English translation

SymBio Pharmaceuticals Limited

Summary of Financial Statements for the Fiscal Year Ended December 31, 2015
[Japanese GAAP] (Non-consolidated)

February 10, 2016

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Securities Exchange	
Securities Code	4582	URL http://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Director, Finance & Accounting	Tetsuya Maruyama	TEL +81-3-5472-1125
Ordinary Annual General Meeting of Shareholders	March 30, 2016	Date of dividend payment (plan)	—
Scheduled Date to File Securities Report	March 31, 2016		

Supplementary materials for the financial statements: Yes [ ] No [x]

Holding of earnings performance review: Yes [x] No (For securities analysts and institutional investors)

(millions of yen – rounded down, unless otherwise stated)

1. Business Results for FY 2015 (January 1, 2015 to December 31, 2015)

(1) Operating Results (Percentages indicate year-on-year changes)

	Net Sales		Operating Income (loss)		Ordinary Income (loss)		Net Income (loss)	
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
FY 2015	1,933	(1.1)	(2,551)	—	(2,630)	—	(2,632)	—
FY 2014	1,955	27.6	(1,303)	—	(1,110)	—	(1,115)	—

	Net Income (loss) per share	Diluted Net Income per share	Ratio of net income (loss) to equity (ROE)	Ratio of ordinary income (loss) to total assets (ROA)	Ratio of operating income (loss) to net sales
	Yen	Yen	%	%	%
FY 2015	(81.26)	—	(48.3)	(42.3)	(132.0)
FY 2014	(36.26)	—	(15.8)	(14.7)	(66.7)

(Reference) Equity in earnings: FY 2015 — million yen FY 2014 — million yen

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio	Net Assets per Share
	millions of yen	millions of yen	%	Yen
FY 2015	4,984	4,431	82.9	127.56
FY 2014	7,453	6,963	90.7	208.80

(Reference) Equity: FY 2015 4,131 million yen FY 2014 6,763 million yen

(3) Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of the year
	millions of yen	millions of yen	millions of yen	millions of yen
FY 2015	(2,271)	1,489	(2)	4,261
FY 2014	(1,266)	314	543	5,092

2. Dividends

	Annual Dividend per Share					Total Dividends	Payout ratio	Ratio of dividends to net assets
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year			
	Yen	Yen	Yen	Yen	Yen	millions of yen	%	%
FY 2014	—	0.00	—	0.00	0.00	—	—	—
FY 2015	—	0.00	—	0.00	0.00	—	—	—
FY 2016 (Forecast)	—	0.00	—	0.00	0.00		—	

3. Earnings Forecasts for FY 2016 (January 1, 2016 to December 31, 2016)

(Percentages indicate year-on-year changes)

	Net Sales		Operating Income (loss)		Ordinary Income (loss)		Net Income (loss)		Net Income (loss) per share
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%	Yen
Full Year	2,339	21.0	(2,778)	—	(2,811)	—	(2,815)	—	(86.91)

Notes:

(1) Changes in accounting policies, changes in accounting estimates and restatements after error corrections

(a) Changes in accounting polices due to revision of accounting standards:	Yes	No
(b) Changes in accounting polices due to other reasons:	Yes	No
(c) Changes in accounting estimates:	Yes	No
(d) Restatements after error correction:	Yes	No

(2) Number of shares outstanding (common stock)

(i) Number of shares outstanding at the end of the year (including treasury stock)	FY 2015	32,390,923 shares	FY 2014	32,390,923 shares
(ii) Number of shares of treasury stock at the end of the year	FY 2015	75 shares	FY 2014	75 shares
(iii) Average number of shares during the year	FY 2015	32,390,848 shares	FY 2014	30,776,721 shares

(Note) Refer to “Per share information” on Page 55 for number of shares that forms the basis for calculating net income (loss) per share.

* Status of the annual audit

The audit of financial statements as required by the Financial Instruments and Exchange Act was underway as of the date of this disclosure document.

* Explanation regarding the appropriate use of earnings forecasts and other matters

(Notes on forward-looking statements)

All forecasts presented in this document, including earnings forecasts, are based on information currently available to management and assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the assumptions on which the Company’s earnings forecasts are based and their usage, please refer to “Business results analysis” on Page 1 of the attachment.

Index of the attachment

1. Business results

(1) Business results analysis

(Business Results for FY 2015)

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.

(Forecast for FY 2016)

The Company expects net sales of 2,339 million yen in FY 2016, a 21.0% increase from FY 2015, mainly as a result of growth in sales of TREAKISYM® in Japan and overseas. Meanwhile, in R&D, along with its active efforts for additional indications of TREAKISYM®, the Company plans to continue development aimed at obtaining marketing approval for the intravenous and oral formulations of rigosertib as well as SyB P-1501 for which a license agreement was concluded in the previous fiscal year. The Company will begin a joint research and development program with Teikyo Heisei University for an anti-cancer drug using the TTR1 nano-agonist molecule. With the aim of further enhancing its corporate value in the long term, the Company will advance the development of its pipeline as a whole. To this end, the Company anticipates R&D expenses of 2,180 million yen (2,034 million yen in FY 2015) and selling, general and administrative expenses of 3,605 million yen (3,134 million yen in FY 2015), including R&D expenses.

Major development plans of the Company's pipeline are as follows:

[TREAKISYM®]

An additional application was submitted for the target indication of first-line low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia in the previous fiscal year, and the Company will swiftly continue the procedures, including response to inquiries from PMDA, aimed at obtaining early approval.

[Intravenous and oral formulation of rigosertib]

As for the intravenous formulation of rigosertib, the Company will actively continue the global Phase III trial in Japan and aim for initial patient enrollment at an early date.

As for the oral formulation of rigosertib, the Company will actively continue the domestic Phase I clinical trial in combination with azacitidine and aim for initial patient enrollment at an early date. The Company will look into development for the target indication of lower-risk transfusion-dependent MDS, while Onconova is making progress with development.

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

With respect to SyB P-1501 for which a license agreement was conducted in the previous fiscal year, the Company will actively pursue preparations aimed at starting a Phase III clinical trial in the third quarter of FY 2016.

As a result of these planned activities, net sales of 2,339 million yen, operating loss of 2,778 million yen, ordinary loss of 2,811 million yen, and net loss of 2,815 million yen are projected for FY 2016.

(2) Financial position analysis

(Analysis of assets, liabilities, net assets, and cash flows)

Total assets as of December 31, 2015 stood at 4,984,289 thousand yen, a decrease of 2,469,510 thousand yen from the previous fiscal year end. This was primarily due to decreases of 1,430,636 thousand yen in cash and deposits, 899,256 thousand yen in marketable securities, 111,559 thousand yen in merchandise and finished goods, 33,235 thousand yen in forward exchange contracts, 19,974 thousand yen in consumption taxes receivable, and 11,766 thousand yen in software, offsetting increases of 28,085 thousand yen in accounts receivable-trade and 19,798 thousand yen in advances paid. Liabilities stood at 552,477 thousand yen, an increase of 62,254 thousand yen from the previous fiscal year end, primarily reflecting increases of 40,806 thousand yen in accounts payable-other, 14,999 thousand yen in forward exchange contracts, and 13,870 thousand yen in accounts payable-trade.

Under net assets, an increase of 99,586 thousand yen in stock acquisition rights was offset primarily by a decrease of 2,632,095 thousand yen in retained earnings (accumulated deficit) due to recording of net loss; thus, total net assets decreased by 2,531,764 thousand yen from the previous fiscal year end to 4,431,811 thousand yen. As a result, the equity ratio decreased by 7.8 percentage points from the previous fiscal year end to 82.9%.

Cash and cash equivalents ("cash") stood at 4,261,438 thousand yen, a decrease of 830,636 thousand yen from the previous fiscal year end. This was mainly due to a cash decrease resulting from loss before income taxes, despite an increase in cash due to redemption of securities.

Cash flows from each activity and factors for this fiscal year end are as follows:

(Cash flow from operating activities)

Cash flow from operating activities showed an overall decrease of 2,271,686 thousand yen (a decrease of 1,266,174 thousand yen in the previous fiscal year) due to decreasing factors such as loss before income taxes of 2,628,295 thousand yen, an increase in accounts receivable-trade of 28,085 thousand yen, and an increase in advances paid of 19,798 thousand yen, despite increasing factors such as a decrease in inventories of 111,559 thousand yen, share-based compensation expense of 102,898 thousand yen, an increase in accounts payable-other of 51,013 thousand yen, foreign exchange losses of 45,459 thousand yen, depreciation of 24,244 thousand yen, a decrease in consumption taxes receivable of 19,974 thousand yen, and an increase in accounts payable-trade of 13,870 thousand yen.

(Cash flow from investing activities)

Cash flows from investing activities showed an overall increase of 1,489,141 thousand yen (an increase of 314,413 thousand yen in the previous fiscal year) mainly due to proceeds from redemption of securities of 900,000 thousand yen, proceeds from withdrawal of time deposits of 600,000 thousand yen, and proceeds from collection of lease and guarantee deposits of 16,420 thousand yen, despite decreasing factors such as the purchase of property, plant and equipment of 22,546 thousand yen.

(Cash flow from financing activities)

Cash flows from financing activities showed a decrease of 2,632 thousand yen (an increase of 543,700 thousand yen in the previous fiscal year) due mainly to payments for issuance of common stock of 1,850 thousand yen.

(Index trend related to cash flow)

	7th Term Fiscal year ended December 2011	8th Term Fiscal year ended December 2012	9th Term Fiscal year ended December 2013	10th Term Fiscal year ended December 2014	11th Term Fiscal year ended December 2015
Equity ratio (%)	91.0	88.6	95.4	90.7	82.9
Equity ratio on a fair market value basis (%)	126.0	104.3	151.4	155.1	150.8
Debt redemption period (years)	—	—	—	—	—
Interest coverage ratio	—	—	—	—	—

Equity ratio: Equity (total shareholders' equity) /total assets
Equity ratio on a fair market value basis: Total market value of common stock/total assets
Debt redemption period: Interest-bearing debt/cash flow from operating activities
Interest coverage ratio: Cash flow from operating activities/interest payments

(Notes)
1. Total market value was calculated based on the number of shares issued, excluding treasury stocks.
2. Debt redemption period and interest coverage ratio are not available due to negative cash flow from operating activities.

(3) Basic policies concerning profit distribution and dividends

Since the foundation of the Company, dividends have not been distributed.

Although the Company has recorded product sales of TREAKISYM®, the Company continues to use funds for development activities. Therefore, it is our policy to attempt to improve the balance sheet and retain funds for sustainable development activities rather than profit distribution. However, we recognize that the return of profit to stockholders is an important management issue and will consider the distribution of profit based on future business performance and financial conditions.

The articles of incorporation state that the Company can pay an interim dividend, based on a corporate resolution by the Board of Directors, on June 30 every year as the recorded date. The Company can also distribute surplus by designating a record date in addition to year-end and interim dividends. The decision making body is the Board of Directors for the interim dividend, and shareholders (shareholders' meeting) for the year-end dividend.

(4) Business risks

Described below are major issues that may lead to potential risks in the Company's business activities. Issues that are not necessarily considered significant by the Company are also disclosed in view of our commitment to actively disclosing information to investors and shareholders as these issues may carry weight in making investment decisions or in understanding our business activities. The Company is fully aware of the potential risks, and will make utmost efforts to prevent such risks from materializing, but should they occur, we intend to take appropriate action. However, we realize that investment decisions regarding our stock should be made carefully by evaluating the following matters, as well as other matters mentioned in other sections of this document. We would add that the following descriptions do not purport to cover all possible risks associated with investment in our stock. The future perspectives mentioned below reflect our understanding of our business circumstances as of the date of publication of this document.

