

March 11, 2016

# **Annual Report**

(January 1, 2015 through December 31, 2015)

### 1. Business Performance of SymBio Pharmaceuticals Limited

### (1) Business conditions and operating results

The Japanese pharmaceutical industry during FY 2015 was again guided toward the "era of generic drugs comprising 80% of all drugs dispensed," with the announcement of the Comprehensive Drug Industry Reinforcement Strategy. With Japan's medical expenditures exceeding 40 trillion yen, the environment surrounding healthcare has been changing at an unprecedented pace while becoming increasingly harsh, as evidenced by the accelerated push to dispense generic drugs, the reorganization of hospital functions, and the strengthening of regional medical coordination.

However, as Japan is one of the few nations leading new drug discovery in the world, the pharmaceutical industry, with its knowledge-intensive industrial structure, has been designated as a growth industry to spearhead "Japan Revitalization Strategy" and "Healthcare Policy."

The Comprehensive Strategy indicated new directions to be taken by the pharmaceutical industry by proposing such measures as "SAKIGAKE Designation System," which will hasten the commercialization of innovative drugs ahead of the world and the commencement of a project by Japan Agency for Medical Research and Development ("AMED") to support the commercialization of drugs in the rare-disease field prior to orphan drug designation (advance orphan drug designation system), to the end of reinforcing drug creation capabilities.

Under such circumstances, progress in the Company's business for FY 2015 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 refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Net sales showed a significant increase of 110.3% year-on-year (NHI price basis), and net sales through Eisai also increased by 103.0% compared to the plan.

Aiming to maximize the product value of TREAKISYM®, the Company continues to pursue three additional indications:

Firstly, regarding the indications of first-line low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, after having completed its domestic Phase II clinical trial, the Company filed a supplemental New Drug Application (sNDA) to the Pharmaceuticals and Medical Devices Agency ("PMDA") in December 2015. Regulatory approval in the EU is also underway with an application submitted by Astellas Pharma GmbH (Head office: Germany).

Secondly, regarding the indication of chronic lymphocytic leukemia, the Company filed an sNDA in December 2015. TREAKISYM® was designated as an orphan drug (pharmaceutical for the treatment of rare diseases) for the indication of chronic lymphocytic leukemia in June 2012. In addition, the "Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs," a committee established by the Ministry of Health, Labour and Welfare ("MHLW") in Japan, requested the Company to further develop TREAKISYM®.

In addition to TREAKISYM® 100mg, the Company filed an sNDA for TREAKISYM® in December 2015, in respect of a 25mg vial for use in an actual clinical setting.

Thirdly, regarding the indication of refractory/relapsed 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]

After having completed patient enrollment in January 2015, the Company continued to conduct its domestic Phase I clinical trial of the intravenous formulation of rigosertib in refractory/relapsed higher-risk myelodysplastic syndrome (HR-MDS), a hematological malignancy. The clinical trial was successfully completed in October 2015.

For the global Phase III trial conducted by Onconova Therapeutics, Inc. (Head office: Pennsylvania, U.S.; "Onconova"), the U.S. Licensor, the Company started the clinical trial in Japan in December 2015.

The global Phase III trial is conducted with clinical trial sites in more than ten countries worldwide, for HR-MDS patients who do not respond to treatment with hypomethylating agents (HMAs) or who relapse after treatment under the current standard of care ("primary HMA failure").

Regarding the oral formulation of rigosertib, the Company's domestic Phase I clinical trial for the target indication of HR-MDS was completed in June 2015. As a result of the

trial, the safety of the oral formulation of rigosertib for monotherapy was confirmed, hence the Company started its domestic Phase I clinical trial of the oral formulation as a rigosertib in combination with azacitidine (Note) in December 2015. The Company plans to complete this clinical trial promptly, and its participation in the global Phase III clinical trial to be conducted by Onconova is under consideration.

(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 postoperative pain: SyB P-1501]

In addition to TREAKISYM® and rigosertib, the Company has continued with search and evaluation activities to identify new drug candidates. In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc. (the "Incline"), a wholly-owned subsidiary of U.S.-based The Medicines Company (Head office: New Jersey, U.S.; "MEDCO"), for an exclusive license to develop and commercialize SyB P-1501 in Japan (U.S. product name: IONSYS®), a patient-controlled iontophoretic transdermal system for the short-term management of acute postoperative pain. The Company will begin preparations for a domestic Phase III clinical trial to test SyB P-1501 in 2016.

As described above, the Company's business made a significant progress towards further growth in FY 2015, by filing three sNDAs for TREAKISYM® in Japan, starting a Phase III clinical trial for the approval of the intravenous formulation of rigosertib, and entering into a license agreement for SyB P-1501, a new drug candidate in the Company's new business domain (pain management), and so forth.

