen for the previous fiscal year) and net loss of 2,313,233 thousand yen (net loss of 2,632,095 thousand yen for the previous fiscal year).

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

(iv) Capital investment

The total amount of capital expenditures during the current fiscal year was 39,682 thousand yen, mainly consisting of office facilities and the purchase of lab equipment.

(2) Status of fund procurement, etc.

Issuance of the third unsecured convertible bonds with stock acquisition rights and the 39th series of stock acquisition rights

In order to secure the funds necessary for its research and development activities, the Company made a resolution at the Board of Directors meeting held on April 6, 2016 to issue the third unsecured convertible bonds with stock acquisition rights (total issue price: 3 billion yen) and the 39th series of stock acquisition rights (total issue price 9,776 thousand yen by way of third-party allotment, total issue price of stocks when issued through the exercise of stock acquisition rights: 943,592 thousand yen), and completed the payment of 3,009,776 thousand yen.

(3) Status of assets, profit and loss in the current fiscal year and the three preceding fiscal years

(Unit: thousands of yen, except for per-share figures)

Fiscal year Classification	FY 2013 The 9th Term	FY 2014 The 10th Term	FY 2015 The 11th Term	FY 2016 The 12th Term (current)
Net sales	1,532,054	1,955,027	1,933,241	2,368,112
Operating loss	(1,680,528)	(1,303,279)	(2,551,662)	(2,127,049)
Ordinary loss	(1,601,424)	(1,110,316)	(2,630,386)	(2,316,806)
Net loss	(1,605,224)	(1,115,877)	(2,632,095)	(2,313,233)
Net loss per share (yen)	(69.29)	(36.26)	(81.26)	(58.82)
Total assets	7,686,947	7,453,799	4,984,289	6,878,384
Net assets	7,432,996	6,963,576	4,431,811	5,484,870
Net assets per share (yen)	239.48	208.80	127.56	108.61

(4) Issues to be addressed

The Company has a commitment to improve the following issues as a priority challenge for management.

(i) Further expansion of pipeline

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

Clinical trials are underway for our anticancer agents: SyB L-0501, SyB L-1101

(intravenous formulation)/SyB C-1101 (oral formulation) and patient-controlled iontophoretic transdermal system for the short-term management of acute post-operative pain SyB P-1501. Currently we are in discussion with counterparties regarding the in-licensing of several new drug candidates, and will continue with our active efforts to in-license new products in order to further expand our pipeline.

(ii) Pursuit of life cycle management in the existing pipeline

In order to enhance the enterprise value, it is critical to maximize returns from each drug under development by adding indications for new drug candidates after their initial introduction in pursuit of life cycle management.

TREAKISYM® has received approval for manufacturing and marketing with the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, chronic lymphocytic leukemia as well as the first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. The Phase II clinical trial was completed for recurrent/refractory intermediate/high-grade non-Hodgkin's lymphoma.

Progress is being made with development of intravenous and oral rigosertib formulations for the indication of myelodysplastic syndromes (MDS). No useful therapeutic agents are currently available for this indication, so it is an area with very high unmet medical needs.

As for the global Phase III 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 the domestic Phase I clinical trial as a monotherapy for the target indication of lower-risk MDS, and a Phase I clinical trial in combination with azacitidine for the target indication of higher-risk MDS is being conducted. 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, with a view to development progress by Onconova.

For the patient-controlled iontophoretic transdermal system for the management of acute post-operative pain SyB P-1501, approval has already been granted for manufacturing and marketing by U.S. and European regulatory agencies, and the domestic Phase I clinical trial has also been completed, and the Phase III clinical trial is underway. The Company is aiming for the prompt acquisition of manufacturing and marketing approval for this drug and will consider subsequent additional indications.

The aim for the future is to maximize the value of TREAKISYM®, rigosertib, and SyB P-1501 by further expansion of indications and by following through with life cycle management.

(iii) Global expansion for further growth

The Company has been operating its businesses not only in Japan, but also in other Asian countries including China, Korea, Taiwan, and Singapore as our important strategic geographic domains.

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 national strategy, the business environment for innovator drug developers is expected to remain severe. Also, similar policies will possibly be implemented in other Asian countries as well.

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 development in Asia.

(iv) Securing people

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 further strengthen our human resources by providing development programs such as OJT and other trainings.

(v) 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 strengthen the financial base by continually diversifying the method for fund procurement and reducing costs through budget control.

(5) Major business activities (As of December 31, 2016)

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 main focus in the areas of oncology, hematology, and pain management; 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, 2016)

Name	Location
Main office	Minato-ku, Tokyo

(ii) Employees (as of December 31, 2016)

Classification	Number of employees ¹	Increase or decrease from previous fiscal year end	Average age (years)	Average number of years of service
Male	53	2 (increase)	50.8	4.0
Female	24	1 (increase)	44.8	5.0
Total or average	77	3 (increase)	48.9	4.3

(Note 1) Number of employees refers to full-time employees (12 temporary employees are not included).

