

February 9, 2017
Symbio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Symbio's Mid-Range Plan: FY 2017 to FY 2019

I. Mid-Range Plan for the Next Three Years

(1) Overview of FY 2016 Business Results as of the Date of the Mid-Range Plan

Progress in the Company's business for FY 2016 (from January 1, 2016 to December 31, 2016) is as follows:

1. Domestic

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

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

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

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

Regarding the first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, the Company filed an sNDA in Japan in December 2015 and received approval for additional

indications in December 2016. In Europe, while the Company received a notice from Astellas Pharma GmbH (Head office: Germany) that they withdrew their application in January 2016, the Company, upon consultation with the PMDA, went ahead with the procedures for obtaining approval for the additional indications in Japan and was able to obtain such approval.

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

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

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

Regarding the oral formulation of rigosertib, the Company started its domestic Phase I clinical trial of the oral formulation of rigosertib sodium in combination with azacitidine (Note 1) for the target indication of HR-MDS in December 2015. However, the provision of the investigational drug of this clinical trial by Onconova has been delayed. At present, patient enrollment has not yet been started. As soon as this issue on the provision of the investigational drug is resolved, the Company will resume patient enrollment, complete this clinical trial as planned, and consider its participation in the global Phase III clinical trial to be conducted by Onconova.

(Note) About azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS, and is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation.

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

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

[New drug candidates]

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

Meanwhile, in May 2016, the Company established a wholly-owned subsidiary, Symbio Pharma USA, Inc. (Head office: Menlo Park, California, U.S., “Symbio Pharma USA”), as the Company’s strategic base for its overseas business development. By actively acquiring the worldwide rights concerning new drug candidates with Symbio Pharma USA as the base of global business, the Company will accelerate its transformation into a global specialty biopharmaceutical company with the aim of developing and commercializing new drugs in the U.S., Japan, Europe and other major global markets

2. Overseas

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

3. Business results

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

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

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

Segment information has been omitted as the Company operates within a single segment of the pharmaceutical industry which includes the development and commercialization of drugs,

manufacturing, marketing and other related activities.

(2) SymBio's Mid-Range Plan – Summary and Background

SymBio is the first Japanese “specialty pharma” to specialize in the following three areas: oncology, hematology and pain management. Although strong demand exists in these therapeutic areas, development remains challenging due to the need for a high degree of specialization. “Underserved therapeutic areas” in oncology, hematology and pain management remain untapped, where large pharmaceutical companies are cautious in development due to a concern over operational efficiency and resulting low profitability.

The Company sees business opportunities in these “underserved therapeutic areas” despite the relatively small market potential, introducing new drug candidates to fulfil high unmet medical needs instead of pursuing new “blockbuster” drugs (where sales often surpass 100 billion yen). Capturing revenue opportunities through the development and sale of drugs in these therapeutic areas is at the core of business development in the Company.

One significant aspect of the Company’s business model is to in-license drug candidates with clinically confirmed efficacy and safety from pharmaceutical companies in the U.S. and Europe after strict evaluation, while not having its own in-house research and manufacturing function. This enables the Company to avoid a large capital investment for research and manufacturing facilities as it aims to conduct effective business operations with low fixed costs. Also, by focusing on later stage drug candidates that have been tested for efficacy and safety in mainly clinical trials, the development period is shortened, thus lowering the overall development cost and risk.

The Company is building a strong pipeline portfolio and aiming for a steady return to profitability through the continuation of these efforts.

SymBio’s Mid-Range Plan is as follows:

- To maximize the value of our main product, TREAKISYM[®], which has already achieved a high market share as a treatment for relapsed/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma, and solidify the Company’s earning’s base by also promoting its penetration as first-line treatment of these diseases as it has obtained the approval of such additional indications in December 2016, and establish its position as the initial drug of choice as soon as practicable.
- To proceed with clinical trials to obtain approval for rigosertib sodium (intravenous formulation/oral formulation), which is a therapy for myelodysplastic syndromes (MDS), a hematological malignancy, and for SyB P-1501, a drug for patient-controlled, short-term management of acute post-operative pain during hospitalization, as new drug candidates after TREAKISYM[®], thereby enhancing the Company’s growth potential and expanding revenue opportunities.
- To consider establishing the Company’s own salesforce, giving particular attention to the timing of marketing approval for SyB P-1501, a patient-controlled pain management drug, and rigosertib (intravenous), as well as to the timing of introducing new drug candidates for development.