(i) Risks associated with pharmaceutical development in general

The Company's main business is to in-license new drug candidate compounds created by pharmaceutical companies and bioventures, and to develop these into pharmaceutical products. The R&D field of pharmaceuticals is replete with strong competition, including pharmaceutical giants. What is more, specialty pharmaceutical companies, including the Company, emulate each other in quality and speed within the sector. The process from development to manufacture and marketing involves many regulatory hurdles, necessitating a vast amount of capital input over a long period of time in business operations. Their future prospects involve uncertainty and these risk factors are associated with the Company's present and future business activities.

a) Uncertainty involved in pharmaceutical development

Generally speaking, the pharmaceutical development process leading up to the launch of a drug requires a vast amount of expenditure over a long period. The probability of success is by no means high. In every stage of development, it is not uncommon for a decision to be made to halt or delay progress. In pharmaceutical development, the different stages of development have to be conducted in phases, and at each phase a decision is made regarding whether or not development should continue. Therefore, it is not rare for a decision to be made to stop development in mid-process. The probability is low for development to progress successfully and for a product to be launched. Even after a product is successfully developed and launched onto the market, there remains the risk that product approval is revoked due to the potential to damage a patient's health (for details, refer to "(f) risk associated with side effects"). To reduce these risks, the Company aims to possess several drug candidates in its pipeline and endeavors to prioritize insofar as possible the in-licensing of drug candidates with confirmed POC (Note 1) in human subjects. For small specialty pharmaceutical business such as the Company, the impact is huge if a single drug candidate is removed from its pipeline. This could have a significant effect on the Company's financial position, business performance, and cash flow.

(Note 1) POC (Proof of Concept) means confirming the efficacy and safety of a new drug candidate in clinical trials, and verifying the appropriateness of its concept.

b) Uncertainty of income

In order to raise income from the drugs we are developing, we need to succeed at all the stages of new drug candidate development, namely obtaining approval from regulatory authorities, manufacture and marketing either on our own or in partnership with a third party. However, we may not necessarily succeed in these activities, or even if we do succeed, we may not be able to ensure the margin of profitability needed to continue our business. Of the products currently in the development pipeline, SyB L-0501 achieved approval for manufacturing and marketing in Japan on October 27, 2010, for the indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and was launched as the anticancer agent TREAKISYM® in December 2010. For additional indications, in December 2015, we filed supplemental New Drug Applications (sNDAs) in Japan for the target indication of first-line low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia. Furthermore, we have completed the Phase II clinical trial for refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma. With respect to rigosertib, we are currently conducting a global Phase III trial in Japan with the intravenous formulation for the target indication of refractory/relapsed higher-risk MDS and a Phase I clinical trial with the oral formulation in combination with azacitidine for the target indication of higher-risk MDS. For the patient-controlled iontophoretic transdermal system for the management of acute postoperative pain SyB P-1501 for which a license agreement was concluded October 2015, preparations are underway for starting a Phase III clinical trial for the indication of short-term management of acute postoperative pain in the hospital. We are promoting the development of these compounds, aiming to successfully launch the products onto the market to obtain income. In some cases, we may consider entering into an alliance with other pharmaceutical companies in development and marketing so as to expedite the inflow of income. Notwithstanding our efforts, these drug candidates in our pipeline will require a considerable amount of time under development before they reach the marketplace. There is no guarantee that they will make it onto the market as viable products, or that an alliance agreement can be signed with other pharmaceutical companies. We are of the opinion that the selection of indications and the methods of alliance and marketing identified thus far promise sufficient future profitability after considering the market size and marketing performance of approved drugs. However, should we prove to be wrong in our assessment, or should there be any change in the conditions on which the assessment is based and we fail to promptly adjust to such changes, there could be a significant impact on our financial position, business performance, and cash flow.

c) Uncertainty in legislation and regulations requiring compliance, and the health insurance system

The pharmaceutical industry, the Company's core business, is subject to various regulatory restrictions imposed by laws and administrative guidance related to the pharmaceutical drugs as well as other relevant legislations regarding all aspects of business operations (i.e., research, development, manufacturing, marketing). We formulate our business plans in accordance with the PMD Act and other current legislative regulations as well as the health insurance system, together with drug pricing guidelines that emerge from this legislation. Notwithstanding, there is a possibility that these regulations, regulatory systems and pricing will change before the products that we are developing reach the marketplace. If any major change does occur, there may be a significant impact on our financial position, business performance, and cash flow.

d) Risk concerning development and marketing overseas

We conduct our pharmaceutical business in Asian and other countries globally, not exclusively in Japan, where we anticipate the growth of healthcare needs and our position in certain therapeutic areas. In overseas markets, as in Japan, pharmaceutical development and marketing generally require a vast amount of expenditure and are associated with business risk. To reduce investment expenditure and business risk, we out-license the development and marketing of some of our drug candidates to other overseas companies. Before out-licensing the rights we possess, we select a licensee after careful due diligence and careful monitoring when necessary. The development and sales of out-licensed products are subject to business conditions of the licensee or any changes in the regulatory and competitive environment in respective countries, and may fall below initial expectations, resulting in lower milestone revenue and royalty income. In such cases, there may be an impact on our financial position, business performance, and cash flow.

e) Competition in the pharmaceutical industry

The pharmaceutical industry is an intensely competitive sector. A large number of both Japanese and foreign pharmaceutical companies and research institutions, including giant multinational pharmaceuticals, compete in the arena. Technological innovation is progressing rapidly. Many competitors have a comparative advantage over the Company in terms of technology, marketing and financial position. Thus, these companies may more efficiently produce and sell competitor products which are more effective than the Company's developed products. This means that what transpires in the competitive landscape with regards to development, manufacturing and marketing operations may have a significant impact on our financial position, business performance, and cash flow.

f) Risk associated with side effects

Unexpected side effects may occur from the use of pharmaceutical products, from their clinical trial stage to post-marketing stage. When serious and unexpected side effects occur, compensation claims may arise, or depending on the situation, there is the risk of a delay in clinical trial timelines or even discontinuation of product development. In the case where such side effects could lead to further damage to the health of patients, there is the risk of cancellation of approval or discontinuation of sales. Regarding compensation claims, the Company has in place the liability insurance necessary to minimize the financial damage should such claims arise. However, this does not exclude the possibility that the compensation awarded exceeds the amount insured. If this should occur, it could have a significant impact on the Company's financial position, business performance, and cash flow.

g) Product liability

The development and manufacture of pharmaceutical products involves product liability risk. If in the future any products that we have developed cause damage to health or any adverse events are discovered during clinical trials, manufacturing, sales or marketing of the drug, the Company will be subject to product liability. This may have a significant impact on the Company's financial position, business performance, and cash flow. Indeed, if a product liability suit is filed against the Company, the Company's corporate image could be damaged, leading to a loss of confidence in the Company and the drugs it develops, impacting future business.

(ii) Risk in business operations

a) Risk concerning the Company's business model

The Company does not own research and manufacturing facilities instead, mainly targeting orphan drugs (Note 2) in the areas of oncology, hematology and pain management, in-licensing drug candidates having POC established in human subjects from pharmaceutical companies and bioventures, developing and marketing pharmaceutical products in Japan, Asian and other countries globally (China, South Korea, Taiwan, Singapore, etc.). The Company has adopted a business model to raise income and profit from such activities. In developing the pipeline and marketing, the Company plans to

engage in alliances with other pharmaceutical companies. However, there is no guarantee that the Company can continuously in-license drug candidate compounds that satisfy in-house criteria and secure these partner companies. In addition, as the Company mainly targets orphan drugs for in-licensing (Note 3), it may not be able to generate expected sales turnover. Furthermore, in the event that development at a licensor is delayed or fails, there may be impact on the development in Japan. These factors could impact the Company's financial position, business performance, and cash flow. Needless to say, intense competition within the pharmaceutical sector and changes in the Company's financial position may force the Company to revise its business model. Should this occur, there may be a significant impact on the Company's business.

(Note 2) The rare-disease field is one in which the number of patients requiring drugs are small. Drugs for this field are termed "orphan drugs." The Japanese Ministry of Health, Labour and Welfare has established an orphan drug designation system for drugs meeting the criteria of (1) a drug to treat a disease that affects less than 50,000 people in Japan, and (2) there is a great need for medical treatment. Once designation is obtained, the drug will enjoy various advantages including shortening of the time from regulatory submission for review of the drug to approval and the extension of the re-examination period of up to 10 years.

(Note 3) "In-licensed drug candidates" are compounds or products for which the rights of development and commercialization are obtained from other companies.

b) Dependency on a specific customer

As a specialty pharmaceutical company without production facilities, the Company needs to depend on the supply of product from other companies when conducting clinical trials and marketing approved drugs. Given this fact, the financial position and production conditions of the product supplier may have a significant impact on the Company's financial position, business performance, and cash flow. In pipeline development and marketing, while the Company has plans to conduct sales on its own in the future, its current business plan focuses on forming alliances with pharmaceutical companies. However, if the partner company's management situation deteriorates unexpectedly or if management policies change, which are matters beyond the Company's control, initial business plans may not be realized. Also, if any breach of contract occurs that necessitates the termination of the license agreement as stipulated, the alliance may also end. In such cases, there may be a significant impact on the Company's financial position, business performance, and cash flow. Typically, in license agreements with partner companies, revenues to be gained before the drug reaches the marketplace will include an upfront payment upon signing the contract, funding for co-development and milestone payments. Of these, milestone payments are extremely unstable and unpredictable income as they are based on the attainment of predefined results. If development progress is delayed, there may be a significant impact on the Company's financial position, business performance, and cash flow.

c) Risk concerning intellectual property rights

During drug development activities, the Company makes use of various intellectual property rights. The use of these rights basically has been granted from other companies such as pharmaceuticals and bioventures. However, the possibility remains that the Company's in-licensed drug candidate does not succeed in the pending patent application made by the licensor. Moreover, it is difficult to completely avoid the possible creation of an intellectual property right by a third party that supersedes the intellectual property right of the Company's in-licensed drug candidate. These situations could lead to a significant impact on the Company's financial position, business performance, and cash flow. To date, no lawsuit has been filed by a third party against the Company concerning intellectual property rights, including patents in connection with product development. When in-licensing a product, the Company seeks advice from lawyers and conducts a thorough due diligence investigation through patent firms in order to reduce such intellectual property risks. Nevertheless, it is difficult to realize full protection from the occurrence of intellectual property right disputes involving the infringement of third party rights, and these may have a significant impact on the Company's financial position, business performance, and cash flow. The candidate compounds that the Company in-licenses are not necessarily protected by patent. On the other hand, even if a drug candidate is not protected by patent, the assignment of the compound for review by the regulatory authorities would virtually restrict the entry of generic drugs during the review period, realizing the monopolistic protection for a certain period of time.

d) Data protection

To reduce the risk of significant confidential information relating to pipeline development and other business activities from leaking outside the company, the Company engages in rigorous data protection. The Company requires directors,

Scientific Advisory Board (SAB) members, outsourcing partners, and other business partners to sign confidentiality agreements. Even with the agreement in place, directors, SAB members, outsourcing partners and other business partners may not adhere to confidentiality, and should this occur, significant confidential information may be divulged elsewhere, which may impact the Company's business, financial position, business performance, and cash flow.

e) Risk concerning important contracts

If any contracts that may have a significant impact on conducting the Company's business operations are terminated due to expiration, breach of contract or for any other reason, there may be a significant impact on the Company's financial condition, business performance, and cash flow.