(7) Status of parent company and significant subsidiaries

Not applicable.

(8) Status of main lenders (as of December 31, 2016)

Not applicable.

2. Matters related to stock (as of December 31, 2016)

(1) Total number of authorized shares	Common stock	167,000,000 shares
(2) Total number of shares outstanding	Common stock	46,530,749 shares (excluding 75 shares of treasury stock)
(3) Number of shareholders		20,538
(4) Major shareholders (10 largest)		

Name of shareholder	Number of shares held	Shareholding ratio
Fuminori Yoshida	3,120,000	6.7%
Cephalon, Inc.	2,589,000	5.6%
SBI SECURITIES Co., Ltd.	1,924,000	4.1%
Japan Securities Finance Co., Ltd.	835,400	1.8%
Eisai Co., Ltd.	833,400	1.8%
Nomura Securities Co., Ltd.	691,100	1.5%
Waseda No. 1 Investment LP	684,000	1.5%
Daiwa Securities Co. Ltd.	676,600	1.5%
Matsui Securities Co., Ltd.	661,900	1.4%
Rakuten Securities, Inc.	422,200	0.9%

(Note) Calculation of issued shares (%) excludes treasury stock from the number of shares outstanding.

3. Matters related to stock acquisition rights

- (1) Stock acquisition rights held by the Company's Directors and Audit & Supervisory Board Members that were issued as compensation for services (as of December 31, 2016)

	The 12th series of stock acquisition rights by resolution of the Extraordinary General Meeting of Shareholders on December 1, 2006	The 16th series of stock acquisition rights by resolution of the Extraordinary General Meeting of Shareholders on September 30, 2008	The 20th series of stock acquisition rights by resolution of the Ordinary General Meeting of Shareholders on March 30, 2010
Number of stock acquisition rights	230	700	3,445
Number of shares to be issued upon the exercise of stock acquisition rights	23,000	70,000	344,500
Amount paid for stock acquisition rights	None	None	None
Value of property to be contributed upon the exercise of each stock acquisition right (Note 1)	1,461 yen per share	1,169 yen per share	585 yen per share
Period in which exercise of stock acquisition rights is possible	From: August 29, 2009 To: August 28, 2017	From: October 1, 2010 To: September 30, 2018	From: April 1, 2012 To: March 31, 2020
Status of possession by Directors (excluding Outside Directors)	-	-	1,800 units (1 holder) 180,000 shares
Status of possession by Outside Directors	90 units (1 holder) 9,000 shares	60 units (1 holder) 6,000 shares	600 units (2 holders) 60,000 shares

	The 22nd series of stock acquisition rights by resolution of the Ordinary General Meeting of Shareholders on March 30, 2010	The 24th series of stock acquisition rights by resolution of the Ordinary General Meeting of Shareholders on March 30, 2011	The 26th series of stock acquisition rights by resolution of the Ordinary General Meeting of Shareholders on March 29, 2012
Number of stock acquisition rights	1,530	1,920	3,625
Number of shares to be issued upon the exercise of stock acquisition rights	153,000	192,000	362,500
Amount paid for stock acquisition rights	None	None	None
Value of property to be contributed upon the exercise of each stock acquisition right (Note 1)	585 yen per share	682 yen per share	555 yen per share
Period in which exercise of stock acquisition rights is possible	From: April 1, 2012 To: March 31, 2020	From: March 31, 2013 To: March 30, 2021	From: April 18, 2014 To: April 17, 2022
Status of possession by Directors (excluding Outside Directors)	-	1,200 units (1 holder) 120,000 shares	2,600 units (1 holder) 260,000 shares
Status of possession by Outside Directors	200 units (1 holder) 20,000 shares	300 units (2 holders) 30,000 shares	625 units (2 holders) 62,500 shares

	The 30th series of stock acquisition rights by resolution of the Board of Directors meeting on May 14, 2013	The 32nd series of stock acquisition rights by resolution of the Board of Directors meeting on April 15, 2014	The 35th series of stock acquisition rights by resolution of the Board of Directors meeting on March 26, 2015
Number of stock acquisition rights	1,160	2,520	2,042
Number of shares to be issued upon the exercise of stock acquisition rights	116,000	252,000	204,200
Amount paid for stock acquisition rights	None	22,900 yen per unit (Note 2)	30,600 yen per unit (Note 2)
Value of property to be contributed upon the exercise of each stock acquisition right (Note 1)	799 yen per share	1 yen per share	1 yen per share
Period in which exercise of stock acquisition rights is possible	From: May 15, 2015 To: May 14, 2023	From: April 16, 2017 To: April 15, 2024	From: March 27, 2018 To: March 26, 2025
Status of possession by Directors (excluding Outside Directors)	645 units (1 holder) 64,500 shares	1,830 units (1 holder) 183,000 shares	1,480 units (1 holder) 148,000 shares
Status of possession by Outside Directors	305 units (3 holders) 30,500 shares	690 units (4 holders) 69,000 shares	459 units (4 holders) 45,900 shares