- To expand our pipeline portfolio, in order to ensure long-term growth opportunities. The Company will proactively search for and evaluate new drug candidates for development, and consider obtaining global licenses as well as taking a stake in companies possessing new drug candidates for development.
- With these initiatives, the Company aims for further growth, in order to transform from a specialty pharma in Asia with a focus on Japan, to a truly global specialty pharma with enhanced economic and social value.

(3) Business Status, Outlook and Other Assumptions

- SyB L-0501 (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)
 - Domestic sales of TREAKISYM® began through Eisai Co., Ltd., (“Eisai”) our business partner, with the drug’s launch in December 2010, for relapsed/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma. Sales have been increasing steadily and the market share among patients with relapsed/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma has reached a high point.
 - TREAKISYM® received approval for the additional indications of chronic lymphocytic leukemia in August 2016, and of first-line treatment of low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma in December 2016.
 - Going forward, in order to further increase sales of TREAKISYM®, the Company will make efforts to maximize the product value of TREAKISYM® by further reinforcing marketing collaboration with Eisai to achieve maximized market penetration and encourage its full and proper use, especially as first-line treatment of low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma, to establish its position as the initial drug of choice.
 - Regarding relapsed/refractory intermediate/high-grade non-Hodgkin’s lymphoma, the Phase II study has been completed, and the Company will continue to consider pursuing additional indications.

- SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation); generic name: rigosertib sodium
 - With regard to rigosertib (intravenous), the Company completed the first patient enrollment in Japan in July 2016 for the global Phase III study (INSPIRE trial) for higher-risk myelodysplastic syndromes (HR-MDS) patients who do not respond to treatment with hypomethylating agents (HMAs) or who relapse after the treatment under the current standard of care (“Primary HMA Failure”). The Company will continue to conduct the trial steadily aiming to file a new drug application for manufacturing and marketing approval in 2018.
 - With regard to rigosertib (oral), the Company will continue to advance the Phase I study in Japan using the oral formulation of rigosertib sodium in combination with azacitidine for HR-MDS patients, and consider participating in the global Phase III study in 2019 in collaboration with its U.S.-based business partner, Onconova Therapeutics, Inc. (Pennsylvania) (“Onconova”).
 - Additionally, the Company will discuss the development plan for the indication of transfusion-dependent lower-risk MDS, taking Onconova’s development status into account.

- SyB P-1501 for a patient-controlled pain management drug
 - Regarding SyB P-1501, the Company completed the first patient enrollment in November 2016 for the Phase III study, for the indication of short-term acute post-operative pain management during hospitalization. The Company will continue to make steady progress in the trial, aiming to file a new drug application for manufacturing and marketing approval in 2018.

- Establishment of the Company's own salesforce
 - While marketing TREAKISYM® in Japan through its business partner, Eisai, the Company regards it as one of the important management issues to shift to the Company's own salesforce to raise profitability. The Company considers it beneficial to establish its own salesforce so that the Company can respond to market needs more quickly and accurately to contribute to the advancement of medicine as well as to clients and patients. This will also lead to maximizing product value by providing more specialized information, and realizing a specialty pharma with enhanced economic and social value.
 - However, the Company regards it essential to carefully consider the timing of the establishment of the salesforce and its optimally effective and suitable system, since it could require additional costs to establish the salesforce and to maintain continuous employment of Medical Representatives and other required new staff. Consequently, the Company intends to closely monitor the progress of the development of SyB P-1501, a patient-controlled pain management drug, and SyB L-1101 (rigosertib intravenous formulation) and the timing of their manufacturing and marketing approval, as well as the timing of introducing new drug candidates for development, and thereby make a prudent decision regarding the establishment of its salesforce in a timely manner.

- New drug candidates and global business expansion
 - The Company continues to evaluate several new drug candidates for development. Upon discovery of candidates that will eventually contribute to the improvement of corporate value, the Company will enter into negotiations for in-licensing at the appropriate time.
 - When researching, evaluating and negotiating new drug candidates for development, the Company will focus on obtaining exclusive rights to commercialize the new drug candidates on a global basis, and thus aims to become a global specialty pharma, transforming from a specialty pharma focused on the Asian region.