(iii) Risk associated with organization

a) Risk of being a young company

SymBio is a young company founded in March 2005. Since inception, the Company has engaged in in-licensing activities of drug candidates for development. The founding President and CEO built up the pharmaceutical development business from scratch, and the Company recorded income from product sales in August 2010, for the first time in its history. There is the possibility that business issues that SymBio has never encountered arise in the future. At the moment, however, it is difficult to predict any changes in the external environmental factors that may affect the Company's business results. Therefore, the Company considers business results for the past several years to be an inadequate reference to pass judgment on whether or not the Company can continue to grow.

b) Risk of being a small corporation

The Company uses contract research organizations (CROs (Note 4)) in conducting R&D, thereby forming a development framework requiring relatively small staff numbers. With progress in the development of the pipeline already in place and with newly in-licensed drug candidates coming on line, the Company's human resources in R&D is likely to be further increased. However, for whatever reason should an alliance with a CRO terminate, or should the Company fail to secure the planned number of staff or should existing staff decide to leave, the Company's business operations may be hampered, leading to a possible impact on the Company's financial position, business performance, and cash flow.

(Note 4) A contract research organization (CRO) is an organization to which a pharmaceutical company commissions certain activities so as to avoid delays in the progress of its drug development activities. The details of the commissioned activities may include monitoring to ensure that clinical studies are carried out in full accordance with study protocols and clinical data management.

c) Dependency on a specific person

Fuminori Yoshida, the Representative Director, founding President and CEO, has played a key role since the Company's foundation in the implementation and execution of all operations in the company business management. Thus, in the event that he cannot continue to perform his corporate responsibilities for some unforeseen reason, this could have a significant impact on the Company's business operations.

d) Scientific Advisory Board (SAB)

The Scientific Advisory Board ("SAB") is an advisory panel to the Company on the potential in-licensing of new drug candidates. The Company invites members of the panel from clinicians and scientists engaged in basic research who are highly regarded in the healthcare industry due to their successful track records and wealth of experience. The SAB meets two or three times a year to engage in active discussion and debate, with each member giving his/her own perspective on an in-licensed drug candidate. The Company will continue in its efforts to acquire members of excellence for the SAB. However, if difficulty should arise in procuring members for reasons such as the cancellation of contracts with existing members, retirement or refusal to renew, or should a brain drain occur, there may be an impact on the Company's ability to evaluate and in-license quality drug candidates.

(iv) Business Results

a) Business performance in previous years

The Company's key business indicators are given below:

Term	7th Term	8th Term	9th Term	10th Term	11th Term
Fiscal Year Ended	December 2011	December 2012	December 2013	December 2014	December 2015
Net sales (thousand yen)	1,882,521	1,955,178	1,532,054	1,955,027	1,933,241
Operating income (loss) (thousand yen)	(2,066,846)	(1,700,273)	(1,680,528)	(1,303,279)	(2,551,662)
Ordinary income (loss) (thousand yen)	(2,095,382)	(1,729,480)	(1,601,424)	(1,110,316)	(2,630,386)

To date, with the exception of the 4th Term, the Company’s total R&D expenses and other general administrative expenses exceeded the Company’s income, resulting in the posting of operating loss, ordinary loss and net loss. For this reason, the Company does not consider the financial statements and indicators of previous years to provide adequate reference data in making timely comparisons of business performance or in forecasting future business performance.

b) Expected Increase in R&D Expenditures

The Company’s R&D expenses for the past five fiscal years are provided below:

Term	7th Term	8th Term	9th Term	10th Term	11th Term
Fiscal Year Ended	December 2011	December 2012	December 2013	December 2014	December 2015
R&D expenses (thousands of yen)	1,945,029	1,438,125	1,052,790	774,103	2,034,714

The Company intends to continue with R&D activities, resulting in an increase of cumulative loss for the foreseeable future. With future increases in product sales revenue from additional indications of TREAKISYM®, the product sales channels upon early approval for the intravenous and oral formulations of rigosertib and SyB P-1501, and the income from alliances with pharmaceutical companies, the Company intends to improve business performance as soon as possible; however, there is no guarantee that such assumptions will materialize and swift performance improvement realized.

c) Retained earnings (accumulated deficits) brought forward

SymBio is a specialty pharmaceutical company. Until products under development at the clinical stage reach the market so that the Company can continuously earn stable income through product sales and royalty income, the Company will post a huge up-front outlay of R&D expenditures. Due to this, with the exception of the 4th term (2008), the Company has posted net current losses since its foundation. At the end of the 11th Term, the fiscal year ended December 31, 2015, the Company recorded a negative balance of 12,499,609 thousand yen as retained earnings brought forward (accumulated deficits brought forward). SymBio intends to become a profitable business entity as early as possible by advancing its quality clinical programs in a rapid, precise and efficient manner as planned. However, the possibility still exists that profits may not be generated at the time initially planned. Should the Company’s business fail to develop as planned and net profits are not generated, the Company faces the possibility of a considerable delay in negative retained earnings (accumulated deficits) brought forward turning positive.

d) Fundraising

The nature of the Company’s specialty pharmaceutical business means that the Company will require huge R&D funding. If SymBio’s business plan does not take shape as planned and it suffers a shortfall in funding, the Company will endeavor to procure funds by changing strategic alliances, securing new alliance contracts or issuing new stock. However, if the Company fails to generate funds exactly when they are required, there may be serious doubt cast over the continuation of its business operations.

e) Net operating loss for tax purposes

The Company currently has net operating loss carryforwards for tax purposes. For this reason, the Company is not subject to corporate tax, local inhabitant tax and local enterprise tax at the standard rates and expects this to continue for several terms into the future.

However, if net operating loss expires earlier than expected and can no longer be used as an offset to taxable income due to such reasons as the revision of current tax treatment of net operating loss, the Company would become liable for the payments of corporate tax, local inhabitant tax and local enterprise tax at standard rates, which may have an impact on net profit/loss and cash flow currently planned.

(v) Other Risks

a) Profit distribution to stockholders

Since the foundation of the Company, dividends have not been distributed. SymBio is currently at the business stage of making upfront investment for the development of pharmaceutical drugs and continues to prioritize the use of funds for strengthening its financial position and for continued R&D activities. Thus, the Company has at present no plans for making dividend payouts. However, the Company recognizes that the return of profit to stockholders is an important management issue and will consider profit distribution based on future business performance and financial condition.

b) Procurement of funds

As the Company rapidly expands its business, it expects to see an increase in development funding requirements. One option for procuring funds is to issue new stock. By doing so, the number of outstanding stock will increase, potentially diluting the value per share of the Company's stock.

c) Stock value dilution by execution of stock acquisition rights

The Company adopted the stock option plan in order to motivate and encourage higher business performance of board directors, employees, and collaborators, and to attract human resources of excellence. In accordance with the Commercial Code of 1890 Article 280-19, 280-20 and 280-21, and the Companies Act Article 236, 238, 239 and 240, stock acquisition rights are granted to board directors and employees.

The Company made a resolution at the Board of Directors meeting held on December 27, 2012 to issue the first unsecured convertible bond with stock acquisition rights (total issue price: 1 billion yen) and the 29th warrant (total issue price: 5.1 million yen by way of third-party allotment, total issue price of stocks when issued through the exercise of stock acquisition rights: 500 million yen). Moreover, the Company made a resolution at the Board of Directors meeting held on November 14, 2014 to issue the second unsecured convertible bond with stock acquisition rights (total issue price: 500 million yen) and the 34th warrant (total issue price 10,363 thousand yen by way of third-party allotment, total issue price of stocks when issued through the exercise of stock acquisition rights: 1 billion yen). As of December 31, 2015, the following warrants remained unexercised: 30 units of the 29th warrant (the number of shares issued upon the exercise of warrants: 795,750) and 30,304 units of the 34th warrant (the number of shares issued upon the exercise of warrants: 3,030,400). As of December 31, 2015, the number of potential dilutive shares from the above-mentioned stock acquisition rights ("number of potential shares") totaled 6,901,550 shares and comprised approximately 17.6 % of the total number of outstanding shares and potential shares added together. There is the possibility that stock value per share for the Company will be diluted if these potential shares are exercised in the future. To attract talent, the Company may continue to offer similar incentives. This means that if these stock acquisition rights are exercised in the future, the stock value per share of the Company may be diluted.

d) Stock holding by venture capital

In general, venture capital and investment partnerships own shares for the purpose of realizing capital gains by selling shares after IPO. There is the possibility that venture capitals and investment partnerships that own SymBio shares may sell all or a portion of such shares, and should this occur, it could have an impact on the market price of the Company's shares.

e) Risk of loss on foreign exchange

While continuously performing research on drug candidates for new development to expand its pipeline, the Company arranges large amounts of fund procurements by means of deposits denominated in foreign currency or foreign exchange contracts based on the assumption that deposit payments in U.S. dollars will be required upon in-licensing. Where such assets denominated in foreign currency are stated at market value in financial statements at every year end, there is a risk of loss from fluctuating currency valuation in the future and this may have an impact on the Company's financial position, business performance, and cash flow.

f) Risk associated with natural disasters

Any disasters (earthquake, typhoon, fire, etc.) and plague that occur in the Company's geographic business domain, leading to the occurrence of human and material damage, or suspension and delay in business, fall in social credibility and compensation issues, may have an impact on the Company's financial position, business performance, and cash flow.

2. Status of corporate group

None to be reported.

3. Management policies

(1) Basic policy of company management

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Inc. (Note 5) (United States) and President of Amgen K.K., a wholly owned subsidiary of Amgen Inc., (now part of Takeda Pharmaceutical Company Limited) for 12 years since its establishment.

The Company aims to achieve social and management responsibilities by responding to unmet medical needs (Note 6) based on the guiding principle of mutual harmony, creating an intricate symbiotic relationship between patients, physicians, scientists, regulators and investors.

The Company regards underserved therapeutic areas with extremely significant medical needs as a business opportunity and remains focused on the areas of oncology, hematology, and pain management where high entry barriers exist due to the high degree of specialization required. In this sense, SymBio is the first specialty pharmaceutical company (Note 7) in Japan. Rather than exploring opportunities to in-license and develop new blockbuster drugs (with sales exceeding 100 billion yen), the Company channels its resources into the development of drugs in underserved markets where medical needs are high despite limited patient numbers. Securing multiple drug approvals in these key therapeutic areas will enable the Company to build a solid and diverse pipeline to ensure business sustainability.

(Note 5) Applied Molecular Genetics, or Amgen Inc., the world's largest company in the biopharmaceutical field, was founded in Thousand Oaks, California, in 1980, and started business in Japan as Amgen K.K. on May 1, 1993. After Takeda Pharmaceutical Company Limited ("Takeda") acquired 100% of Amgen K.K.'s stock in February 2008, its operations were merged into Takeda.

(Note 6) "Unmet medical needs" means requirements for medical treatment that have not yet been fulfilled. It refers to a situation in which no effective drugs or treatments are currently available, despite strong demand by patients and/or physicians.

(Note 7) "Specialty pharmaceutical company" refers to a company that develops new drugs and has been given a consistently high international evaluation for a particular field of excellence. This is based on the definition in the Ministry of Health, Labor and Welfare's "Vision for the pharmaceutical industry" (2002).

(2) Key performance index

In order to enhance SymBio's enterprise value as a specialty pharmaceutical company, it is important to continually in-license drug candidates for development, to successfully complete clinical development and secure marketing approvals in order to sell drugs in the marketplace with the establishment of a sales and support system. To this end, the Company intends to continue aggressively investing resources into R&D activities.

For the current fiscal year end, the Company has recorded net sales from SyB L-0501 for the first time since the drug was initially approved for sale in Japan and Singapore in 2010. However, product sales have not generated sufficient revenue to cover the aforementioned upfront investment at this time, and generating net profit has still to be realized. While the Company continuously seeks stable profitability through active promotion of expanded sales and additional indications for TREAKISYM® in collaboration with Eisai, acquisition of early approvals for the intravenous and oral formulations of rigosertib and SyB P-1501, as well as introduction, promotion of development and acquisition of approval for new pipeline products, no performance index targets such as ROE or ROA will be set until profits are recorded in a single year through the achievement of these measures.