	The 37th series of stock acquisition rights by resolution of the Board of Directors meeting on March 30, 2016
Number of stock acquisition rights	2,365
Number of shares to be issued upon the exercise of stock acquisition rights	236,500
Amount paid for stock acquisition rights	27,200 yen per unit (Note 2)
Value of property to be contributed upon the exercise of each stock acquisition right	1 yen per share
Period in which exercise of stock acquisition rights is possible	From: March 31, 2019 To: March 30, 2026
Status of possession by Directors (excluding Outside Directors)	1,490 units (1 holder) 149,000 shares
Status of possession by Outside Directors	875 units (5 holders) 87,500 shares

(Note)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 stock acquisition right. Therefore, the stated value of property to be contributed upon the exercise of each stock acquisition right excluding those of the 32nd, 35th and 37th series is adjusted in accordance with the adjustment provision.

2. The person who receives the allotment of stock acquisition rights shall offset the amount to be paid for the relevant stock acquisition rights against cash compensation equivalent to the amount.
3. There are no stock acquisition rights held by Audit & Supervisory Board Members.

- (2) Stock acquisition rights distributed to the Company's employees as compensation for services during the current fiscal year (as of December 31, 2016)

	The 38th series of stock acquisition rights by resolution of the Board of Directors meeting on March 30, 2016
Number of stock acquisition rights	3,950
Number of shares to be issued upon the exercise of stock acquisition rights	395,000
Amount paid for stock acquisition rights	27,200 yen per unit (Note 2)
Value of property to be contributed upon the exercise of each stock acquisition right	1 yen per share
	From: March 31, 2019 To: March 30, 2026
Status of allotment to the Company's employees	3,950 units (73 holders) 395,000 shares

- (Notes) 1. Of the stock acquisition rights mentioned above, 495 units (49,500 shares) have been forfeited due to the retirement of employees.
2. The person who receives the allotment of stock acquisition rights shall offset the amount to be paid for the relevant stock acquisition rights against cash compensation equivalent to the amount.

- (3) Other important matters concerning stock acquisition rights (as of December 31, 2016)
 Details of stock acquisition rights attached to the third unsecured convertible bonds with stock acquisition rights and the 39th stock acquisition rights issued by resolution of the Board of Directors meeting held on April 6, 2016 are as follows.

	The 3rd unsecured convertible bonds with stock acquisition rights by resolution of the Board of Directors meeting on April 6, 2016	The 39th series of stock acquisition rights by resolution of the Board of Directors meeting on April 6, 2016
Number of stock acquisition rights	40	104
Number of shares to be issued upon the exercise of stock acquisition rights	14,218,009	4,472,000
Amount paid for stock acquisition rights	None	94,000 yen per share
Value of property to be contributed upon the exercise of each stock acquisition right	211 yen per share	211 yen per share
Period in which exercise of stock acquisition rights is possible	From: April 23, 2016 To: April 19, 2019	From: April 23, 2016 To: April 22, 2021

4. The Company's Executives (as of December 31, 2016)

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

Company Position	Name	Responsibility / Significant Concurrent Position
Representative Director	Fuminori Yoshida	Chief Executive Officer
Director	Naoko Iino	
Director	Lowell Sears	Sears Capital Management Inc. Chief Executive Officer
Director	George Morstyn	G & R Morstyn Pty. Ltd. Chief Executive Officer
Director	Milton Grannatt	
Director	George Vandeman	Vandeman & Company Principal
Full-time Audit & Supervisory Board Member	Takeshi Masuda	
Audit & Supervisory Board Member	Saneaki Ichijo	
Audit & Supervisory Board Member	Chikara Shimazaki	

- (Notes)1. Of the Directors, Naoko Iino, Lowell Sears, George Morstyn, Milton Grannatt and George Vandeman are Outside Directors.
2. Takeshi Masuda, Saneaki Ichijo and Chikara Shimazaki are outside members of the Audit & Supervisory Board.
3. Audit & Supervisory Board Member Chikara Shimazaki has been designated as an independent officer pursuant to the provisions of the Tokyo Stock Exchange and registered as such with the Tokyo Stock Exchange.
4. Full-time Audit & Supervisory Board Member Takeshi Masuda has years of experience as a corporate Audit & Supervisory Board Member at listed companies, and possesses deep insight in finance and accounting.
5. Audit & Supervisory Board Member Chikara Shimazaki is a certified public accountant (Representative of the Shimazaki accounting office) with expertise in finance and accounting.
6. Changes in Directors during the current fiscal year are as follows:
- Director Takako Ebata resigned upon expiration of her term of office at the closing of the 11th Ordinary General Meeting of Shareholders held on March 30, 2016.
 - Director Naoko Iino was newly appointed as Director at the 11th Ordinary General Meeting of Shareholders held on March 30, 2016.
7. The Company has adopted the Corporate Officer System. Corporate Officers who do not hold a concurrent position as Director are as follows:
- | | |
|---|---------------|
| Corporate Officer, Executive Vice President (COO) | Kazuo Asakawa |
| Corporate Officer | Tsutomu Abe |