# (ii) Overseas

Product sales of SyB L-0501 in South Korea, Taiwan and Singapore grew steadily as planned.

# (iii) Business results

As a result of the above, net sales totaled 1,933,241 thousand yen for the fiscal year ended December 31, 2015, primarily reflecting product sales of SyB L-0501 in Japan and

overseas markets. Although net domestic sales of TREAKISYM® increased by 24.0% compared to the previous fiscal year, overall net sales showed a year-on-year decrease of 1.1% reflecting a decline in overseas net sales of 76.1% year on year, due to factors such as front-loading orders in the previous fiscal year in Korea.

Selling, general and administrative expenses totaled 3,134,659 thousand yen (a year-on-year increase of 71.3%), including research and development ("R&D") expenses of 2,034,714 thousand yen (a year-on-year increase of 162.8%) primarily due to expenses associated with (i) clinical trials of TREAKISYM® and the intravenous and oral formulations of rigosertib, and (ii) the introduction of the patient-controlled iontophoretic transdermal system for the management of acute postoperative pain SyB P-1501, as well as other selling, general and administrative expenses of 1,099,944 thousand yen (a year-on-year increase of 4.2%).

As a result, operating loss of 2,551,662 thousand yen was recognized for the fiscal year ended December 31, 2015 (operating loss of 1,303,279 thousand yen for the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 96,087 thousand yen primarily comprising foreign exchange loss of 86,242 thousand yen and commission fees of 9,000 thousand yen, and non-operating income totaling 17,363 thousand yen primarily due to interest income of 12,949 thousand yen, and interest on securities of 3,316 thousand yen. This resulted in an ordinary loss of 2,630,386 thousand yen (ordinary loss of 1,110,316 thousand yen for the previous fiscal year) and net loss of 2,632,095 thousand yen (net loss of 1,115,877 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 17,910 thousand yen, mainly consisting of the purchase of network equipment and software for business use.

# (2) 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 2012 The 8th Term	FY 2013 The 9th Term	FY 2014 The 10th Term	FY 2015 The 11th Term (current)
Net sales	1,955,178	1,532,054	1,955,027	1,933,241
Operating loss	(1,700,273)	(1,680,528)	(1,303,279)	(2,551,662)
Ordinary loss	(1,729,480)	(1,601,424)	(1,110,316)	(2,630,386)
Net loss	(1,733,320)	(1,605,224)	(1,115,877)	(2,632,095)
Net loss per share (yen)	(90.60)	(69.29)	(36.26)	(81.26)
Total assets	5,502,190	7,686,947	7,453,799	4,984,289
Net assets	4,899,957	7,432,996	6,963,576	4,431,811
Net assets per share (yen)	254.71	239.48	208.80	127.56

# (3) 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 and SyB L-1101 (intravenous formulation)/SyB C-1101 (oral formulation). In addition, preparations are underway for starting a Phase III clinical trial for the patient-controlled iontophoretic transdermal system for the management of acute postoperative pain SyB P-1501.

For an anti-cancer drug using TTR1 nano-agonist molecule, the Company is working on a joint research and development with Teikyo Heisei University, striving for the introduction of global license. We continue with ongoing efforts to in-license new products in order to 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 manufacture and marketing with the approved indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. For additional indications, the Company filed a supplemental New Drug Application (sNDA) for first-line low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia. The Phase II clinical trial was completed for refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma.

Progress is being made with development of intravenous and oral rigosertib formulations for the indication of myelodysplastic syndrome (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 refractory/relapsed 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 higher-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 considers 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 postoperative pain SyB P-1501, approval has already been granted for manufacturing and marketing by U.S. and European regulatory agencies, and a domestic Phase I clinical trial has also been completed. 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<sup>®</sup>, 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 skyrocketing medical expenditure 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 a 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 people as the company management resource. We cannot make superior achievements in exploring and developing new drugs without talent. We have been continually recruiting talented people, especially after 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 thorough budget control.

# (4) Major business activities (As of December 31, 2015)

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.

- (5) Main office and employees
  - (i) Main office (as of December 31, 2015)

Name	Location
Main office	Minato-ku, Tokyo

(ii) Employees (as of December 31, 2015)

Classification	Number of employees <sup>1</sup>	Increase or decrease from previous fiscal year end	Average age (years)	Average # of years of service
Male	51	6 (increase)	50.3	4.4
Female	23	1 (decrease)	44.3	4.4
Total or average	74	5 (increase)	48.4	4.4

- (Note) Number of employees refers to full time employees (8 temporary employees not included).
- (6) Status of parent company and significant subsidiaries Not applicable.
- (7) Status of main lenders (as of December 31, 2015)
  Not applicable.