(3) Pipeline

The Company currently has the following pipeline products under development: SyB L-0501, SyB L-1101, SyB C-1101 and SyB P-1501. The Company will continue to in-license candidate drugs to expand and build its pipeline portfolio with a balanced risk-return trade-off.

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

Bendamustine hydrochloride (the generic name), the active pharmaceutical ingredient of TREAKISYM®, is an anticancer agent that has been in use for a number of years in Germany under the trade name of Ribomustin for the treatment of non-Hodgkin's lymphoma (Note 8), multiple myeloma, and chronic lymphocytic leukemia. The Company decided to in-license this product because there is currently no effective medication for the indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. These are underserved therapeutic areas aligned with the Company's corporate mission and also fall within one of SymBio's targeted therapeutic fields (hematologic cancer). Astellas Pharma GmbH is the worldwide licensor of bendamustine hydrochloride. Cephalon, Inc. (United States) licensed rights to bendamustine for North America from Astellas Pharma GmbH and obtained approvals from the U.S. Food and Drug Administration (FDA) to use the drug for the treatment of chronic lymphocytic leukemia and refractory B-cell non-Hodgkin's lymphoma in March 2008 and October 2008, respectively. Mundipharma International Corporation Limited (United Kingdom) and Janssen-Cilag (United Kingdom) are also licensed from Astellas Pharma GmbH and have obtained exclusive rights for the development and commercialization of bendamustine in Europe and other regions, respectively. The Company is licensed from Astellas Pharma GmbH with exclusive rights for the development and commercialization of bendamustine in Japan, China, South Korea, Singapore and Taiwan. In Japan, the drug has received approval for the indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (October 27, 2010), and was launched under the trade name TREAKISYM® on December 10, 2010.

For additional indications, in December 2015, the Company filed supplemental New Drug Applications (sNDAs) for the target indications of first-line low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia, respectively. The Phase II clinical trial for refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma has been completed. The Company intends to maximize the commercial value of bendamustine by further promoting life cycle management. Eisai has signed an agreement with SymBio for the right of joint development and exclusive marketing right in Japan, and it is currently marketing TREAKISYM®.

In Asia, SyB L-0501 received the approval for the indication of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia in Hong Kong in December 2009. In Hong Kong, Cephalon, Inc. has the exclusive right to develop and sell bendamustine, and is currently generating sales. In addition, approval for the indications of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia was obtained in Singapore in January 2010. In South Korea, approval for the indications of chronic lymphocytic leukemia and multiple myeloma was obtained in May 2011, and approval for the indication of refractory/relapsed low-grade non-Hodgkin's lymphoma was achieved in June 2014.

In South Korea and Singapore, Eisai has agreements in place with SymBio for exclusive development and marketing rights. Eisai's subsidiaries launched the product in Singapore and South Korea in September 2010 and October 2011, respectively.

Cephalon is making progress with clinical development in China, and in Taiwan SymBio's business partner, InnoPharmax, Inc. (Taiwan), achieved approval for the indications of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia in October 2011, followed by product launch in February 2012.

(Note 8) Non-Hodgkin's lymphoma (NHL) is a cancer of the lymphatic system in which lymphocytes develop malignant growths other than Hodgkin's lymphoma. The majority of Japanese patients are suffering from NHL. Antibody therapy with rituximab (Note 9) administered as the first-line drug is the standard treatment for NHL. However, there is currently no established therapy for failed or relapsed cases.

(Note 9) Rituximab is an anti-CD20 monoclonal antibody used to treat the indication of CD20-positive B-cell non-Hodgkin's lymphoma. The formulation marketed in Japan is 10 mg/mL Rituxan® injection, with manufacturing and marketing by Zenyaku Kogyo Co., Ltd., and sales by Chugai Pharmaceutical Co., Ltd.

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

Rigosertib is an anticancer agent with a unique type of multi-kinase inhibitory activity (Note 10). It is currently being developed in the U.S. and Europe by a U.S. company, Onconova Therapeutics, Inc. ("Onconova"), for the target indications of myelodysplastic syndrome ("MDS"). MDS is the pre-pathological state for malignant tumors of blood cells, which has shown increasing numbers of patients in recent years; it frequently affects elderly people; and it is a refractory disease, with a high

probability of developing into leukemia. No effective medication is available yet, especially for refractory/relapsed MDS, and it therefore constitutes an underserved therapeutic area. In July 2011, the Company signed a license agreement with Onconova, providing the exclusive right to develop and commercialize rigosertib in Japan and South Korea. Based on this agreement, the Company continues to develop the intravenous (IV) rigosertib formulation for the target indication of refractory/relapsed higher-risk MDS and the oral formulation for each target indication of higher-risk MDS (in combination with azacitidine) and transfusion-dependent lower-risk MDS.

In February 2014, Onconova released the results from the Phase III randomized ONTIME trial of IV rigosertib in patients with refractory/relapsed higher-risk MDS. Treatment with IV rigosertib plus Best Supportive Care (BSC) did not demonstrate a statistically significant improvement in median overall survival when compared to BSC only. However, a post-hoc analysis demonstrated a statistically significant increase in median overall survival in the subset of patients who had progressed on or failed previous treatment with hypomethylating agents (HMAs), thus demonstrating potential activity or rigosertib in these MDS patients.

Based on this, Onconova is conducting a global Phase III trial with clinical trial sites in more than ten countries worldwide, for HR-MDS patients who do not respond to treatment with HMAs (“primary HMA failure”) or who relapse after treatment under the current standard of care.

The Company is participating in the global Phase III trial and conducting the clinical trial in Japan.

As for the oral formulation of rigosertib, Onconova has been conducting a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS and Phase I/II clinical trial for the indication of frontline higher-risk MDS (in combination with azacitidine).

The Company has completed its domestic Phase I clinical trial of the oral formulation of rigosertib as a monotherapy for the target indication of higher-risk MDS, and a Phase I clinical trial in combination with azacitidine is being conducted for the target indication of higher-risk MDS. 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.

While Onconova is making steady progress with development, we will look into the option of developing for indications other than MDS. By allocating development of the intravenous and oral formulations to different indications, it is hoped that progress will be made with development of treatment methods that are easy for patients to use, and that place sufficient importance on the need for compliance.

(Note 10) Multi-kinase inhibitors impede the growth, proliferation and metastasis of cancer cells, thereby eradicating them.

(iii) [Patient-controlled iontophoretic transdermal system for the short-term management of acute postoperative pain: SyB P-1501]

SyB P-1501 is a patient-controlled iontophoretic transdermal system for management of post-operative pain in patients. A patient recovering from surgery in the hospital simply presses the button on the credit-card-sized device attached to the upper arm or chest, and a certain amount of ionized drug is delivered transdermally to achieve an analgesic effect without using a needle (patient controlled analgesia, “PCA”). The Company acquired the exclusive development and distribution rights for SyB P-1501 in Japan from the U.S.-based The Medicines Company (note that the contract counterparty is its wholly-owned subsidiary of Incline Therapeutics, Inc.) on October 2, 2015. Current PCA methods consist of the administration of an analgesic agent through an intravenous needle or the use of tube to connect a catheter in the spinal canal and a PCA pump (intravenous PCA and epidural PCA). The number of patients in Japan requiring post-operative pain management by PCA is estimated to be approximately one million a year. SyB P-1501 is attached to the skin, and delivers an ionized drug transdermally to achieve an analgesic effect after the patient presses the button on the controller when they feel pain (iontophoresis principle). The administration of an analgesic agent in this method achieves an analgesic effect in a manner as rapid as a needle while being needle-free and painless, and for this reason it is expected to substantially reduce the physical and mental burden on patients and improve the level of treatment satisfaction. In addition, because it is superior to traditional PCA methods in terms of simplicity and safety, it can also be expected to lead to reductions in labor and other costs at medical institutions. SyB P-1501 was approved by the U.S. Food and Drug Administration (FDA) on April 30, 2015, and sales have commenced in the U.S. It was also approved by the European Medicines Agency (EMA) on November 20, 2015. In Japan, a Phase I clinical trial of SyB P-1501 targeting healthy volunteers has been completed with a favorable level of safety confirmed, and the Company has plans to promptly initiate a Phase III clinical trial. Establishment of innovative PCA methods using SyB P-1501 is expected to lead to significant improvements in convenience for patients and medical professionals and QOL (quality of life) of patients undergoing treatment for post-operative pain.

The Company is pursuing preparations aimed at starting a Phase III clinical trial in the third quarter of FY 2016.

(4) Medium to long-term strategy

The Company is pursuing primarily the following five strategies in order to achieve our Long Range Plan (LRP).

(i) De-risking by post-POC strategy

We in-license drug candidates for which POC (proof of concept) is already confirmed in human subjects in principle. Accordingly, they should be drugs that are in a relatively late stage of clinical development or already on the market overseas. The advanced development is already conducted overseas for these drug candidates and their efficacy and safety are already confirmed in human subjects, thereby reducing the development risk. We utilize existing clinical data available overseas so as to compress development timelines, reduce the development costs, and increase the likelihood of regulatory approvals in Japan and Asian markets.

(ii) Building a high-quality pipeline with exceptional search and evaluation capabilities

Our new drug search engine is connected to the diverse network of pharmaceutical companies and bioventures, and enables us to select promising drug candidates from the vast amount of chemical compounds after the careful review by internal experts. Using their wealth of experience at the forefront of research and development, Scientific Advisory Board (SAB) members carefully evaluate and render final judgment on each drug candidate. The highly established screening process up to the final selection of drug candidate, coupled with the post-POC strategy, reduces the development risk and compresses timelines. It also helps to understand how satisfactorily the healthcare needs are met and to improve the accuracy of revenue projections after the product launch.

(iii) Containment of fixed costs by labless/fabless strategy

The Company does not own any research or production facilities, which are often regarded as the main cause of fixed costs. Once drug candidates are searched and selected, we focus on value-added activities such as the formulation and implementation of development strategy and outsource other necessary routines. This enables us to reduce development costs of pharmaceutical drugs and secure the mobility of financial strategy.

(iv) Realization of high business efficiency by “Blue Ocean strategy” (Note 11)

There are many cases that the standard drug used overseas cannot be prescribed in Japan or a new drug is launched in Japan five years behind its initial approval overseas. This problem is called “drug lag” and becoming aggravated, and the term “cancer patient refugee” has been created. This drug lag is particularly conspicuous in our strategic drug development areas of refractory cancer and hematological diseases, as well as moderate to severe pain management. The market of anticancer agents, in particular, is huge and still continues to grow with the population being aged. However, anticancer agents have a wide range of indications and they are fragmented by type of cancer. There is only a limited number of patients in some therapeutic areas depending on type of cancer. The therapeutic area of pain management is an unsatisfied area with many current cases of undertreatment. Many patients who suffer pain are the elderly, and the pain management market is expected to grow. An extremely high degree of specialization is required for the development of new agents in these therapeutic areas, which are often financially unattractive for larger pharmaceutical companies to pursue despite the high degree of development difficulty. This partially accounts for the causes for the drug lag. Contrarily, once a new drug succeeds in receiving an approval and reaching the market for these therapeutic areas, we would be able to achieve a superior growth and profitability due to the lack of fierce competition by continuously expanding the indications and bringing new products into the market.

(Note 11) “Blue Ocean strategy” means a strategy of redefining the market, avoiding marketplaces where there is fierce competition to snatch pieces of a finite market-share “pie,” termed “red oceans,” and instead creating a “blue ocean,” which is a competition-free, entirely unexploited market, enabling profits to be maximized while providing customers with high-value products and services.

(v) Going global beyond Asia

The Company has been operating its businesses in Asia centered on Japan. However, there would be no significant growth expected if we stay in Asia, amid a rapidly changing environment surrounding healthcare in Japan. The Company will carry out search and evaluation activities for new drug candidates for development in light of global development.