(2) The 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 the higher of the amount of 1,000,000 yen or the amount set forth in laws and regulations as the maximum shall be borne, in cases where such Directors or members of the Audit & Supervisory Board 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/Board Members Paid	Total Amount of Compensation (thousands of yen)
Board of Directors	7 (Outside: 6)	130,918 (Outside: 51,244)
Audit & Supervisory Board	3 (Outside: 3)	19,371 (Outside: 19,371)
Total	10 (Outside: 9)	150,289 (Outside: 70,615)

(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 stock 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/Board Members paid as stated above includes one person who resigned at the closing of the 11th Ordinary General Meeting of Shareholders held on March 30, 2016.

5. The total compensation paid includes expenses (for seven (7) Directors, a total of 70,098 thousand yen) in connection with stock acquisition rights as stock options for the current fiscal year.

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

(i) Status of concurrent positions as an executive at other companies, and the relationship between such companies and the Company

Position	Name	Responsibility at the Company and significant concurrent position
Director	Lowell Sears	Sears Capital Management Inc. - Chief Executive Officer Cellerant Therapeutics, Inc. - Chairman & Board Member
Director	George Morstyn	G & R Morstyn Pty. Ltd. - Chief Executive Officer Biomedical Research Victoria - Chairman
Director	George Vandeman	Vandeman & Company - Principal

(Note) There are no significant transactions between any of the above companies and the Company.

(ii) Status of concurrent positions as an outside officer at other companies and the relationship between such companies and the Company

Position	Name	Responsibility and significant concurrent position
Director	Lowell Sears	Vital Therapies, Inc. – Member of the Board Directors SiteOne Therapeutics, Inc. - Member of the Board Directors Halcyon Medical, Inc. - Member of the Board Directors
Director	George Morstyn	GBS Venture Partners Pty. Ltd. - Member of the Board Directors Proacta, Inc. - Member of the Board Directors Cooperative Research Centre for Cancer Therapeutics - Member of the Board Directors Biomedical Research Victoria - Chairman
Director	Milton Grannatt	ARKAY Therapeutics LLC - Member of the Board Directors

Director	George Vandeman	Genelux Corporation - Vice Chairman
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(Note) There are no significant transactions between any of the above companies and the Company.

(iii) Status of main activities during the current fiscal year

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	Naoko Iino	11 out of 11 (100%)	-	Naoko Iino expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging her wealth of knowledge and experience in senior management.
Director	Lowell Sears	14 out of 15 (93%)	-	Lowell Sears expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his wealth of knowledge and experience in senior management.
Director	George Morstyn	15 out of 15 (100%)	-	George Morstyn expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his wealth of knowledge and experience as a doctor.

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	Milton Grannatt	15 out of 15 (100%)	-	Dr. Grannatt expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his wealth of knowledge of and experience in healthcare industries.
Director	George Vandeman	14 out of 15 (93%)	-	Mr. Vandeman expressed opinions from an objective perspective independent from the Company's management engaged in business operations, leveraging his wealth of knowledge and experience as an attorney and in various industries.
Full-time Audit & Supervisory Board Member	Takeshi Masuda	15 out of 15 (100%)	13 out of 13 (100%)	Mr. Masuda proactively expressed opinions in an effort to fulfill his duty of supervising management from a neutral standpoint and to carry out highly effective audits by leveraging his wealth of experience as a corporate Audit & Supervisory Board Member at listed companies.

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	15 out of 15 (100%)	13 out of 13 (100%)	Mr. Ichijo proactively expressed opinions in an effort to fulfill his duty of supervising management from a neutral standpoint and to carry out highly effective audits by leveraging his expertise and wealth of experience as an attorney.
Audit & Supervisory Board Member	Chikara Shimazaki	15 out of 15 (100%)	13 out of 13 (100%)	Mr. Shimazaki proactively expressed opinions in an effort to fulfill his duty of supervising management from a neutral standpoint and to carry out highly effective audits by leveraging his expertise and wealth of experience as a certified public accountant.

(Notes) 1. With regard to Director Naoko Iino, her status of attendance at the meetings is calculated from the Board of Directors meetings held after her appointment in March 2016.

2. In addition to the Board of Directors meetings mentioned above, two resolutions in writing were approved without holding a meeting, pursuant to Article 370 of the Companies Act and Article 26, Paragraph 2 of the Articles of Incorporation of the Company, and three reports were made to the Directors pursuant to Article 372, Paragraph 1 of the Companies Act.