# 2. Matters related to stock (as of December 31, 2015)

56,000,000 shares (1) Total number of authorized shares Common stock (2) Total number of shares outstanding Common stock 32,390,848 shares

(excluding 75 shares of treasury stock)

(3) Number of shareholders 13,156

(4) Major shareholders (10 largest)

Name of shareholder	Number of shares held	Shareholding ratio
Fuminori Yoshida	3,120,000	9.6%
Cephalon, Inc.	2,589,000	8.0%
Eisai Co., Ltd.	833,400	2.6%
Waseda No.1 Investment LP	684,000	2.1%
Oak Capital Corporation	614,566	1.9%
SBI SECURITIES Co., Ltd.	386,300	1.2%
Matsui Securities Co., Ltd.	319,200	1.0%
Japan Securities Finance Co., Ltd.	314,200	1.0%
Rakuten Securities, Inc.	240,400	0.7%
Hideyuki Hase	204,200	0.6%

(Note) Calculation of issued shares (%) excludes treasury stock from 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
  - (i) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 31, 2006 (7th series of stock acquisition rights)

(as of December 31, 2015)

- Number of stock acquisition rights 610

- Number of shares to be issued upon the exercise of stock acquisition rights 61,000

Amount paid for stock acquisition rights

None

- Value of property to be contributed upon the exercise of

each stock acquisition right (Note)

- Period during which stock acquisition rights may be exercised From: July 2, 2008

To: March 30, 2016

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1	-	-
Outside Directors	100	10,000	1
Audit & Supervisory Board Members	-	-	-

(ii) Stock acquisition rights granted by resolution of the Extraordinary General Meeting of Shareholders held on December 1, 2006 (12th series of stock acquisition rights)

(as of December 31, 2015)

Number of stock acquisition rights 230

- Number of shares to be issued upon the exercise of stock acquisition rights 23,000

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 1,461 yen

Period during which stock acquisition rights may be exercised
 From: August 29, 2009
 To: August 28, 2017

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1	1	-
Outside Directors	90	9,000	1
Audit & Supervisory Board Members	-	-	-

(iii) Stock acquisition rights granted by resolution of the Extraordinary General Meeting of Shareholders held on September 30, 2008 (16th series of stock acquisition rights)

(as of December 31, 2015)

Number of stock acquisition rights
 Number of shares to be issued upon the exercise of stock

- Number of snares to be issued upon the exercise of stock acquisition rights 70,000

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 1,169 yen

 Period during which stock acquisition rights may be exercised
 From: October 1, 2010
 To: September 30, 2018

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1	1	-
Outside Directors	60	6,000	1
Audit & Supervisory Board Members	-	-	-

(iv) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 30, 2010 (20th series of stock acquisition rights)

(as of December 31, 2015)

- Number of stock acquisition rights 3,445

- Number of shares to be issued upon the exercise of stock acquisition rights 344,500

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 585 yen

Period during which stock acquisition rights may be exercised
 From: April 1, 2012
 March 31, 2020

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1,800	180,000	1
Outside Directors	600	60,000	2
Audit & Supervisory Board Members	-	-	-

(v) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 30, 2010 (22nd series of stock acquisition rights)

(as of December 31, 2015)

Number of stock acquisition rights 1,530

Number of shares to be issued upon the exercise of stock acquisition rights

153,000

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 585 yen

Period during which stock acquisition rights may be exercised From: April 1, 2012

To: March 31, 2020

 Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	-	-	-
Outside Directors	200	20,000	1
Audit & Supervisory Board Members	-	-	-

(vi) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 30, 2011 (24th series of stock acquisition rights)

(as of December 31, 2015)

Number of stock acquisition rights

Number of shares to be issued upon the exercise of stock acquisition rights

Amount paid for stock acquisition rights

None

Value of property to be contributed upon the exercise of each stock acquisition right (Note)

Period during which stock acquisition rights may be

From: March 31, 2013

exercised exercised From: March 31, 2013

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1,200	120,000	1
Outside Directors	300	30,000	2
Audit & Supervisory Board Members	-	-	-

(vii) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 29, 2012 (26th series of stock acquisition rights)

(as of December 31, 2015)

- Number of stock acquisition rights 3,625

- Number of shares to be issued upon the exercise of stock acquisition rights 362,500

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 555 yen

Period during which stock acquisition rights may be exercised
 From: April 18, 2014
 To: April 17, 2022

- Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	2,600	260,000	1
Outside Directors	625	62,500	2
Audit & Supervisory Board Members	-	-	-

(viii) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 28, 2013 (30th series of stock acquisition rights)

(as of December 31, 2015)

Number of stock acquisition rights 1,160

Number of shares to be issued upon the exercise of stock acquisition rights

116,000

- Amount paid for stock acquisition rights None

- Value of property to be contributed upon the exercise of each stock acquisition right (Note) 799 yen

Period during which stock acquisition rights may be exercised
 From: May 15, 2015
 May 14, 2023

Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	645	64,500	1
Outside Directors	305	30,500	3
Audit & Supervisory Board Members	-	-	-

(ix) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 27, 2014 (32nd series of stock acquisition rights)

(as of December 31, 2015)

April 15, 2024

To:

Number of stock acquisition rights 2,520 Number of shares to be issued upon the exercise of stock 252,000 acquisition rights Amount paid for stock acquisition rights \*The person who receives the allotment of stock 22,900 acquisition rights shall set off his/her claims for compensation against the Company in lieu of payment of monies for the stock acquisition rights allotted. Value of property to be contributed upon the exercise of 1 yen each stock acquisition right Period during which stock acquisition rights may be From: April 16, 2017

Status of possession by the Company's Directors and

exercised

Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1,830	183,000	1
Outside Directors	690	69,000	4
Audit & Supervisory Board Members	-	-	-

(x) Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 26, 2015 (35th series of stock acquisition rights)

(as of December 31, 2015)

30,600

1 yen

- Number of stock acquisition rights 2,042

Number of shares to be issued upon the exercise of stock acquisition rights 204,200

- Amount paid for stock acquisition rights

\*The person who receives the allotment of stock acquisition rights shall set off his/her claims for compensation against the Company in lieu of payment of

monies for the stock acquisition rights allotted.

 Value of property to be contributed upon the exercise of each stock acquisition right

Period during which stock acquisition rights may be exercised
 From: March 27, 2018
 To: March 26, 2025

 Status of possession by the Company's Directors and Audit & Supervisory Board Members

	Number of stock acquisition rights	Number of shares	Number of holders
Directors (excluding Outside Directors)	1,480	148,000	1
Outside Directors	562	56,200	5
Audit & Supervisory Board Members	-	-	-

(Note) 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 and 35th series is adjusted in accordance with the adjustment provision.

(2) Stock acquisition rights distributed to the Company's employees as compensation for services during the current fiscal year

Stock acquisition rights granted by resolution of the Ordinary General Meeting of Shareholders held on March 26, 2015 (36th series of stock acquisition rights)

Number of stock acquisition rights
 Number of shares to be issued upon the exercise of stock acquisition rights

\*The person who receives the allotment of stock acquisition rights shall set off his/her claims for compensation against the Company in lieu of payment of monies for the stock acquisition rights allotted.

- Value of property to be contributed upon the exercise of each stock acquisition right 1 yen

Period during which stock acquisition rights may be exercised
 From: March 27, 2018
 To: March 26, 2025

- Status of allotment to the Company's employees

	Number of stock acquisition rights	Number of shares	Number of holders
Company employees	3,120 (Note)	312,000 (Note)	61

(Note) Of the stock acquisition rights mentioned above, 395 units (39,500 shares) have been forfeited due to the retirement of employees.

# 4. The Company's Executives (as of December 31, 2015)

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

Company Position	Name	Responsibility / Significant Concurrent Position
Representative Director	Fuminori Yoshida	Chief Executive Officer
Director	Takako Ebata	Takako Ebata Office Inc. Representative Director
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, Takako Ebata, Lowell Sears, George Morstyn, Milton Grannatt and George Vandeman are Outside Directors.
  - Takeshi Masuda, Saneaki Ichijo and Chikara Shimazaki are outside members of the Audit & Supervisory Board.
  - 3. Audit & Supervisory Board Member Chikara Shimazaki is registered with the Tokyo Stock Exchange as an independent officer.
  - 4. Full-time Audit & Supervisory Board Member Takeshi Masuda has years of experience as corporate auditor at listed companies, and possesses deep insight in finance and accounting.
  - Audit & Supervisory Board Member Saneaki Ichijo is an attorney (Partner at Anderson, Mori & Tomotsune), with expertise in corporate legal affairs.
  - 6. Audit & Supervisory Board Member Chikara Shimazaki is a certified public accountant (Representative of the Shimazaki accounting office) with expertise in finance and accounting.
  - Changes in Directors and Audit & Supervisory Board Members during the current fiscal year are as follows:
    - Audit & Supervisory Board Member Koshi Ohizumi resigned upon expiration of his term of
      office at the closing of the 10th Ordinary General Meeting of Shareholders held on March 26,
      2015.
    - Audit & Supervisory Board Member Takeshi Masuda was newly appointed as Director at the 10th Ordinary General Meeting of Shareholders held on March 26, 2015.
  - 8. The Company has adopted the Corporate Officer System. Corporate Officers who do not hold a concurrent position as Director are as follows:
    - Corporate Officer Masamitsu Harata

# (2) Summary of contents of liability limitation agreement

The Company has executed an agreement with each of the Outside Directors and outside members of the Audit & Supervisory Board with respect to the liability in Article 423, Paragraph 1 of the Companies Act, setting forth that in the event it is with good faith and no gross negligence that an Outside Director or outside member of the Audit & Supervisory Board performs his or her duties, the higher of the amount of 1,000,000 yen or the amount set forth in laws and regulations at the maximum shall be borne.