II. Earnings Forecast and Performance Targets

Unit: millions of yen

Fiscal Year	Net Sales	Operating Income (loss)	Ordinary Income (loss)	Net Income (loss)
FY 2016 (actual)	2,368	(2,127)	(2,317)	(2,313)
FY 2017 (forecast)	2,903	(3,239)	(3,303)	(3,307)
FY 2018 (target)	3,926 ~3,401	(2,309) ~(2,509)	(2,373) ~(2,573)	(2,377) ~(2,577)
FY 2019 (target)	4,605 ~3,586	(1,872) ~(2,261)	(1,936) ~(2,325)	(1,940) ~(2,329)

Assumptions and Numerical Bases for Projections and Performance Targets

- Net sales are mainly comprised of product sales for TREAKISYM®. The performance targets for drug sales are derived after detailed analysis and discussions on market size projections, competitive positioning and advantages vis-à-vis existing therapies, and sales performance after commencement of sales. Furthermore, while the Company is currently in the midst of the Phase III study for SyB P-1501, a patient-controlled pain management drug, aiming to file a new drug application for manufacturing and marketing approval in 2018, it will need to monitor the progress of its clinical development going forward. Hence, estimated sales from SyB P-1501 are not included if approval is obtained and the drug launched during the period of this Mid-Range Plan.
- Cost of sales is estimated based on the provisions of the licensing and distribution agreements relating to TREAKISYM®.
- Selling and general administrative expenses mainly consist of research and development (selling expenses or other selling expenses and general administrative expenses).
 - Research and development expenses are estimated based on “III. Other Reference Information – Status of the Development Portfolio and Performance Targets”. With regard to SyB P-1501, a patient-controlled pain management drug, and SyB L-1101 (rigosertib intravenous formulation), milestone payments to the licensors triggered at the time approval is obtained are not accounted for, as the Company will need to monitor the progress of the Phase III studies going forward. Additionally, with regard to new drug candidates for development, in-licensing and development costs are not accounted for, although the Company is proceeding with continuous evaluation and negotiation for the candidates.
 - Other selling and general administrative expenses mainly consist of expenses incurred from TREAKISYM® marketing, production & distribution, business development and administrative operations. With regard to TREAKISYM®, since the business alliance

agreement with Eisai provides that marketing expenses shall be divided equally between the two parties, half of the estimated expenses are assumed, as the case for R&D expenses.






- With respect to the additional indication of relapsed/refractory intermediate/high-grade non-Hodgkin's lymphoma, no related sales or expenses are assumed.
- In terms of personnel planning, there were 77 employees as of December 31, 2016, and the Company plans to assign the minimum number of staff required to develop SyB P-1501, a patient-controlled pain management drug, SyB L-1101 (rigosertib intravenous formulation) and SyB C-1101 (rigosertib oral formulation). When the Company establishes its own salesforce, a certain increase in the number of staff, especially Medical Representatives, is expected from 2019. However, as stated in "I. Mid-Range Plan for the Next Three Years, (3) Business Status, Outlook and Other Assumptions," the plan requires careful consideration going forward, and hence the personnel expenses relating to the establishment of the Company's own salesforce have not been accounted for.
- During the period of this Mid-Range Plan, the market share of TREAKISYM® for first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, for which approval for this additional indication was obtained in December 2016, will have a considerable effect on the Company's performance. Consequently, sales assumptions were made for the market share in 2019 based on two scenarios (80% and 50%), and presented as the maximum and minimum target figures, respectively.
- With regard to the Company's financial plan, the Company makes it a basic policy to maintain 18 months' worth of business funds in order to ensure business continuity. Funding is required for development of in-licensed drugs; and investments for new in-licensing and M&As to ensure long-term growth opportunities and other funding requirements for the establishment of the Company's own salesforce, are anticipated. The Company will consider various means of flexible fund procurement, including raising funds from the financial and capital markets, as well as business partnerships, in line with future business development needs.
- The total number of the Company's authorized shares was increased from 56,000,000 shares to 167,000,000 shares, following the approval of partial amendment to the Articles of Incorporation at the Extraordinary Shareholders' Meeting held on November 11, 2016.