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 current fiscal year	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' 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 this fiscal year, 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 refrain from reappointing the accounting auditor for reasons such as difficulty in execution of duty by the accounting auditor, 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 of the accounting auditor. 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 upon 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.

- (5) Matters concerning disposition of business suspension imposed on the accounting auditor during the past two years
- (i) The entity on which the disposition was imposed
Ernst & Young ShinNihon LLC
- (ii) Description of the disposition
- Suspension of business related to concluding new engagement contracts: three months (from January 1, 2016 to March 31, 2016)
 - An order to improve business operations (improvement of the operation management system)
 - An administrative surcharge payment order (in the amount of 2,111 million yen)
- (iii) Reasons for the disposition
- For the audit of financial documents of Toshiba Corporation, the audit firm, in negligence of due care, attested financial documents containing material misstatements as if they contained no misstatements.
 - The audit firm's operation was found to be significantly unjust.

6. System to ensure the appropriateness of operations

- (1) The corporate system to ensure that Directors, other officers and employees comply with laws and ordinances, as well as the Articles of Incorporation, in the process of performing their duties
 - (i) The Company has its Representative Director and President to instill in all Directors, Audit & Supervisory Board Members, and employees the Company's policy that any and all corporate activities should be based on the spirit of compliance with laws and the maintenance of ethics (hereinafter "Compliance") by repeatedly urging them to abide by the spirit of the Corporate Action Charter.
 - (ii) The Company promotes thorough activities for Compliance by setting up a compliance committee comprised of the senior manager in charge of the corporate division as Chairman, and the head or senior managers of relevant departments as members thereof.
 - (iii) The Company sets up compliance hot-lines within and outside the Company, as designated compliance liaisons for compliance-related problems, to respond to requests for consultation from employees and make efforts to find and cure any and all unfair acts and practices as early as possible.
 - (iv) The Company sets up an internal audit office as an independent organizational unit which acts under the direct control of the Representative Director and President and regular audits are conducted by this office. Through such audits, objective assessments are made for the effectiveness and efficiency of business, reliability of various financial reports, safeguarding of assets, status of compliance operation and appropriateness and effectiveness of corporate risk management, and if necessary, reasonable assurance is obtained for advice and suggestions for the improvement in maintenance and operation of internal control.
 - (v) The Company resolutely opposes antisocial forces and organizations that threaten the order or safety of society as a whole.

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

The head of the Legal Department of the Company is the person responsible for 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 policy and related rules for such risk control. Usually the Company's permanent risk-management committee, which is chaired by its Representative Director and President, monitors the conditions of risk control, and will take appropriate measures on a company-wide basis if necessary. In the case of an emergency, the Company will temporarily set up a headquarters with its Representative Director and President acting as chairman thereof, and take necessary measures in accordance with decisions made at this temporary headquarters.
- (4) Corporate system to ensure the efficient performance of duties by Directors
- (i) Directors, other officers and employees perform their duties as provided in the procedural rules for appropriate decision-making under the "Rules for the Board of Directors" and "Rules for the Internal Approvals" and other similar regulations.
 - (ii) The Company regularly holds Executive Management Committee meetings as provided in the "Rules for the Executive Management Committee" for the purpose of contributing to sound and appropriate decision-making by the Representative Director and President.
 - (iii) The Company develops long-term business plans, and operates and expands its business in accordance with such long-term plans. The Company also predetermines numerical targets for each business year for inclusion in such long-term plans, and conducts the evaluation of business results and the control of budgets in relation to such numerical targets. The Company reports to the Board of Directors every month on the status of achieving such numerical targets.
- (5) Matters related to an assistant to Audit & Supervisory Board Members to be appointed at their request
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, and if deemed to be necessary, the Representative Director and President shall appoint such an assistant.
- (6) Matters related to the independence of the employees who assist the Audit & Supervisory Board Members in executing their duties
Any employee shall, if and when he/she is ordered by an Audit & Supervisory Board Member in the performance of audit-related tasks, not receive any instruction or direction from the Director in charge, the internal audit section or any other similar

section; further instruction or direction is to be received from the Audit & Supervisory Board Member.