# (3) Compensation of Board of Directors and Audit & Supervisory Board

Company Board	Number of Directors/Board Members Paid	Amount of Compensation (thousands of yen)
Board of Directors	6	121,819
Board of Directors	(Outside: 5)	(Outside: 49,388)
Audit & Cumanicany Doord	4	19,045
Audit & Supervisory Board	(Outside: 4)	(Outside: 19,045)
Total	10	140,865
10(a)	(Outside: 9)	(Outside: 68,433)

(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 (of which 22 million yen is for Outside Directors) at the 9th Ordinary General Meeting of Shareholders held on March 27, 2014.
- 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.
- The number of Directors/Board Members paid as stated above includes one person who resigned at the closing of the 10th Ordinary General Meeting of Shareholders held on March 26, 2015.
- The total compensation paid includes expenses (six (6) Directors 57,056 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) Director: Ms. Takako Ebata
  - a. Status of concurrent position(s) of an executive at other companies, and relationship between such companies and the Company
    - She holds the concurrent position of Representative Director at Takako Ebata Office Inc. The Company has a business connection with this office such as subcontract

- agreements concerning management consulting, but the ratio of the amount paid for such transactions to all outsourcing expenses is negligible.
- Status of concurrent positions as outside officer at other companies, and relationship between such company and the Company Not applicable.
- c. Relationship with certain related companies, such as the Company's main customers Not applicable.
- d. Status of main activities during the fiscal year reported
   Ms. Takako Ebata attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%).
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

### (ii) Director: Lowell Sears

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company
  - He holds the concurrent position of Chief Executive Officer at Sears Capital Management Inc.
  - There is no business transaction between the above company and the Company.
- b. Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company
  - He holds the concurrent position of Outside Director at Cellerant Therapeutics, Inc., Vital Therapies, Inc., SiteOne Therapeutics, Inc. and Halcyon Medical, Inc.
  - There is no business transaction between either of the above companies and the Company.
- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year
   Lowell Sears attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%).
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

# (iii) Director: George Morstyn

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company
  - He holds the concurrent position of Chief Executive Officer at G & R Morstyn Pty Ltd.

There is no business transaction between the above company and the Company.

b. Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company

He holds concurrent positions of Outside Director at GBS Venture Partners Pty Ltd., Proacta, Cooperative Research Centre for Cancer Therapeutics, Therapeutics Innovation and BioMedVic. He also holds concurrent positions at Victorian Comprehensive Cancer Centre (Deputy Chairman of the Board). There is no business transaction between the above companies/cancer centre and the Company.

- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year George Morstyn attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%).
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

### (iv) Director: Milton Grannatt

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company
  - Not applicable.
- b. Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company

He holds the concurrent position of Advisory Board Member at VOX Telehealth and Biohealthonomics.

There is no business transaction between either of the above companies and the Company.

- Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year Milton Grannatt attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%).
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

### (v) Director: George Vandeman

a. Status of concurrent positions of executives at other companies and relationship

between such companies and the Company

He holds the concurrent position of Principal at Vandeman & Company.

There is no business transaction between the above company and the Company.

b. Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company

He holds the concurrent position of Vice Chairman of Board at Genelux Corporation and Managing Member at Restaurants Hawaii, LLC.

There is no business transaction between either of the above companies and the Company.

- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year George Vandeman attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%).
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

# (vi) Full-time Audit & Supervisory Board Member: Takeshi Masuda

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company Not applicable.
- Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company Not applicable.
- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year
  - (1) Status of attendance at the Board of Directors meetings

Takeshi Masuda was newly appointed as an outside member of the Audit & Supervisory Board at the 10th Ordinary General Meeting of Shareholders held on March 26, 2015. He attended all 10 meetings of the Board of Directors held since taking office (attendance rate: 100.0%), to appropriately give advice and recommendations concerning deliberations on proposals, etc. based on his many years of experience and insight as a member of the Audit & Supervisory Board of listed companies.

(2) Status of attendance at the Audit & Supervisory Board meetings

Takeshi Masuda was newly appointed as an outside member of the Audit & Supervisory Board at the 10th Ordinary General Meeting of Shareholders held on March 26, 2015. He attended all 11 meetings of the Audit & Supervisory Board held since taking office (attendance rate: 100.0%), to exchange views regarding audit results and deliberate key issues related to audits.

e. Amount of compensation received from the Company's subsidiaries Not applicable.