(5) Issues to be addressed by the Company

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 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 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®, 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 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 thorough budget control.

(6) Other important matters concerning the Company's management

Major agreement

On October 2, 2015, the Company entered into an agreement with Incline Therapeutics, Inc. (the "Incline"), a wholly-owned subsidiary of U.S.-based The Medicines Company ("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.

Based on the agreement, the Company will make the following payments to the Incline: (i) an upfront payment, (ii) milestone payments in accordance with development progress and (iii) after launch, the Company will also pay royalties, as well as commercial milestone payments on achievement of annual sales.

4. Basic views on selection of accounting standards

Over the near term, the Company will prepare its financial statements based on Japanese GAAP, taking into account the inter-period comparability of financial statements and comparability across organizations.

In terms of the application of International Financial Reporting Standards (IFRS), the Company will take appropriate measures in consideration of circumstances in Japan and overseas.

5. Financial statements

(1) Balance sheets

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	FY 2015 (as of December 31, 2015)
Assets		
Current assets		
Cash and deposits	5,692,075	4,261,438
Accounts receivable-trade	272,656	300,742
Marketable securities	899,256	―
Merchandise and finished goods	244,588	133,029
Supplies	379	167
Prepaid expenses	36,690	38,591
Advances paid	59,840	79,639
Consumption taxes receivable	19,974	―
Forward exchange contracts	33,235	―
Other	31,392	13,170
Total current assets	7,290,088	4,826,778
Noncurrent assets		
Property, plant and equipment		
Buildings	21,874	24,521
Accumulated depreciation	(320)	(2,313)
Buildings, net	21,554	22,208
Tools, furniture and fixtures	47,032	52,293
Accumulated depreciation	(19,590)	(21,545)
Tools, furniture and fixtures, net	27,441	30,747
Total property, plant and equipment	48,996	52,956
Intangible assets		
Software	62,273	50,506
Software in progress	2,556	900
Lease assets	1,243	594
Total intangible assets	66,073	52,001
Investments and other assets		
Long-term prepaid expenses	1,351	1,227
Lease and guarantee deposits	47,289	51,326
Total investments and other assets	48,641	52,553
Total noncurrent assets	163,710	157,510
Total assets	7,453,799	4,984,289

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	FY 2015 (as of December 31, 2015)
Liabilities		
Current liabilities		
Accounts payable-trade	305,996	319,866
Lease obligations	692	642
Accounts payable-other	142,884	183,690
Income taxes payable	21,254	14,183
Forward exchange contracts	—	14,999
Other	17,119	17,558
Total current liabilities	487,946	550,940
Noncurrent liabilities		
Lease obligations	642	—
Provision for retirement benefits	1,634	1,537
Total noncurrent liabilities	2,276	1,537
Total liabilities	490,223	552,477
Net assets		
Shareholders' equity		
Common stock	8,330,775	8,330,775
Capital surplus		
Legal capital surplus	8,300,775	8,300,775
Total capital surplus	8,300,775	8,300,775
Retained earnings (accumulated deficits)		
Other retained earnings		
Retained earnings (accumulated deficits) brought forward	(9,867,514)	(12,499,609)
Total retained earnings (accumulated deficits)	(9,867,514)	(12,499,609)
Treasury stock	(17)	(17)
Total shareholders' equity	6,764,019	4,131,924
Valuation and translation adjustments		
Unrealized holding gain (loss) on securities	(744)	—
Total valuation and translation adjustments	(744)	—
Stock acquisition rights	200,300	299,887
Total net assets	6,963,576	4,431,811
Total liabilities and net assets	7,453,799	4,984,289

(2) Statements of operations

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Net sales		
Net sales of goods	1,940,027	1,933,241
Rights income	15,000	—
Total net sales	1,955,027	1,933,241
Cost of goods sold		
Beginning goods	125,056	244,588
Cost of purchased goods	1,550,246	1,241,552
Purchase allowance and returns	2,325	2,867
Total	1,672,976	1,483,274
Ending goods	244,588	133,029
Cost of goods sold	1,428,388	1,350,244
Gross profit	526,639	582,996
Selling, general and administrative expenses	1,829,918	3,134,659
Operating loss	(1,303,279)	(2,551,662)
Non-operating income		
Interest income	16,372	12,949
Interest on securities	8,475	3,316
Foreign exchange gains	188,922	—
Dividends income of insurance	1,116	1,072
Other	364	24
Total non-operating income	215,251	17,363
Non-operating expenses		
Interest expenses	67	13
Commission fees	9,596	9,000
Stock issuance costs	10,184	160
Foreign exchange losses	—	86,242
Other	2,438	671
Total non-operating expenses	22,288	96,087
Ordinary loss	(1,110,316)	(2,630,386)
Extraordinary gain		
Gain on reversal of stock acquisition rights	1,555	3,312
Total extraordinary gain	1,555	3,312
Extraordinary loss		
Loss on retirement of noncurrent assets *3	3,317	1,221
Total extraordinary losses	3,317	1,221
Loss before income taxes	(1,112,077)	(2,628,295)
Income taxes-current	3,800	3,800
Total income taxes	3,800	3,800
Net loss	(1,115,877)	(2,632,095)

(3) Statements of changes in net assets

FY 2014 (from January 1, 2014 to December 31, 2014)

(Unit: thousands of yen)

	Shareholders' equity						
		Capital surplus		Retained earnings (Accumulated deficits)			
	Common stock	Legal capital surplus	Total capital surplus	Other retained earnings: Retained earnings (accumulated deficits) brought forward	Total retained earnings (accumulated deficits)	Treasury stock	Total shareholders' equity
Balance at the beginning of the year	8,058,860	8,028,860	8,028,860	(8,751,636)	(8,751,636)	(17)	7,336,067
Changes of items during the year							
Issuance of new shares	271,915	271,915	271,915				543,830
Net loss				(1,115,877)	(1,115,877)		(1,115,877)
Net changes of items other than shareholders' equity							
Total changes of items during the year	271,915	271,915	271,915	(1,115,877)	(1,115,877)	—	(572,047)
Balance at the end of the year	8,330,775	8,300,775	8,300,775	(9,867,514)	(9,867,514)	(17)	6,764,019

(Unit: thousands of yen)

	Valuation and translation adjustments		Stock acquisition rights	Total net assets
	Unrealized holding gain (loss) on securities	Total valuation and translation adjustments		
Balance at the beginning of the year	167	167	96,761	7,432,996
Changes of items during the year				
Issuance of new shares				543,830
Net loss				(1,115,877)
Net changes of items other than shareholders' equity	(911)	(911)	103,539	102,627
Total changes of items during the year	(911)	(911)	103,539	(469,419)
Balance at the end of the year	(744)	(744)	200,300	6,963,576

FY 2015 (from January 1, 2015 to December 31, 2015)

(Unit: thousands of yen)

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

(Unit: thousands of yen)

	Valuation and translation adjustments		Stock acquisition rights	Total net assets
	Unrealized holding gain (loss) on securities	Total valuation and translation adjustments		
Balance at the beginning of the year	(744)	(744)	200,300	6,963,576
Changes of items during the year				
Issuance of new shares				—
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 the year	—	—	299,887	4,431,811

(4) Statements of cash flows

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Net cash provided by (used in) operating activities		
Loss before income taxes	(1,112,077)	(2,628,295)
Depreciation	12,663	24,244
Amortization of guarantee deposits	1,274	(1,092)
Share-based compensation expenses	94,731	102,898
Increase (decrease) in provision for retirement benefits	(41)	(97)
Interest income	(24,848)	(16,265)
Interest expenses	67	13
Foreign exchange losses (gains)	(195,875)	45,459
Commission fees	9,596	9,000
Stock issuance costs	10,184	160
Gain on reversal of stock acquisition rights	(1,555)	(3,312)
Loss on retirement of noncurrent assets	3,317	1,221
Decrease (increase) in accounts receivable-trade	(272,656)	(28,085)
Decrease (increase) in inventories	(119,532)	111,559
Decrease (increase) in prepaid expenses	25,367	(1,821)
Decrease (increase) in advances paid	28,021	(19,798)
Decrease (increase) in consumption taxes receivable	12,577	19,974
Decrease (increase) in other current assets	9,785	49,358
Decrease (increase) in long-term prepaid expenses	8,075	124
Increase (decrease) in accounts payable-trade	305,996	13,870
Increase (decrease) in accounts payable-other	(70,746)	51,013
Increase (decrease) in other current liabilities	(4,647)	(6,632)
Other	90	―
Subtotal	(1,280,230)	(2,276,502)
Interest and dividends income received	26,923	17,654
Commitment fee paid	(9,000)	(9,024)
Interest expenses paid	(67)	(13)
Income taxes paid	(3,800)	(3,800)
Net cash provided by (used in) operating activities	(1,266,174)	(2,271,686)
Net cash provided by (used in) investing activities		
Investments in time deposits	(600,000)	―
Proceeds from withdrawal of time deposits	858,971	600,000
Purchase of marketable securities	(1,500,000)	―
Proceeds from redemption of securities	1,700,000	900,000
Purchase of property, plant and equipment	(44,550)	(22,546)
Purchase of intangible assets	(64,046)	(1,235)
Payments for lease and guarantee deposits	(40,068)	(3,497)
Proceeds from collection of lease and guarantee deposits	4,107	16,420
Net cash provided by (used in) investing activities	314,413	1,489,141

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Net cash provided by (used in) financing activities		
Proceeds from issuance of stock resulting from exercise of stock acquisition rights	43,830	—
Proceeds from issuance of bonds with stock acquisition rights	500,000	—
Proceeds from issuance of stock acquisition rights	10,363	—
Payments for issuance of common stock	(9,720)	(1,850)
Repayments for lease obligations	(682)	(692)
Other payments	(90)	(90)
Net cash provided by (used in) financing activities	543,700	(2,632)
Effect of foreign exchange rate change on cash and cash equivalents	205,998	(45,459)
Net increase (decrease) in cash and cash equivalents	(202,061)	(830,636)
Cash and cash equivalents at the beginning of the year	5,294,137	5,092,075
Cash and cash equivalents at the end of the year	5,092,075	4,261,438

(5) Events and conditions that indicate there could be substantial doubt about going concern assumption

None to be reported.

(6) Significant accounting policies

1. Valuation basis and method of marketable and investment securities
   Available-for-sale securities with determinable market value
   Available-for-sale securities with a determinable market value are stated at fair value 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.
   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.

2. Valuation basis and method of derivative transactions
   Derivative financial instruments are stated at fair value.

3. Valuation basis and method of 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.

4. Depreciation of property, plant and equipment
   (1) Property, plant and equipment (excluding lease assets)
   Depreciation of property, plant and equipment is computed by the straight-line method.
   The useful lives of major property, plant and equipment are summarized as follows:

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

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

5. Deferred assets
   Stock issuance costs are charged to income as incurred.

6. Foreign currency translation
   Monetary assets and liabilities denominated in foreign currencies are translated into yen at the spot exchange rates prevailing at the balance sheet dates, and resulting gains or losses are credited or charged to income.

7. Basis for reserves and provisions
   (1) Allowance for doubtful accounts
   The allowance for doubtful accounts is provided at an amount determined based on the historical experience of bad debt with respect to ordinary receivables and an estimate of uncollectible amounts determined by reference to specific doubtful receivables from customers which are experiencing financial difficulties.
   For FY 2015, no allowance for doubtful accounts is provided due to no historical experience of bad debt and no receivable balances that are deemed uncollectible.
   (2) Provision for retirement benefits
   The provision for retirement benefits is provided at an amount to be required as of the balance sheet date.
   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.

8. Cash and cash equivalents in the statements of cash flows

Cash and cash equivalents consist of cash on hand, cash in banks which can be withdrawn at any time and short-term investments with a maturity of three months or less that can easily be converted to cash and are subject to little risk of change in value.