- (7) Matters related to ensuring effectiveness of the Audit & Supervisory Board Members' instructions to the employees who assist them in executing their duties
Matters such as personnel evaluation and transfer and disciplinary actions concerning the staff who assist the 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 Members; corporate system for other reports to the Audit & Supervisory Board Members to ensure the efficient performance of audits by the Audit & Supervisory Board Members
 - (i) Any Director or employee shall, if and when he/she becomes aware of any fact which threatens to cause any significant damage or could adversely affect the Company, promptly inform the Audit & Supervisory Board Members thereof.
 - (ii) Audit & Supervisory Board Members may attend Board of Directors meetings, Executive Management Committee meetings, and any other important meetings for the purpose of gaining a better understanding of the decision-making process and conditions of business execution.
 - (iii) The Audit & Supervisory Board provides an opportunity for all Directors and employees having significant work responsibilities to consult on an individual basis.
 - (iv) The Audit & Supervisory Board holds meetings for the mutual exchange of views and opinions with the Representative Director and President, and independent Audit & Supervisory Board Members.
- (9) Corporate system to ensure prevention of disadvantageous treatment to the person who made a report to the Audit & Supervisory Board Members merely on account of such conduct
The Company establishes a whistleblowing system with points of contact inside as well as outside the Company, as part of the framework for early detection of violations against laws and regulations within the Company, while ensuring prevention of disadvantageous treatment to whistleblowers.
- (10) Matters related to the treatment of expenses or obligations associated with the execution of duties of the Audit & Supervisory Board Members, including the procedures for prepayment or reimbursement of such expenses
 - (i) With respect to a claim for prepayment of expenses based on Article 388 of the

Companies Act, made by an Audit & Supervisory Board Member in association with the execution of his/her duties, the Company processes settlement of such expenses or obligations without delay, unless such expenses or obligations are recognized as unnecessary for the execution of duties of such Audit & Supervisory Board Member based on careful discussion thereof by responsible departments.

- (ii) The Company authorizes expenses for seeking opinions and advice from external experts including attorneys and certified public accountants, if it is found necessary for the Audit & Supervisory Board Members to execute their duties.

7. Summary of the status of operation of the system to ensure the appropriateness of operations

- (1) The Company is striving to ingrain awareness of legal compliance across the organization, by thorough communication thereon to Directors and employees, through publishing information such as the corporate conduct policy for compliance and the whistleblowing system manual on the bulletin board of the in-house Intranet.
- (2) The Board of Directors of the Company comprises six (6) Directors (including five (5) Outside Directors), in which Outside Directors participate in resolutions from an independent standpoint and monitor and supervise the management, while 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, while having regular exchange of opinions with the Representative Director once a month.

Balance Sheet

(As of December 31, 2016)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	6,685,011	Current liabilities	942,118
Cash and deposits	5,719,325	Accounts payable-trade	321,860
Accounts receivable-trade	487,471	Accounts payable-other	552,510
Merchandise and finished goods	272,725	Income taxes payable	36,586
Supplies	663	Other	31,161
Prepaid expenses	79,104	Non-current liabilities	451,396
Advances paid	66,465	Bonds payable	450,000
Consumption taxes receivable	34,766	Provision for retirement benefits	1,396
Forward exchange contracts	11,603		
Other	12,886		
Non-current assets	193,373	Total liabilities	1,393,514
		(Net assets)	
Property, plant and equipment	74,524	Shareholders' equity	5,053,735
Buildings	35,846	Common stock	9,948,298
Tools, furniture and fixtures	69,497	Capital surplus	9,918,298
(Accumulated depreciation)	(30,819)	Legal capital surplus	9,918,298
Intangible assets	41,985	Retained earnings	(14,812,843)
Software	41,985	(Accumulated deficits)	(14,812,843)
		Other retained earnings	(14,812,843)
Investments and other assets	76,863	Retained earnings	(14,812,843)
Shares of subsidiaries	0	(Accumulated deficits)	(14,812,843)
Long-term prepaid expenses	11,649	brought forward	
Lease and guarantee deposits	65,214	Treasury stock	(17)
		Stock acquisition rights	431,135
Total assets	6,878,384	Total net assets	5,484,870
		Total liabilities and net assets	6,878,384

(Note) Amounts less than one thousand yen have been omitted.

Statement of Operations

(From January 1, 2016
to December 31, 2016)

(Unit: thousands of yen)

Item	Amount	
I. Net sales		2,368,112
II. Cost of goods sold		1,463,919
Gross profit		904,192
III. Selling, general and administrative expenses		3,031,242
Operating loss		(2,127,049)
IV. Non-operating income		
Interest income	5,235	
Interest on securities	249	
Dividend income from insurance	1,221	
Other	4	6,710
V. Non-operating expenses		
Interest expenses	4	
Commission fee	8,975	
Stock issuance cost	11,658	
Foreign exchange loss	158,514	
Other	17,315	196,467
Ordinary loss		(2,316,806)
VI. Extraordinary income		
Gain on reversal of stock acquisition rights	8,512	8,512
VII. Extraordinary loss		
Loss on retirement of non-current assets	1,139	1,139
Loss before income taxes		(2,309,433)
Income taxes – current	3,800	3,800
Net loss		(2,313,233)

(Note) Amounts less than one thousand yen have been omitted.