III. Other Reference Information

Status of the Development Portfolio and Performance Targets

Development Product/Therapeutic Categories	Indication(s)	Phase I	Phase II	Phase III	Filing of a New Drug Application for Approval	Approval
TREAKISYM® Anticancer Drug	Relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma	Approved in October, 2010				
	First-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma	Approved in December, 2016				
	Chronic lymphocytic leukemia	Approved in August, 2016				
	Relapsed/refractory intermediate/high-grade B-cell non-Hodgkin's lymphoma	Phase II completed				
rigosertib (intravenous) Anticancer Drug	Relapsed/refractory higher-risk MDS (myelodysplastic syndromes)	Phase I completed; Phase II target (FY 2017); Phase III target (FY 2018); Approval target (FY 2019)				
rigosertib (oral) Anticancer Drug	Higher-risk MDS in combination with azacitidine	Phase I completed; Phase II target (FY 2017); Phase III target (FY 2018); Approval target (FY 2019)				
	Transfusion-dependent lower-risk MDS	To be determined based on Onconova's development status				
SyB P-1501 Patient-controlled pain management drug	Short-term management of acute post-operative pain during hospitalization	Phase I completed; Phase II target (FY 2017); Phase III target (FY 2018); Approval target (FY 2019)				

Note

-  Shows the development plan
-  Completed as of December 31, 2016 (FY 2016)
-  FY 2017 target
-  FY 2018 target
-  FY 2019 target

The portfolio summary and issues regarding accomplishment of plans are set out below

- SyB L-0501 (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)

Summary:

- SyB L-0501 is a cytotoxic, anticancer agent. It has been in use in Germany since the 1970s for the treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma and chronic lymphocytic leukemia, and is now approved and sold in 88 countries around the world.
- In December 2005, the Company obtained the exclusive rights for development and marketing from its licensor, Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., to develop and sell the drug in Japan, China (incl. Hong Kong), South Korea, Taiwan and Singapore, and has obtained approval in all licensed territories with the exception of China.
- The history of approvals and sales of SyB L-0501 in Japan is as follows. Since its launch in Japan, TREAKISYM® has been administered to approximately 18,000 patients (estimated by the Company) as of the end of FY 2016:

- October 2010: Obtained approval for manufacturing and marketing of TREAKISYM® for the indications of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.
- December 2010: Initiated sales through Eisai, a business partner.
- August 2016: Obtained approval for the additional indication of chronic lymphocytic leukemia.
- September 2016: Obtained approval for marketing of TREAKISYM® intravenous infusion 25mg.
- December 2016: Obtained approval for the additional indications of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.
- January 2017: Initiated sales of TREAKISYM® intravenous infusion 25mg.

Issues and Specific Measures:

- The Company will promote the full and proper use of TREAKISYM® as a new treatment option in order to meet underserved medical needs. It will also take the initiative in maximizing sales and further expand its indications in an effort to optimize its product value.

➤ **Maximizing Sales**

In Japan, our most significant market, sales of TREAKISYM® are generated through Eisai, our business partner. In order to promote further market penetration, the efficacy and safety of the drug as supported by positive data in clinical trials need to be more widely understood so that it is prescribed more often. To that end, the Company considers it essential to work closely with Eisai and plan strategies vis-à-vis competing therapies, and tactically execute strategic marketing activities such as academic conferences and study groups. Going forward, the Company will encourage full and proper use of TREAKISYM® and promote its market penetration particularly for first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, by ever-strengthening its collaboration with Eisai to further increase

sales. This will lead to establishing its position as the initial drug of choice and maximizing the product value of TREAKISYM®.

➤ Promotion of Indication Expansion

Regarding the additional indication of relapsed/refractory intermediate/high-grade non-Hodgkin's lymphoma, the Phase II study has shown positive results and the Company will continue to make best efforts towards obtaining approval. Sales and expenses related to this indication are not reflected in this Mid-Range Plan.

○ SyB L-1101 (intravenous formulation) / SyB C-1101 (oral formulation) (generic name: rigosertib sodium)

Summary:

- rigosertib sodium is an anticancer drug which functions as a unique multi-kinase inhibitor (which has the effect of eradicating cancer cells by inhibiting multi-kinase involved in the growth, proliferation, and metastasis of the cells). Since obtaining exclusive rights to develop and commercialize the drug (both intravenous formulation and oral formulation) in Japan and South Korea from Onconova in July 2011, the Company has been actively conducting clinical development of this drug.
- With regard to rigosertib (intravenous), the Company is in charge of the clinical development in Japan, as part of the global Phase III study (INSPIRE trial) conducted by Onconova, the licensor, and started the domestic trial in December 2015. This global Phase III study is conducted with clinical trial sites in more than ten countries worldwide, for HR-MDS patients who do not respond to treatment with HMAs or who relapse after treatment under the current standard of care ("Primary HMA Failure"). The Company completed the first patient enrollment in July 2016 and is currently working on procedures to enroll more patients with the disease.
- With regard to rigosertib (oral), Onconova is currently in the process of determining the plans for the global Phase III study for HR-MDS patients using the oral formulation of rigosertib in combination with azacitidine. Meanwhile, the Company started its domestic Phase I study for the target indication of HR-MDS in December 2015. However, provision of the investigational drug for Onconova's clinical trial has been delayed, and thus the patient enrollment has been suspended at present.
- The Phase I study in Japan for rigosertib (oral) for the indication of transfusion-dependent lower-risk MDS has already been completed.

Issues and Specific Measures:

- The Company will enhance its growth potential and aim to expand future revenue opportunities by proceeding with clinical trials to obtain marketing approval for rigosertib (intravenous / oral), as a new drug candidate following TREAKISYM®.
- Accelerating Various Clinical Trials for Marketing Approvals
With regard to rigosertib (intravenous), the Company aims to complete the INSPIRE trial promptly in order to file a new drug application for manufacturing and marketing approval in 2018. As for rigosertib (oral), the Company will resume patient enrollments in the Phase I

study in Japan, once the matter of drug provision is resumed. After completion of the trial, it plans to participate in the global Phase III study in 2019. Regarding the future clinical development plans for the indication of transfusion-dependent lower-risk MDS through the oral formulation, the Company will discuss its plan, taking Onconova's development status into account.

○ SyB P-1501 (a patient-controlled pain management drug)

Summary:

- SyB P-1501 is a drug for patient-controlled, short-term management of acute post-operative pain during hospitalization. The Company acquired the exclusive development and distribution rights for SyB P-1501 in Japan from U.S.-based The Medicines Company (New Jersey) in October 2015.
- SyB P-1501 is a highly convenient, patient-controlled iontophoretic transdermal system providing on-demand systemic delivery of analgesia (patient-controlled analgesia, "PCA"). 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.
- For medical institutions also, SyB P-1501 is a very advantageous and innovative product for PCA that can be maintained and managed very easily, thus substantially reducing costs and the labor of healthcare professionals when compared to the current PCA method using an electrical pump.
- SyB P-1501 was approved in the U.S. and Europe (April 2015 and November 2015 respectively) and sales have commenced. In Japan, the Phase I study targeting healthy volunteers has been completed and the Phase III study for the indication of short-term acute post-operative pain management during hospitalization started in June 2016, with the Company completing the first patient enrollment in November 2016.
- For the actual sales of SyB P-1501 after approval is obtained, first the Company will mainly target the replacement market for the IV-PCA (intravenous patient-controlled analgesia) method, and then penetrate the patient-controlled epidural analgesia market and also the overall market for post-operative pain management where PCA is not used, in an effort to expand revenue opportunities in the medium- to long-term.

Issues and Specific Measures:

- The Company will enhance its growth potential and aim to expand future revenue opportunities by proceeding with clinical tests to obtain marketing approval for SyB P-1501, as a new drug candidate following TREAKISYM[®], as well as rigosertib (intravenous formulation / oral formulation).
- Early Application for Marketing Approvals
For SyB P-1501 the Company plans to submit an application for manufacturing and marketing approval upon completion of the Phase III study in Japan since the Phase I study has been completed and the Company can utilize the data from clinical trials carried out in the U.S. and Europe to expeditiously obtain its approval. The Company intends to promptly

complete the Phase III study in Japan, which is underway, and submit an application for approval in 2018.

This disclosure document is for the purpose of providing information on the Company's future business strategies to investors, and is not for the purpose of soliciting investment.

Evaluation of the Company's business strategies and investment decisions shall be made by investors themselves based on their own judgment.

The Company does not guarantee, in any sense, the possibility of realizing and achieving any performance target or other matter of our business strategies and does not assume any liability for any such information.

All forward-looking statements (including, but not limited to, the performance targets in our business plan) contained in this document have been prepared by the Company at its discretion based on the information available as of the date of this document. Therefore, in the event there are future changes to conditions that comprise the assumptions of its business strategy, such as economic conditions, there may be an impact on its actual business condition and performance such that the results will be different from statements in this disclosure document.