# (vii) Audit & Supervisory Board Member: Saneaki Ichijo

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company Not applicable.
- Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company Not applicable.
- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year
  - (1) Status of attendance at the Board of Directors meetings Saneaki Ichijo attended all 13 meeting of the Board of Directors held during the fiscal year (attendance rate: 100.0%), to give advice from an objective perspective regarding the legality of the Company's management execution, etc. from his professional viewpoints as a lawyer.
  - (2) Status of attendance at the Audit & Supervisory Board meetings Saneaki Ichijo attended all 15 meetings of the Audit & Supervisory Board held during the fiscal year (attendance rate: 100.0%) to exchange views regarding audit results and deliberate key issues related to audits.
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

# (viii) Audit & Supervisory Board Member: Chikara Shimazaki

- a. Status of concurrent positions of executives at other companies and relationship between such companies and the Company Not applicable.
- Status of concurrent positions as outside officer at other companies and relationship between such companies and the Company Not applicable.

- c. Relationship with particular related companies, such as main customers Not applicable.
- d. Status of main activities during the current fiscal year
  - (1) Status of attendance at the Board of Directors meetings Chikara Shimazaki attended all 13 meetings of the Board of Directors held during the fiscal year (attendance rate: 100.0%), to appropriately give advice and recommendations concerning deliberations on proposals, etc. from his professional viewpoints as a certified public accountant.
  - (2) Status of attendance at the Audit & Supervisory Board meetings Chikara Shimazaki attended all 15 meetings of the Audit & Supervisory Board held during the fiscal year (attendance rate: 100.0%) to exchange views regarding audit results and deliberate key issues related to audits.
- e. Amount of compensation received from the Company's subsidiaries Not applicable.

Each Outside Director appropriately advised and raised questions regarding resolutions and reports discussed at Board of Directors meetings based on his or her deep personal insight of business administration, and from a point of view that was independent of business operations.

Each outside member of the Audit & Supervisory Board appropriately advised and raised questions during meetings in fulfilling his role as management monitor for resolutions and reports introduced and discussed by the Board of Directors based on his deep personal insight of business administration from an independent and neutral standpoint; Each member also aggressively raised questions and expressed opinions regarding resolutions and reports introduced by the Audit & Supervisory Board in order to execute highly effective audits.

Besides the Board of Directors meetings held during the current fiscal year, notice to Directors in accordance with the provisions of Article 372, Paragraph 1 of the Companies Act was implemented on four separate occasions.

### 5. Status of accounting auditor

- (1) Name of accounting auditor Ernst & Young ShinNihon LLC
- (2) Summary of contents of liability limitation agreement Not applicable.

# (3) Amount of compensation

	Amount paid
Amount of compensation to 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 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 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 Companies Act, and the audits conducted in accordance with 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 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) Disposition of business suspension currently imposed on the accounting auditor
- (i) The party subjected to the disposition
  - 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)
  - Order to improve business operations (improvement of the operation management system)
  - 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) 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 of 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 of 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 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 General Affairs of the Company is the person responsible for general management of corporate documents 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 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 the request of such 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, 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 corporate auditors; corporate system for other reports to corporate auditors to ensure the efficient performance of audits by corporate auditors
  - (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 influence the Company, promptly inform the Audit & Supervisory Board Member 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 discuss 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 auditors.
- (9) Corporate system to ensure prevention of disadvantageous treatment to the person who made 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 of 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 the 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 their 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 at 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 Directors (including five Outside Directors), in which Outside Directors participate in resolution from an independent standpoint and monitor and supervise the management, while each Audit & Supervisory Board Member carries out management audit 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, 2015)

(Unit: thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	4,826,778	Current liabilities	550,940
Cash and deposits	4,261,438	Accounts payable-trade	319,866
Accounts receivable-trade	300,742	Lease obligations	642
Merchandise and finished goods	133,029	Accounts payable-other	183,690
Supplies	167	Income taxes payable	14,183
Prepaid expenses	38,591	Forward exchange contracts	14,999
Advances paid	79,639	Other	17,558
Other	13,170	Noncurrent liabilities	1,537
		Provision for retirement benefits	1,537
Noncurrent assets	157,510		
Property, plant and equipment	52,956	Total liabilities	552,477
Buildings	24,521	(Net assets)	
Tools, furniture and fixtures	52,293	Shareholders' equity	4,131,924
(Accumulated depreciation)	(23,858)	Common stock	8,330,775
		Capital surplus	8,300,775
Intangible assets	52,001	Legal capital surplus	8,300,775
Software	50,506	Retained earnings	(12 400 (00)
Software in progress	900	(Accumulated deficits)	(12,499,609)
Lease assets	594	Other retained earnings	(12,499,609)
Investments and other assets	52,553	Retained earnings (Accumulated deficits) brought forward	(12,499,609)
Long-term prepaid expenses	1,227	Treasury stock	(17)
Lease and guarantee deposits	51,326	Stock acquisition rights	299,887
		Total net assets	4,431,811
Total assets	4,984,289	Total liabilities and net assets	4,984,289