Statement of Changes in Net Assets

(From January 1, 2016
to December 31, 2016)

(Unit: thousands of yen)

	Shareholders' equity				
	Common stock	Capital surplus	Retained earnings (Accumulated deficits)	Treasury stock	Total shareholders' equity
		Legal capital surplus	Other retained earnings Retained earnings (Accumulated deficits) brought forward		
Balance at the beginning of year	8,330,775	8,300,775	(12,499,609)	(17)	4,131,924
Changes of items during the year					
Issuance of new shares (exercise of stock acquisition rights)	1,617,522	1,617,522	—	—	3,235,044
Net loss	—	—	(2,313,233)	—	(2,313,233)
Net changes of items other than shareholders' equity	—	—	—	—	—
Total changes of items during the year	1,617,522	1,617,522	(2,313,233)	—	921,811
Balance at the end of year	9,948,298	9,918,298	(14,812,843)	(17)	5,053,735

	Stock acquisition rights	Total net assets
Balance at the beginning of year	299,887	4,431,811
Changes of items during the year		
Issuance of new shares (exercise of stock acquisition rights)	—	3,235,044
Net loss	—	(2,313,233)
Net changes of items other than shareholders' equity	131,247	131,247
Total changes of items during the year	131,247	1,053,058
Balance at the end of year	431,135	5,484,870

(Note) Amounts less than one thousand yen have been omitted.

Notes on Financial Statements

(Significant accounting policies)

(1) Valuation basis and method for assets

Marketable securities

Shares of subsidiaries	Shares of subsidiaries are stated at cost determined by the moving average method.
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Available-for-sale securities

Available-for-sale securities with determinable market value	Available-for-sale securities with determinable market value are stated at fair value with any changes in unrealized holding gain or loss, net of applicable income taxes, included directly in shareholders' equity. Cost of securities sold is calculated by the moving average method.
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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.
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Derivative transactions	Derivative financial instruments are stated at fair value.
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Inventories	Inventories held for the purpose of ordinary sale are measured at the lower of cost determined by the weighted average method or net selling value.
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(2) Depreciation of non-current assets

Property, plant and equipment (excluding lease assets)	Straight-line method The useful lives of major property, plant and equipment are summarized as follows:
--	--

Building	3 to 18 years
Tools, furniture and fixtures	5 to 15 years

Intangible assets (excluding lease assets)	Straight-line method Capitalized software costs are being amortized over the period of the internal use of 5 years.
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Lease assets	Depreciation of lease assets is computed by the straight-line method over the lease term with no residual value.
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(3) Accounting for deferred assets

Stock issuance cost and bond issuance cost are charged to income when incurred.

(4) Foreign currency translation

Monetary assets and liabilities denominated in foreign currencies are translated into yen at the spot exchange rate prevailing on the balance sheet dates, 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.
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For FY 2016, 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 at an amount to be required as of the balance sheet date.
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The Company applies the simplified method to calculate amounts of retirement benefit obligation and retirement benefit expenses. That is, amounts of retirement benefit obligation are the payments required for voluntary retirement as of each fiscal year end.

(6) Accounting for consumption taxes

Transactions are recorded at amounts exclusive of consumption taxes.

(Notes on balance sheet)

Not applicable.

(Notes on income statement)

R&D expenses included in general and administrative expenses 1,667,098 thousand yen

(Notes on statement of changes in net assets)

(1) Shares issued and outstanding / Treasury stock

(Unit: number of shares)

		At the beginning of the year	Increase	Decrease	At the end of the year
Common stock	Shares issued	32,390,923	14,139,901	—	46,530,824
	Treasury stock	75	—	—	75

(2) Number of shares to be issued upon exercise of stock acquisition rights issued at the end of the current fiscal year

Common stock 9,316,133 shares

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

(Notes on deferred tax accounting)

(1) Significant components of deferred tax assets and liabilities

Deferred tax assets:	(thousands of yen)
Excess depreciation for lump-sum depreciable assets	2,192
Excess amortization for deferred assets	871,030
Research and development expenses	854,810
Accounts payable-other	243
Provision for retirement benefits	427
Enterprise tax payable	10,704
Asset retirement obligation	967
Share-based compensation expense	95,125
Loss carried forward	1,881,788
Subtotal	<u>3,717,291</u>
Valuation allowance	<u>(3,717,291)</u>
Total deferred tax assets	<u>—</u>

(2) Revision of amounts of deferred tax assets and liabilities due to changes in rates of corporate tax, etc.

Following the enactment of the “Act for Partial Revision of the Income Tax Act, etc.” and the “Act for Partial Revision of the Local Tax Act, etc.” on March 29, 2016 and the enactment of the “Act for Partial Revision of the Consumption Tax Act and for the Drastic Reform of the Taxation System for Ensuring Stable Financial Resources for Social Security” and the “Act for Partial Revision of the Local Tax Act and Local Allocation Tax Act for the Drastic Reform of the Taxation System for Ensuring Stable Financial Resources for Social Security” in the Diet on November 18, 2016, the statutory tax rate used in the calculation of deferred tax assets and liabilities for this fiscal year (however, limited to those expected to be reversed on or after January 1, 2017), has been changed from 32.34% of the previous fiscal year to 30.86% for those that are expected to be collected or paid during the period from January 1, 2017 to December 31, 2018, and to 30.62% for those that are expected to be collected or paid on or after January 1, 2019. There is no impact from this change in the tax rate.