9. Other significant basis for the preparation of financial statements

Accounting for consumption tax

Transactions are recorded at amounts exclusive of consumption tax.

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(7) Notes on financial statements

(Balance sheets)

1. 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 each fiscal year is as follows:

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	FY 2015 (as of December 31, 2015)
Total amounts of bank overdraft limit and loan commitment line	1,350,000	1,350,000
Balance of borrowing outstanding	—	—
Unused balance	1,350,000	1,350,000

(Statements of operations)

* 1 Selling expense ratio is roughly 1.2% and 0.4% for FY 2014 and FY 2015, respectively, and administrative expense ratio is roughly 98.8 % and 99.6% for FY 2014 and FY 2015, respectively.
Major expense items and amounts are as follows.

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Directors' compensation	142,686	140,865
Salaries	336,071	346,954
Retirement benefit expenses	797	867
Research and development expenses	774,103	2,034,714
Depreciation expenses	8,426	11,625

* 2 Total amounts of research and development expenses included in general and administrative expenses

(Unit: thousands of yen)

FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
774,103	2,034,714

* 3 Details of loss on retirement of noncurrent assets

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Buildings and accompanying facilities	2,261	—
Tools, furniture and fixtures	1,055	1,037
Software	—	183

(Statements of changes in net assets)

FY 2014 (from January 1, 2014 to December 31, 2014)

1. Shares issued and outstanding / Treasury stock

(Unit: number of shares)

	At the beginning of the fiscal year	Increase	Decrease	At the end of the fiscal year
Shares issued				
Common stock	30,634,257	1,756,666	—	32,390,923
Total	30,634,257	1,756,666	—	32,390,923
Treasury stock				
Common stock	75	—	—	75
Total	75	—	—	75

(Note) The increase in common stock of 1,756,666 shares was due to exercise of stock acquisition rights.

2. Stock acquisition rights and treasury acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2014 (thousands of yen)
			At the beginning of the fiscal year	Increase	Decrease	At the end of the fiscal year	
The Company	The 2nd unsecured bonds with convertible bond type stock acquisition rights	Common stock	—	1,666,666	1,666,666	—	—
	The 29th warrant	Common stock	795,750	—	—	795,750	3,060
	The 34th warrant	Common stock	—	3,030,400	—	3,030,400	10,363
	Stock acquisition rights as stock options	—	—	—	—	—	186,876
Total			795,750	4,697,066	1,666,666	3,826,150	200,300

(Note) The information about type of shares to be issued and the number of shares to be issued is described in “Stock options.”

3. Dividends

None to be reported.

FY 2015 (from January 1, 2015 to December 31, 2015)

1. Shares issued and outstanding / Treasury stock

(Unit: number of shares)

	At the beginning of the fiscal year	Increase	Decrease	At the end of the fiscal year
Shares issued				
Common stock	32,390,923	—	—	32,390,923
Total	32,390,923	—	—	32,390,923
Treasury stock				
Common stock	75	—	—	75
Total	75	—	—	75

2. Stock acquisition rights and treasury acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2015 (thousands of yen)
			At the beginning of the fiscal year	Increase	Decrease	At the end of the fiscal year	
The Company	The 29th warrant	Common stock	795,750	—	—	795,750	3,060
	The 34th warrant	Common stock	3,030,400	—	—	3,030,400	10,363
	Stock acquisition rights as stock options	—	—	—	—	—	286,463
Total			3,826,150	—	—	3,826,150	299,887

(Note) The information about type of shares to be issued and the number of shares to be issued is described in “Stock options.”

3. Dividends

None to be reported.

(Statements of cash flows)

* Cash and cash equivalents as of the fiscal year end are reconciled to the accounts reported in the balance sheets as follows:

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Cash and deposits	5,692,075	4,261,438
Marketable securities	899,256	―
Time deposits with maturities of more than three months	(600,000)	―
Debt securities with a remaining maturity in excess of three months	(899,256)	―
Cash and cash equivalents	5,092,075	4,261,438

(Lease transactions)

Finance lease transactions

Finance lease transactions other than those which transfer the ownership of leased property

(1) Description of lease assets

Intangible assets –Software

(2) Depreciation and amortization of lease assets

Depreciation and amortization of lease assets is described in "(6) Significant accounting policies, 4. Depreciation of property, plant and equipment."

(Financial instruments)

1. Financial instruments

(1) 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.

(2) 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 1 year after the current fiscal year end.

(3) Risk management for financial instruments

(i) 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.

(ii) 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 division executes and monitors derivative transactions. Monthly transaction performances are reported to the executive management committee.

(iii) 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.

(4) 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. In addition, the notional amounts of derivatives in notes to "Derivative transactions" are not necessarily indicative of the actual market risk involved in derivative transactions.

(5) 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 sheets, fair values and their differences are as follows. The financial instruments whose fair value is extremely difficult to determine are not included. (See Note 2.)

FY 2014 (as of December 31, 2014)

(Unit: thousands of yen)

	Carrying value	Fair value	Differences
(1) Cash and deposits	5,692,075	5,692,075	―
(2) Accounts receivable-trade	272,656	272,656	―
(3) Marketable securities	899,256	899,256	―
(4) Advances paid	59,840	59,840	―
(5) Consumption taxes receivable	19,974	19,974	―
Assets, total	6,943,803	6,943,803	―
(1) Accounts payable-trade	305,996	305,996	―
(2) Lease obligations (current)	692	693	1
(3) Accounts payable-other	142,884	142,884	―
(4) Income taxes payable	21,254	21,254	―
(5) Lease obligations (non-current)	642	642	0
Liabilities, total	471,470	471,472	1
Derivative transactions, total (*)	33,235	33,235	―

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

FY 2015 (as of December 31, 2015)

(Unit: thousands of yen)

	Carrying value	Fair value	Differences
(1) Cash and deposits	4,261,438	4,261,438	―
(2) Accounts receivable-trade	300,742	300,742	―
(3) Marketable securities	―	―	―
(4) Advances paid	79,639	79,639	―
(5) Consumption taxes receivable	―	―	―
Assets, total	4,641,819	4,641,819	
(1) Accounts payable-trade	319,866	319,866	―
(2) Lease obligations (current)	642	643	1
(3) Accounts payable-other	183,690	183,690	―
(4) Income taxes payable	14,183	14,183	―
(5) Lease obligations (non-current)	―	―	―
Liabilities, total	518,383	518,384	1
Derivative transactions, total (*)	(14,999)	(14,999)	―

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

(Notes)

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, (4) Advances paid and (5) Consumption taxes receivable

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

(3) Marketable securities

The fair value of debt securities is based on the quoted price obtained from financial institutions. See notes to “Marketable and investment securities” for notes pertaining to securities by holding purpose.

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 (current) and (5) Lease obligations (non-current)

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

See notes to “Derivative transactions.”

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

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	FY 2015 (as of December 31, 2015)
Lease and guarantee deposits	47,289	51,326

Lease and guarantee deposits are not included in above tables since no market quote is available and their fair value is extremely difficult to determine.

3. The redemption schedule for monetary assets and securities with maturities

FY 2014 (as of December 31, 2014)

(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	5,692,064	—	—	—
Accounts receivable-trade	272,656	—	—	—
Marketable securities				
Available-for-securities with maturities				
Debt securities				
Corporate bond	500,000	—	—	—
Other	400,000	—	—	—
Advances paid	59,840	—	—	—
Total	6,924,561	—	—	—

FY 2015 (as of December 31, 2015)

(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	—	—	—
Marketable securities				
Available-for-securities with maturities				
Debt securities				
Corporate bond	—	—	—	—
Other	—	—	—	—
Advances paid	79,639	—	—	—
Total	4,641,791	—	—	—

4. Maturities of lease obligations after the fiscal year end

FY 2014 (as of December 31, 2014)

(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
Lease obligations (current)	692	—	—	—	—	—
Lease obligations (non-current)	—	642	—	—	—	—
Total	692	642	—	—	—	—

FY 2015 (as of December 31, 2015)

(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
Lease obligations (current)	642	—	—	—	—	—
Lease obligations (non-current)	—	—	—	—	—	—
Total	642	—	—	—	—	—

(Marketable and investment securities)

1. Available-for-sale securities

FY 2014 (as of December 31, 2014)

(Unit: thousands of yen)

	Type	Carrying value	Acquisition cost	Difference
Carrying value exceeds the acquisition cost	(1) Equity securities	—	—	—
	(2) Debt securities			
	(a) Government and municipal bonds	—	—	—
	(b) Corporate bonds	—	—	—
	(c) Other	—	—	—
	(3) Other	—	—	—
	Total	—	—	—
Carrying value does not exceed the acquisition cost	(1) Equity securities	—	—	—
	(2) Debt securities			
	(a) Government and municipal bonds	—	—	—
	(b) Corporate bonds	499,260	500,000	(740)
	(c) Other	—	—	—
	(3) Other	399,996	400,000	(4)
	Total	899,256	900,000	(744)

FY 2015 (as of December 31, 2015)
None to be reported.

2. Available-for-sale securities sold

FY 2014 (from January 1, 2014 to December 31, 2014)
None to be reported.

FY 2015 (from January 1, 2015 to December 31, 2015)
None to be reported.

(Derivative transactions)

1. Derivative transactions to which hedge accounting is not applied
Currency-related transaction

FY 2014 (as of December 31, 2014)

(Unit: thousands of yen)

Classification	Type	Notional amount	Portion due after one year included herein	Fair value	Unrealized gain
OTC transactions	Forward exchange contract				
	Buy				
	U.S. dollar	—	—	—	—
	Euro	824,522	—	33,235	33,235
Total		824,522	—	33,235	33,235

(Note) Fair value measurement
The fair value is measured based on the quoted prices obtained from financial institutions with business relationship.

FY 2015 (as of December 31, 2015)

(Unit: thousands of yen)

Classification	Type	Notional amount	Portion due after one year included herein	Fair value	Unrealized gain
OTC transactions	Forward exchange contract				
	Buy				
	U.S. dollar	—	—	—	—
	Euro	783,735	—	(14,999)	(14,999)
Total		783,735	—	(14,999)	(14,999)

(Note) Fair value measurement
The fair value is measured based on the quoted prices obtained from financial institutions with business relationship.

2. Derivative transactions to which hedge accounting is applied
None to be reported.

(Retirement benefits)

1. Outline of retirement benefit plans

The Company has adopted a defined contribution pension plan. A lump-sum payment plan (non-contributory plan) is applied for certain employees based on the internal rules of retirement benefits.

The simplified method is applied to calculate amounts of retirement benefit obligation and retirement benefit expenses.

2. Retirement benefit plan under simplified method

(1) The reconciliation between retirement benefit obligation at the beginning and the end of the fiscal year is as follows.

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Retirement benefit obligation at the beginning of the fiscal year	1,675	1,634
Service costs	196	235
Contribution made for defined contribution pension plan	(237)	(332)
Retirement benefit obligation at the end of the fiscal year	1,634	1,537

(2) The reconciliation between retirement benefit obligation or provision for retirement benefits and net defined benefit liability on the balance sheet is as follows.

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Unfunded retirement benefit obligation	1,634	1,537
Net defined benefit liability on the balance sheet	1,634	1,537

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Provision for retirement benefits	1,634	1,537
Net defined benefit liability on the balance sheet	1,634	1,537

(3) Retirement benefit expenses

Retirement benefit expenses calculated under simplified method FY 2014: 196 thousand yen
FY 2015: 235 thousand yen

3. Defined contribution pension plan

The amount of the Company's contribution to the defined contribution pension plan for FY 2014 and FY 2015 were 1,733 thousand yen and 1,693 thousand yen, respectively.