# **Statement of Operations**

From January 1, 2015 to December 31, 2015

(Unit: thousands of yen)

Item	Amount	
I. Net sales		1,933,241
II. Cost of goods sold		1,350,244
Gross profit		582,996
III.Selling, general and administrative expenses		3,134,659
Operating loss		(2,551,662)
IV. Non-operating income		
Interest income	12,949	
Interest on securities	3,316	
Dividend income from insurance	1,072	
Other	24	17,363
V. Non-operating expenses		
Interest expenses	13	
Commission fee	9,000	
Stock issuance cost	160	
Foreign exchange loss	86,242	
Other	671	96,087
Ordinary loss		(2,630,386)
VI. Extraordinary income		
Gain on reversal of stock	2 212	2 212
acquisition rights	3,312	3,312
VII. Extraordinary loss		
Loss on retirement of noncurrent	1,221	1,221
assets	1,221	1,221
Loss before income taxes		(2,628,295)
Income taxes – current	3,800	3,800
Net loss		(2,632,095)

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

# **Statement of Changes in Net Assets**

From January 1, 2015 to December 31, 2015

(Unit: thousands of yen)

	Shareholders' equity				
		Capital surplus	Retained earnings		
	Common stock		Other retained earnings		Total shareholders'
	Stock	Legal capital surplus	Retained earnings (Accumulated deficits) brought forward	stock	equity
Balance at the beginning of year	8,330,775	8,300,775	(9,867,514)	(17)	6,764,019
Changes of items during the year					
Net loss	_	-	(2,632,095)	_	(2,632,095)
Net changes of items other than shareholders' equity	ı	_	_	_	-
Total changes of items during the year		_	(2,632,095)	_	(2,632,095)
Balance at the end of year	8,330,775	8,300,775	(12,499,609)	(17)	4,131,924

	Valuation and transla	tion adjustments	Stock	
	Unrealized holding gain (loss) on securities	Total valuation and translation adjustments	acquisition rights	Total net assets
Balance at the beginning of year	(744)	(744)	200,300	6,963,576
Changes of items during the year				
Net loss	_	-	-	(2,632,095)
Net changes of items other than shareholders' equity	744	744	99,586	100,330
Total changes of items during the year	744	744	99,586	(2,531,764)
Balance at the end of year	I	ı	299,887	4,431,811

(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

Available-for-sale securities

Available-for-sale securities Available-for-sale securities with determinable market with determinable market value

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

without determinable market value

Available-for-sale securities 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 held for the purpose of ordinary sale are

measured at lower of cost determined by the weighted

average method or net selling value.

(2) Depreciation of noncurrent assets

Property, plant and equipment Straight-line method

The useful lives of major assets are as follows: (excluding lease assets)

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

Intangible assets Straight-line method

(excluding lease assets) Capitalized software costs are being amortized over the

period of the internal use of 5 years.

Depreciation is calculated on the straight-line method Lease assets

over the lease term with no residual value.

# (3) Accounting for deferred assets

Stock issuance costs are expensed when incurred.

### (4) Foreign currency translation

Monetary assets and liabilities denominated in foreign currencies are translated into yen at the spot exchange rate prevailing at the balance sheet 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.

As of December 31, 2015, 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 the amount of retirement benefit obligations to be required as of the balance sheet date.

For the calculation of the provision for retirement benefits and the retirement benefit expenses, the Company adopts the simplified method, where retirement benefit obligations are estimated at the amount of retirement benefit payments required for voluntary terminations as of the balance sheet date.

# (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 2,034,714 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 year	Increase	Decrease	At the end of year
Common	Shares issued	32,390,923	-	-	32,390,923
stock	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

5,547,250 shares

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

# (Notes on deferred tax accounting)

# (1) Significant components of deferred tax assets

Deferred tax assets:	(thousands of yen)
Excess depreciation for lump-sum depreciable assets	2,357
Excess amortization for deferred assets	391,435
Research and development expenses	1,011,607
Accounts payable-other	8,458
Provision for retirement benefits	497
Enterprise tax payable	4,396
Asset retirement obligation	360
Share-based compensation expense	59,480
Loss carried forward	1,818,206
Subtotal	3,296,798
Valuation allowance	(3,296,798)
Total deferred tax assets	

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

Following the promulgation of the "Act for Partial Amendment of the Income Tax Act, etc." and the "Act for Partial Amendment of the Local Tax Act, etc." on March 31, 2015, the effective statutory tax rate used in the calculation of deferred tax assets and liabilities (however, limited to those expected to be reversed on or after January 1, 2016), has been changed from 35.64% of the previous fiscal year to 33.10% for those that are expected to be collected or paid during the period from January 1, 2016 to December 31, 2016, and to 32.34% for those that are expected to be collected or paid on or after January 1, 2017.