(Notes on properties under lease arrangements)

Not applicable.

(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 stock 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, such 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 exports and imports 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.

Bonds with convertible bond type stock acquisition rights are used primarily for financing relating to R&D and have a maturity of two years and four months after the current fiscal year end.

(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 December 31, 2016, all operating receivables are from one particular major customer.

(2) Fair value of financial instruments

The carrying value on the balance sheets, fair values and their difference as of December 31, 2016 are as follows.

(Unit: thousands of yen)

	Carrying value	Fair value	Difference
(1) Cash and deposits	5,719,325	5,719,325	—
(2) Accounts receivable-trade	487,471	487,471	—
(3) Advances paid	66,465	66,465	—
Assets, total	6,273,262	6,273,262	—
(1) Accounts payable-trade	321,860	321,860	—
(2) Accounts payable-other	552,510	552,510	—
(3) Income taxes payable	36,586	36,586	—
(4) Bonds with convertible bond type stock acquisition rights	450,000	448,935	(1,064)
Liabilities, total	1,360,956	1,359,892	(1,064)
Derivative transactions, total (*)	11,603	11,603	—

(*) Net assets 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.

(4) Bonds with convertible bond type stock acquisition rights

The fair value of bonds with convertible bond type stock acquisition rights is calculated by discounting total amounts of principal and interests at a rate reflecting the remaining redemption period and credit risk.

Derivative transactions

Forward exchange contract

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 65,214 thousand yen) are not included in the above tables 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

(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	5,719,293	—	—	—
Accounts receivable-trade	487,471	—	—	—
Advances paid	66,465	—	—	—
Total	6,273,230	—	—	—

(Note) 4. Maturities of bonds with convertible bond type stock acquisition rights after the fiscal year end

(Unit: thousands of yen)

	Due in one year or less	Due after one year through two years	Due after two years through three years	Due after three years through four years	Due after four years through five years	Due after five years
Bonds with convertible bond type stock acquisition rights	—	—	450,000	—	—	—
Total	—	—	450,000	—	—	—

(Notes on per-share information)

(1) Net assets per share	108.61 yen
(2) Net loss per share	(58.82) yen
Average number of shares outstanding during the year	39,329,706 shares

(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 current fiscal year 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

(Significant subsequent events)

(Significant subsequent events)

(1) Issuance of new shares through the exercise of stock acquisition rights regarding bonds with stock acquisition rights

During the period from January 1, 2017 to February 17, 2017, third unsecured bonds with convertible bond type stock acquisition rights was converted into new shares through the exercise of the rights. The summary of such exercise of stock acquisition rights is as follows.

Number and type of shares issued:	2,132,700 shares of common stock
Total amount issued:	450,000 thousand yen
Amount of decrease in bonds with convertible bond type stock acquisition rights:	450,000 thousand yen
Amount transferred to common stock (capital):	225,000 thousand yen

(2) Issuance of new shares through the exercise of stock acquisition rights

During the period from January 1, 2017 to February 17, 2017, a portion of the 39th series of stock acquisition rights was executed to new shares. The summary of such exercise of stock acquisition rights is as follows.

Number and type of shares issued:	301,000 shares of common stock
Number of stock acquisition rights	7 units
Number of unexercised stock acquisition rights	97 units
Total amount issued:	64,169 thousand yen
Amount transferred to common stock (capital):	32,084 thousand yen

Independent Auditor's Report

February 17, 2017
The Board of Directors
SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC

Tomoaki Minamiyama
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 net assets, the notes to the financial statements and the related supplementary schedules of SymBio Pharmaceuticals Limited (the "Company") applicable to the 12th fiscal year from January 1, 2016 through December 31, 2016.

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 12th fiscal year ended December 31, 2016 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 12th Term of the Company from January 1, 2016 to December 31, 2016, 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 documents 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, profit and loss statement, statement of changes in net assets, and notes on non-consolidated financial statements) and supplementary statements for the Term reported.

2. Results of audit

(1) Results of the audit of the business report

- a. We admit that the business report and supplementary statements 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. We admit that 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 statements

We admit that the method for and result of audits conducted by Ernst & Young ShinNihon LLC, the accounting auditor, are appropriate.

February 23, 2017

**Audit & Supervisory Board,
SymBio Pharmaceuticals Limited**

Takeshi Masuda, (seal)
Full-time Audit & Supervisory Board
Member (Outside)

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

Chikara Shimazaki, (seal)
Audit & Supervisory Board Member
(Outside)

End of Report

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