(Stock options)

1. The account name and the amount of stock options charged as expenses

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Selling, general and administrative expenses	94,731	102,898

2. The account name and the amount of income recognized for vested shares that expired unexercised

(Unit: thousands of yen)

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Gain on reversal of stock acquisition rights	1,555	3,312

3. Description of stock options / Changes in the size of stock options

(1) Description of stock options

	The 6th Series	The 7th Series
Individuals covered by the plan and number of persons granted	Auditors & supervisory board members of the Company 1 Employees of the Company 3 External collaborators 6 Total 10	Directors of the Company 6 Auditors & supervisory board members of the Company 2 Employees of the Company 16 External collaborators 9 Total 33
Class and number of shares to be issued upon the exercise of the stock option	Common stock 45,000 shares	Common stock 200,000 shares
Grant date	April 18, 2006	July 1, 2006
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the board of directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From April 19, 2008 to March 30, 2016	From July 2, 2008 to March 30, 2016

	The 8th Series	The 9th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 6 External collaborators 5 Total 11	Directors of the Company 3 Auditors & supervisory board members of the Company 2 Total 5
Class and number of shares to be issued upon the exercise of the stock option	Common stock 52,000 shares	Common stock 66,000 shares
Grant date	December 4, 2006	February 1, 2007
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From December 2, 2008 to March 30, 2016	From January 24, 2009 to January 23, 2017

	The 11th Series	The 12th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 6 External collaborators 3 Total 9	Directors of the Company 5 Auditor & supervisory board member of the Company 1 Total 6
Class and number of shares to be issued upon the exercise of the stock option	Common stock 34,000 shares	Common stock 82,000 shares
Grant date	March 15, 2007	August 29, 2007
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From March 3, 2009 to March 2, 2017	From August 29, 2009 to August 28, 2017

	The 13th Series	The 14th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 33 External collaborators 12 Total 45	Directors of the Company 5 Auditor & supervisory board member of the Company 1 Total 6
Class and number of shares to be issued upon the exercise of the stock option	Common stock 170,000 shares	Common stock 207,000 shares
Grant date	August 29, 2007	October 1, 2008
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From August 29, 2009 to August 28, 2017	From October 1, 2010 to September 30, 2018

	The 16th Series	The 17th Series
Individuals covered by the plan and number of persons granted	External collaborators 14	Directors of the Company 3 Auditor & supervisory board member of the Company 1 Total 4
Class and number of shares to be issued upon the exercise of the stock option	Common stock 85,000 shares	Common stock 72,000 shares
Grant date	October 1, 2008	March 18, 2009
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From October 1, 2010 to September 30, 2018	From March 19, 2011 to March 18, 2019

	The 19th Series	The 20th Series
Individuals covered by the plan and number of persons granted	External collaborators 2	Directors of the Company 6 Auditor & supervisory board member of the Company 1 Total 7
Class and number of shares to be issued upon the exercise of the stock option	Common stock 12,500 shares	Common stock 361,000 shares
Grant date	March 18, 2009	March 31, 2010
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From March 19, 2011 to March 18, 2019	From April 1, 2012 to March 31, 2020

	The 21st Series	The 22nd Series
Individuals covered by the plan and number of persons granted	Employees of the Company 50	External collaborators 13
Class and number of shares to be issued upon the exercise of the stock option	Common stock 326,500 shares	Common stock 153,000 shares
Grant date	March 31, 2010	March 31, 2010
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From April 1, 2012 to March 31, 2020	From April 1, 2012 to March 31, 2020

(This part is intentionally left blank)

	The 23rd Series	The 24th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 9	Directors of the Company 5
Class and number of shares to be issued upon the exercise of the stock option	Common stock 32,000 shares	Common stock 192,000 shares
Grant date	October 15, 2010	March 31, 2011
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	Vesting period is not fixed.	Same as on the left
Exercise period	From October 15, 2012 to October 14, 2020	From March 31, 2013 to March 30, 2021

	The 25th Series	The 26th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 59	Directors of the Company 4
Class and number of shares to be issued upon the exercise of the stock option	Common stock 195,000 shares	Common stock 362,500 shares
Grant date	March 31, 2011	May 2, 2012
Vesting condition	1. The Person Granted must be in a status of the Company's director, auditor & supervisory board member, advisor or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or the compulsory retirement, if otherwise the Board of Directors approves, or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	No specific conditions are prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise condition. The exercise conditions are described in *(1) to (6).
Vesting period	Vesting period is not fixed.	The period that fulfills the requirement of the exercise conditions *(2) and (3).
Exercise period	From March 31, 2013 to March 30, 2021	From April 18, 2014 to April 17, 2022

	The 27th Series	The 28th Series
Individuals covered by the plan and number of persons granted	Employees of the Company 70	Employees of the Company 5
Class and number of shares to be issued upon the exercise of the stock option	Common stock 430,700 shares	Common stock 16,500 shares
Grant date	May 2, 2012	September 28, 2012
Vesting condition	No specific conditions are prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise condition. The exercise conditions are described in *(1) to (6).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise conditions *(2) and (3).	Same as on the left
Exercise period	From April 18, 2014 to April 17, 2022	From September 14, 2014 to September 13, 2022

	The 30th Series	The 31st Series
Individuals covered by the plan and number of persons granted	Directors of the Company 5	Employees of the Company 68
Class and number of shares to be issued upon the exercise of the stock option	Common stock 116,000 shares	Common stock 124,000 shares
Grant date	May 29, 2013	May 29, 2013
Vesting condition	No specific conditions are prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise condition. The exercise conditions are described in *(1) to (6).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise conditions *(2) and (3).	Same as on the left
Exercise period	From May 15, 2015 to May 14, 2023	From May 15, 2015 to May 14, 2023

	The 32nd Series	The 33rd Series
Individuals covered by the plan and number of persons granted	Directors of the Company 5	Employees of the Company 68
Class and number of shares to be issued upon the exercise of the stock option	Common stock 252,000 shares	Common stock 333,000 shares
Grant date	April 30, 2014	April 30, 2014
Vesting condition	No specific conditions are prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise condition. The exercise conditions are described in *(1), (3), (4), (7) and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(3).	Same as on the left
Exercise period	From April 16, 2017 to April 15, 2024	From April 16, 2017 to April 15, 2024

	The 35th Series	The 36th Series
Individuals covered by the plan and number of persons granted	Directors of the Company 6	Employees of the Company 61
Class and number of shares to be issued upon the exercise of the stock option	Common stock 204,200 shares	Common stock 312,000 shares
Grant date	April 10, 2015	April 10, 2015
Vesting condition	No specific conditions are prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise condition. The exercise conditions are described in *(1), (3), (4), (7) and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(3).	Same as on the left
Exercise period	From March 27, 2018 to March 26, 2025	From March 27, 2018 to March 26, 2025

*(1) Fraction less than one unit of a stock acquisition rights shall be un-exercisable.

(2) Those who received the allotment of the stock acquisition rights (the "Person Granted") may exercise all or part of the rights in accordance with the following classifications:

＜The 26th Series and the 27th Series stock option＞

(a) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-fourth (1/4) from April 18, 2014 to April 17, 2015.

(b) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-half (1/2) from April 18, 2015 to April 17, 2016.

(c) Those who were granted the stock acquisition rights may exercise the rights within the limit of three-fourths (3/4) from April 18, 2016 to April 17, 2017.

(d) Those who were granted the stock acquisition rights may exercise all the rights from April 18, 2017 to April 17, 2022.

＜The 28th Series stock option＞

(a) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-fourth (1/4) from September 14, 2014 to September 13, 2015.

(b) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-half (1/2) from September 14, 2015 to September 13, 2016.

(c) Those who were granted the stock acquisition rights may exercise the rights within the limit of three-fourths (3/4) from September 14, 2016 to September 13, 2017.

(d) Those who were granted the stock acquisition rights may exercise all the rights from September 14, 2017 to September 13, 2022.

＜The 30th and the 31st Series stock option＞

(a) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-fourth (1/4) from May 15, 2015 to May 14, 2016.

(b) Those who were granted the stock acquisition rights may exercise the rights within the limit of one-half (1/2) from May 15, 2016 to May 14, 2017.

(c) Those who were granted the stock acquisition rights may exercise the rights within the limit of three-fourths (3/4) from May 15, 2017 to May 14, 2018.

(d) Those who were granted the stock acquisition rights may exercise all the rights from May 15, 2018 to May 14, 2023.

(3) The Person Granted shall exercise the rights starting from the date of resolution by the below-mentioned stockholders' meeting or the Board of Directors' meeting until one day before the effective date of the Organizational Restructuring as followed, regardless the conditions of exercise period originally stipulated, when the Organizational Restructuring are approved by the resolution of the Company's stockholders' meeting (including the case where resolution of a stockholders' meeting is deemed to exist pursuant to the provision of Article 319 of the Companies Act) or the Board of Directors' meeting (limited to the case where no stockholders' meeting is required for the said Organizational Restructuring) before the exercise period ("Exercise Period") of the stock acquisition rights comes into effect: an absorption-type merger or an incorporation-type merger where the Company becomes a dissolving company and an absorption-type split or an incorporation-type company split where the Company becomes a split company or a share exchange or a share transfer where the Company becomes a wholly-owned subsidiary (collectively, "Organizational Restructuring" as mentioned above).

(4) The stock acquisition rights shall not be offered for pledge or disposed of in any other way.

(5) The Person Granted must be in a status of the director, auditor & supervisory board member or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the cases where;

(a) The Person Granted is the director or auditor & supervisory board member of the Company or its affiliates and retires due to the expiry of her/his term.
(b) The Person Granted is the employee of the Company or its affiliates and retires due to the compulsory retirement.
(c) The Person Granted is the director, auditor & supervisory board member or employee of the Company or its affiliates and the Board of Directors resolves that he/she resigns or retires with honorable recognition.

(6) In the event where;
(a) The Person Granted died before the exercise period comes into effect, the inheritor shall exercise the rights of up to one-half (1/2) within six months from the date of inherited, or
(b) The Person Granted died during the exercise period, the inheritor shall exercise all the rights within six months from the date of inherited.
However, in the event that the inheritor died, the rights shall be discarded and shall not be exercised by his/her inheritor.

(7) The Person Granted must be in a status of the director, auditor & supervisory board member or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the cases where;

(a) The Person Granted is the director of the Company or its affiliates and retires due to the expiry of her/his term.
(b) The Person Granted is the employee of the Company or its affiliates and retires due to the compulsory retirement.
(c) The Person Granted is the director or employee of the Company or its affiliates and the Board of Directors resolves that he/she resigns or retires with honorable recognition.

(8) In the event where the Person Granted died, the inheritor shall be able to succeed and exercise the stock acquisition rights as prescribed in the allotment agreement of stock acquisition rights entered between the Company and the Person Granted. However, in the event that the inheritor dies, the rights shall be discarded and shall not be exercised by his/her inheritor.

(2) Change in the size of stock option

The number of shares which may arise upon exercise of stock option as of December 31, 2015 is as follows.