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). 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 purpose but uses them within the scope prescribed in the 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 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 relatively low risk of falling below initial investments. However, it might carry 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 actual volume of exports and imports transactions denominated in foreign currencies.

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

Lease obligations are associated with the finance lease transactions that intend to finance capital expenditures and the longest maturity of lease term is one year after the fiscal year end.

# (iii) Risk management for financial instruments

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

In accordance with the internal credit policies for managing credit risk arising from operating receivables, the Company's marketing department periodically monitors the credit worthiness of major customers and monitors due dates and outstanding balances by individual customer. 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 the satisfactory credit rating and investment period in accordance with the 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 internal rules, 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 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 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, 2015, all operating receivables are from one particular major customer.

### (2) Fair value of financial instruments

Carrying value on the balance sheet, fair value and their difference as of December 31, 2015 are as follows.

(Unit: thousands of ven)

	(Unit: thousands of yen)				
	Carrying value	Fair value	Difference		
(1) Cash and deposits	4,261,438	4,261,438	_		
(2) Accounts receivable-trade	300,742	300,742	_		
(3) Advances paid	79,639	79,639			
Assets, total	4,641,819	4,641,819			
(1) Accounts payable-trade	319,866	319,866	_		
(2) Lease obligations	642	643	1		
(3) Accounts payable-other	183,690	183,690	_		
(4) Income taxes payable	14,183	14,183	_		
Liabilities, total	518,383	518,384	1		
Derivative transactions, total (*)	(14,999)	(14,999)			

<sup>(\*)</sup> The value of assets and liabilities arising from derivative transactions is shown at net value and ( ) is used for items that come to be liabilities in total.

(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, (3) Accounts payable-other and (4) 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.

(2) Lease obligations

The fair value of lease obligations is determined at present value calculated by discounting total amounts of principle and interests at a presumable rate used for similar new lease transactions.

# Derivative transactions

Forward exchange contract

The fair value of forward exchange contract 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 51,326 thousand yen) are not included in 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	4,261,410	_	_	_
Accounts receivable-trade	300,742	_	_	_
Advances paid	79,639	_	_	_
Total	4,641,791	_	_	_

(Note) 4. Maturities of lease obligations after the fiscal year end

(Unit: thousands of yen)

	Due in one year or less	through	two years through	Due after three years through four years	four years through	Due after five years
Lease obligations	642	_	_	_	_	_
Total	642	_	_	_	_	_

(Notes on per-share information)

(1) Net assets per share127.56 yen(2) Net loss per share(81.26) yen

Average number of shares outstanding during the year 32,390,848 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 fiscal year is as follows:

(Unit: thousands of yen)
Total amount of bank overdraft limit and loan 1,350,000

commitment line

Balance of borrowing outstanding -

Unused balance 1,350,000

(Significant subsequent events)

Not applicable.

# **Independent Auditor's Report**

February 25, 2016 The Board of Directors SymBio Pharmaceuticals Limited

Ernst & Young ShinNihon LLC

Eishi Yoshida Certified Public Accountant Designated and Engagement Partner

Tomoaki Minamiyama Certified Public Accountant Designated and Engagement Partner

Kazuto Shiratori Certified Public Accountant Designated and Engagement Partner

Pursuant to Article 436, Paragraph 2, Item 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 11th fiscal year from January 1, 2015 through December 31, 2015.

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 11th fiscal year ended December 31, 2015 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 Audit & Supervisory Board

We, Audit and Supervisory Board Members, prepare this report of audit with regard to the execution of Directors' duties during the 11th Term from January 1, 2015 to December 31, 2015, as the uniformed opinion of all Audit and Supervisory Board Members after careful discussion based on the audit reports prepared by respective Audit and Supervisory Board Members, and report as follows.

 Method and Contents of Audit by the Audit & Supervisory Board Member and the Audit & Supervisory Board

The Audit & Supervisory Board formulated the audit policy and plan for the Term reported, and received the reporting from respective auditors 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 requesting additional explanations as deemed necessary.

Respective auditors, 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 were compliant with laws and ordinances and the Company's Article 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 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. Besides, we received the notification

from the accounting auditor that "the system to ensure that its duties are executed as appropriate (the items listed by respective paragraphs of Ordinance on Accounting of Companies Article 131)" are maintained in accordance with "the standards for quality control of audits (Business Accounting Council, October 28, 2005)," requesting additional explanation as deemed necessary. Furthermore, with regard to the order to improve business operations issued by the Financial Services Agency on December 22, 2015, we received explanations on the outline and implementation status of the plan to improve business operations submitted by the accounting auditor. 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 audit of 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. Any misconduct in the execution of Directors' duties or any material facts in violation of laws and ordinances and the Company's Articles of Incorporation are not noticed.
- 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 audit of financial statements and the related supplementary statements

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

March 2, 2016

# 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