(a) Number of stock options

(Unit: number of shares)

	The 1st Series	The 5th Series	The 6th Series	The 7th Series
Grant date	June 20, 2005	January 31, 2006	April 18, 2006	July 1, 2006
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	202,000	2,000	2,000	61,000
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	202,000	2,000	—	—
At the end of the year	—	—	2,000	61,000

(Unit: number of shares)

	The 8th Series	The 9th Series	The 11th Series	The 12th Series
Grant date	December 4, 2006	February 1, 2007	March 15, 2007	August 29, 2007
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	1,000	3,000	7,000	23,000
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	1,000	3,000	7,000	23,000

(Unit: number of shares)

	The 13th Series	The 14th Series	The 16th Series	The 17th Series
Grant date	August 29, 2007	October 1, 2008	October 1, 2008	March 18, 2009
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	61,000	28,000	70,000	4,000
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	61,000	28,000	70,000	4,000

(Unit: number of shares)

	The 19th Series	The 20th Series	The 21st Series	The 22nd Series
Grant date	March 18, 2009	March 31, 2010	March 31, 2010	March 31, 2010
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	2,500	344,500	220,500	153,000
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	—	23,000	—
At the end of the year	2,500	344,500	197,500	153,000

(Unit: number of shares)

	The 23rd Series	The 24th Series	The 25th Series	The 26th Series
Grant date	October 15, 2010	March 31, 2011	March 31, 2011	May 2, 2012
Non-vested shares:				
At the beginning of the year	—	—	—	241,875
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	80,625
At the end of the year	—	—	—	161,250
Vested shares:				
At the beginning of the year	20,000	192,000	143,000	120,625
Vested	—	—	—	80,625
Exercised	—	—	—	—
Expired	10,000	—	26,000	—
At the end of the year	10,000	192,000	117,000	201,250

(Unit: number of shares)

	The 27th Series	The 28th Series	The 30th Series	The 31st Series
Grant date	May 2, 2012	September 28, 2012	May 29, 2013	May 29, 2013
Non-vested shares:				
At the beginning of the year	218,550	9,000	95,000	95,200
Granted	—	—	—	—
Expired	28,375	—	—	11,325
Vested	73,375	3,000	23,750	27,475
At the end of the year	116,800	6,000	71,250	56,400
Vested shares:				
At the beginning of the year	103,150	3,000	21,000	—
Vested	73,375	3,000	23,750	27,475
Exercised	—	—	—	—
Expired	16,825	—	—	1,575
At the end of the year	159,700	6,000	44,750	25,900

(Unit: number of shares)

	The 32nd Series	The 33rd Series	The 35th Series	The 36th Series
Grant date	April 30, 2014	April 30, 2014	April 10, 2015	April 10, 2015
Non-vested shares:				
At the beginning of the year	252,000	274,100	—	—
Granted	—	—	204,200	312,000
Expired	—	53,200	—	39,500
Vested	—	7,000	—	—
At the end of the year	252,000	213,900	204,200	272,500
Vested shares:				
At the beginning of the year	—	—	—	—
Vested	—	7,000	—	—
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	—	7,000	—	—

(b) Per share prices

	The 1st Series	The 5th Series	The 6th Series	The 7th Series
Grant date	June 20, 2005	January 31, 2006	April 18, 2006	July 1, 2006
Exercise price (yen) (Note 1)	487	974	974	1,461
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	—	—	—	0

	The 8th Series	The 9th Series	The 11th Series	The 12th Series
Grant date	December 4, 2006	February 1, 2007	March 15, 2007	August 29, 2007
Exercise price (yen) (Note 1)	1,461	1,461	1,461	1,461
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 13th Series	The 14th Series	The 16th Series	The 17th Series
Grant date	August 29, 2007	October 1, 2008	October 1, 2008	March 18, 2009
Exercise price (yen) (Note 1)	1,461	1,169	1,169	1,169
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 19th Series	The 20th Series	The 21st Series	The 22nd Series
Grant date	March 18, 2009	March 31, 2010	March 31, 2010	March 31, 2010
Exercise price (yen) (Note 1)	1,169	585	585	585
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 23rd Series	The 24th Series	The 25th Series	The 26th Series
Grant date	October 15, 2010	March 31, 2011	March 31, 2011	May 2, 2012
Exercise price (yen) (Note 1)	585	682	682	555
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	(a) 179 (b) 187 (c) 195 (d) 202

	The 27th Series	The 28th Series	The 30th Series	The 31st Series
Grant date	May 2, 2012	September 28, 2012	May 29, 2013	May 29, 2013
Exercise price (yen) (Note 1)	555	555	799	799
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	(a) 179 (b) 187 (c) 195 (d) 202	(a) 203 (b) 208 (c) 213 (d) 217	(a) 586 (b) 602 (c) 617 (d) 631	(a) 586 (b) 602 (c) 617 (d) 631

	The 32nd Series	The 33rd Series	The 35th Series	The 36th Series
Grant date	April 30, 2014	April 30, 2014	April 10, 2015	April 10, 2015
Exercise price (yen) (Note 1)	1	1	1	1
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	229	229	306	306

(Notes) 1. The Company increased its capital through the public offering on December 4, 2013 and through the third party allotment on December 25, 2013, at the per share amount less than the exercise price of options. Thus, the exercise amounts above are stated after price adjustments clause.

2. (a), (b), (c) and (d) above correspond to each of (a), (b), (c) and (d) of the exercise periods as previously described in 3 (1)*(2).

4. Method for estimating the fair value of stock options

The fair value of stock options that were granted during this fiscal year is estimated based on the following method.

(1) Estimate technique used: Black-Scholes option pricing model

(2) Major assumptions and estimate method

	The 35th Series	The 36th Series
Volatility of stock price (Note 1)	74.54%	74.54%
Estimated remaining outstanding period (Note 2)	3.0 years	3.0 years
Estimated dividend (Note 3)	0 yen per share	0 yen per share
Risk free interest rate (Note 4)	0.028%	0.028%

(Notes) 1. The volatility was calculated based on the actual stock prices from April 23, 2012 to April 10, 2015.

2. The period from the allotment date to the start date of the exercise period is used.

3. The Company estimates dividends to be zero since no dividends have been paid in the past.

4. It represents yields of Japanese government bonds corresponding to estimated remaining outstanding period.

5. Estimation of the number of stock options vested

The number of expired shares is estimated based on the historical turnover ratio.

(Deferred tax accounting)

1. Significant components of deferred tax assets and liabilities

(Unit: thousands of yen)

	FY2014 (as of December 31, 2014)	FY2015 (as of December 31, 2015)
Deferred tax assets:		
Excess depreciation for lump-sum depreciable assets	2,339	2,357
Excess amortization for deferred assets	76,203	391,435
Research and development expenses	835,059	1,011,607
Account payable-other	8,342	8,458
Provision for retirement benefits	582	497
Enterprise tax payable	6,897	4,396
Asset retirement obligation	786	360
Share-based compensation expense	36,584	59,480
Loss carried forward	1,739,209	1,818,206
Subtotal	2,706,006	3,296,798
Valuation allowance	(2,706,006)	(3,296,798)
Total deferred tax assets	—	—

2. The reconciliation between the effective tax rates reflected in the financial statements and the statutory tax rate is omitted since the Company reported loss before income taxes for the years ended December 31, 2014 and 2015.

3. Revision 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 Revision of the Income Tax Act, etc.” and the “Act for Partial Revision of the Local Tax Act, etc.” on March 31, 2015, the 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.

(Asset retirement obligations)

The Company has future restoration obligations related to leasehold contracts of office premises.
Carrying the balance of lease and guarantee deposits as an asset, the Company reasonably estimates non-recoverable amounts of lease and guarantee deposits under lease contracts and records the amount attributable to the respective fiscal year as expenses, instead of accounting for asset retirement obligations by recognizing a liability and an associated asset.

(Segment information)

【Segment information】

FY 2014 (from January 1, 2014 to December 31, 2014) and FY 2015 (from January 1, 2015 to December 31, 2015)

Segment information is omitted since the Company operates a single segment of pharmaceutical businesses including research and development of pharmaceutical drugs as well as manufacturing and marketing and other related activities.

【Related information】

FY 2014 (from January 1, 2014 to December 31, 2014)

1. Information by product and service

Information by product and service is omitted since external sales of a single service category account for more than 90% of total net sales stated in the statement of income.

2. Information about geographical area

(1) Net sales

Net sales information about geographical area is omitted since external sales to Japanese customers account for more than 90% of total net sales stated in the statement of income.

(2) Property, plant and equipment

All property, plant and equipment are located in Japan.

3. Information by major customer

(Unit: thousands of yen)

Name of customer	Net sales	Name of related segment
Eisai Co., Ltd.	1,908,388	Pharmaceutical businesses including research and development of pharmaceutical drugs as well as manufacturing marketing and other related activities.

FY 2015 (from January 1, 2015 to December 31, 2015)

1. Information by product and service

Information by product and service is omitted since external sales of a single service category account for more than 90% of total net sales stated in the statement of income.

2. Information about geographical area

(1) Net sales

Net sales information about geographical area is omitted since external sales to Japanese customers account for more than 90% of total net sales stated in the statement of income.

(2) Property, plant and equipment

All property, plant and equipment are located in Japan.

3. Information by major customer

(Unit: thousands of yen)

Name of customer	Net sales	Name of related segment
Eisai Co., Ltd.	1,852,304	Pharmaceutical businesses including research and development of pharmaceutical drugs as well as manufacturing marketing and other related activities.

【Information about impairment loss on long-lived assets by reportable segment】

FY 2014 (from January 1, 2014 to December 31, 2014) and FY 2015 (from January 1, 2015 to December 31, 2015)

None to be reported.

【Information about the amortization and unamortized balance of goodwill by reportable segment】

FY 2014 (from January 1, 2014 to December 31, 2014) and FY 2015 (from January 1, 2015 to December 31, 2015)

None to be reported.

【Information about the gain recognized on negative goodwill by reportable segment】

FY 2014 (from January 1, 2014 to December 31, 2014) and FY 2015 (from January 1, 2015 to December 31, 2015)

None to be reported.

(Related party information)

Transactions with related parties

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

FY 2014 (from January 1, 2014 to December 31, 2014)

Type	Name	Address	Capital contribution (in thousands of yen)	Occupation	Ownership of voting rights (%)	Relationship	Transaction details	Amounts (in thousands of yen)	Account name	Balance (in thousands of yen)
Director	Fuminori Yoshida	—	—	Representative Director, President and CEO of the Company	Direct 9.63%	—	Exercise of stock options	43,830 (90,000 shares)	—	—

(Note) The amount presents for the stock acquisition rights exercised during FY 2014, of which the stock acquisition rights granted are based on the resolution of the Company's extraordinary stockholders' meeting held on June 20, 2005.

FY 2015 (from January 1, 2015 to December 31, 2015)

None to be reported.

(Per share information)

FY 2014 (from January 1, 2014 to December 31, 2014)		FY 2015 (from January 1, 2015 to December 31, 2015)	
Net assets per share	208.80 yen	Net assets per share	127.56 yen
Net loss per share	(36.26) yen	Net loss per share	(81.26) yen

(Notes) 1. While having potential dilutive stocks, diluted net income per share is not provided since the Company reported net loss per share.

2. The basis for calculating net loss per share is as follows:

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Net loss (thousand yen)	(1,115,877)	(2,632,095)
Amount not attributable to the shareholders of common stock (thousand yen)	—	—
Net loss attributable to the shareholders of common stock (thousand yen)	(1,115,877)	(2,632,095)
Average number of shares outstanding during the year (shares)	30,776,721	32,390,848
Description of potential dilutive stocks not included in the earning-per-share calculation due to anti-dilution	26 types of stock acquisition rights (54,803 units) in accordance with the Commercial Code of 1890 Article 280 (20) and (21), and the Companies Act Article 236, 238, and 239.	24 types of stock acquisition rights (51,592 units) in accordance with the Commercial Code of 1890 Article 280 (20) and (21), and the Companies Act Article 236, 238, and 239.

3. The basis for calculating net assets per share is as follows:

	FY 2014 (from January 1, 2014 to December 31, 2014)	FY 2015 (from January 1, 2015 to December 31, 2015)
Net assets (thousand yen)	6,963,576	4,431,811
Amount to be deducted from net assets (thousand yen)	200,300	299,887
[Of which, stock acquisition rights herein (thousand yen)]	[200,300]	[299,887]
Net assets attributable to the shareholders of common stock (thousand yen)	6,763,275	4,131,924
Number of shares used in the calculation of net assets per share (shares)	32,390,848	32,390,848

(Significant subsequent events)

None to be reported.

6. Other

(1) Change in officers

None to be reported.

(2) Other

None to be reported.