English translation

February 10, 2016

SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and CEO
(Securities code: 4582)

Tetsuya Maruyama
Director
Finance & Accounting
(TEL. +81-3-5472-1125)

SymBio's Long Range Plan: FY 2016 to FY 2018

I. Long Range Plan for the Next Three Years

(1) Overview of FY 2015 Business Results as of the Date of the Long Range Plan

Progress in the Company's business for FY 2015 (from January 1, 2015 to December 31, 2015) 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 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.

2. Overseas

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

3. 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).

(2) SymBio's Long 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. Because major pharmaceutical companies are reluctant to develop drugs for smaller indications and lower patient numbers in these areas due to questionable returns versus the amount of investment required, various therapeutic areas in oncology, hematology and pain management are regarded as "underserved therapeutic areas" in terms of development.

The Company sees business opportunities in these "underserved therapeutic areas" despite the relatively small market potential, focusing on new drug candidates having high unmet medical needs instead of pursuing new "blockbuster" drugs (where sales often surpass 100 billion yen). Capturing high revenues 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 the lack of its own research and manufacturing facilities. The Company outsources and oversees the clinical development of quality in drug candidates that it has in-licensed from pharmaceutical companies in the U.S. and/or Europe. This enables the Company to avoid a large capital investment and 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 an early return to profitability through the continuation of these efforts.

SymBio's Long Range Plan is as follows:

- To maximize the value of our main product, TREAKISYM®, for which manufacturing

and marketing approval has been granted in refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and aggressively pursue the expansion of indications (life cycle management). The Company has submitted an application for approval in the treatment of first-line low-grade non-Hodgkin's lymphoma ("Lg-NHL"), mantle cell lymphoma ("MCL"), and Chronic Lymphocytic Leukemia (CLL). The Company will make every effort to receive these approvals as soon as possible.

- To develop rigosertib (intravenous formulation / oral formulation) as a therapy for MDS.
- To promote the development of SyB P-1501, a drug for patient-controlled analgesia introduced in October 2015, for the indication of short-term acute post-operative pain management during hospitalization.
- To conduct joint research and development of an anti-cancer drug, which uses the TTR1 nano-agonist molecule, in collaboration with Teikyo Heisei University, with an aim to develop and commercialize the drug globally.
- To increase selling, general and administrative expenses, mainly research and development costs, in order to undertake clinical trials with the aim of launching rigosertib (intravenous formulation / oral formulation) and SyB P-1501.
- To consider and prepare for establishing in-house sales and distribution channels, giving particular attention to the timing of marketing approval for rigosertib.
- To proactively search for and evaluate new development candidates as well as expanding ourdevelopment phases and areas in order to establish a stronger pipeline/portfolio.
- With these initiatives, SymBio 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.

(3) Business Status, Outlook and Other Assumptions

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

- Domestic sales of TREAKISYM® began through Eisai, our business partner, with the drug's launch in December 2010, for refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Sales have been increasing steadily and the market share has reached a high point.
- Going forward, in order to further increase sales of TREAKISYM®, the Company has focused its efforts on maximizing the value of TREAKISYM® by continuously promoting its strategic marketing collaboration with Eisai, encouraging continuous proper use of TREAKISYM®, and obtaining early approval for additional indications.
- In December 2015, the Company completed the filing of marketing approval for indications of frontline low-grade non-Hodgkin's lymphoma, mantle cell lymphoma and

chronic lymphocytic leukemia. In order to receive approval as soon as possible, the Company will make every effort to quickly address any questions the PMDA might have.

- Regarding the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Phase II clinical trial generated positive data and the Company will continue to pursue approval for this indication.

○ SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation); generic name: rigosertib

- With regard to rigosertib intravenous formulation, the Company will carry out a clinical trial in Japan as part of Onconova's global Phase III clinical trial for the indication of refractory/relapsed higher risk MDS, aiming for early approval.
- With regard to rigosertib oral formulation, the Company will proactively continue the Phase I clinical trial in Japan, in combination with azacitidine, for the indication of higher risk MDS. 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 patient-controlled analgesia

- Regarding SyB P-1501, the Company will proceed with preparations for launching a Phase III clinical trial, for the indication of short-term acute post-operative pain management during hospitalization, in the 3rd quarter of FY 2016. The Company will make steady progress with the trial, aiming for early approval and launch in Japan.

○ Anti-cancer Drug using the TTR1 Nano-agonist Molecule

- The Company will carry out joint research and development with Teikyo Heisei University with an aim to develop and commercialize the drug globally.

○ Establishment of the Company's own sales and distribution channels

- While marketing TREAKISYM® in Japan through its business partner, Eisai, the Company believes it necessary to establish its own sales and distribution channels to raise profitability. The Company should make an appropriate decision about the timing of the establishment of these channels and the effectiveness of its system since it could require additional costs to establish the channels and to maintain continuous employment of many Medical Representatives.
- Closely monitoring the timing of the marketing approval for rigosertib intravenous formulation, the Company will consider establishing its own sales and distribution

channels.

○ Shift from an Asian regional strategy to a global strategy

➢ Going forward, the Company's strategy is to focus on business growth as a global specialty pharma, instead of a specialty pharma focused on the Asian region. When researching, evaluating and negotiating for in-licensing for new drug candidates, the Company will focus on obtaining an exclusive right to commercialize the new drug candidates on a global basis.

○ New drug candidates

➢ The Company continues to evaluat several new drug candidates under 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 times.

II. Earnings Forecast and Performance Targets

(Unit: millions of yen)

Fiscal year	Net sales	Operating income (loss)	Ordinary income (loss)	Net income (loss)
FY 2015 (Actual)	1,933	(2,551)	(2,630)	(2,632)
FY 2016 (Forecast)	2,339	(2,778)	(2,811)	(2,815)
FY 2017 (Target)	2,604 to 2,188	(3,379) to (3,521)	(3,412) to (3,554)	(3,416) to (3,558)
FY 2018 (Target)	2,974 to 2,298	(3,526) to (3,778)	(3,559) to (3,811)	(3,563) to (3,815)

Assumptions and Numerical Basis for Projections and Performance Targets

○ With regard to sales, TREAKISYM® makes up the majority of product sales. The performance target for drug sales assumes that new drugs (additional indications) are approved as assumed in the business plan, and figures are derived after detailed analysis and discussions on market size projections, competitive positioning vis-à-vis existing therapies, market dominance, and sales performance after the commencement of sales. Furthermore, milestone revenue is estimated based on the Company's development plan.

○ Cost of sales is estimated based on the provisions of existing license agreements.

○ Selling and general administrative expenses mainly consist of research and development ("R&D") expenses or other selling expenses and general administrative expenses.

- Research and development expenses are estimated based on "III. Other Reference Information – Status of Development Portfolio and Performance Targets". With regard to TREAKISYM®, since the business alliance agreement with Eisai provides that R&D expenses shall be split equally between the two parties, half of the estimated expenses are assumed. Milestone payments are estimated in accordance with provisions in the existing contract. In-licensing and development costs are not accounted for, although the Company is proceeding with continuous evaluation and discussion for the candidates.
- Other selling and general administrative expenses mainly consist of expenses incurred from TREAKISYM® marketing, new business development, production & distribution and administrative operations. With regard to TREAKISYM®, since the business alliance agreement with Eisai provides that marketing expenses shall be split equally between the two parties, half of the estimated expenses are assumed, similar to the R&D expenses.
- As stated in "I. (3) Business Status, Outlook and Other Assumptions," the Company plans to establish its own sales and distribution channels. In this Long Rage Plan, the respective costs are accounted for based on the assumption that preparations will begin in FY 2017.

○ With respect to the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, no related sales and expenses are assumed.

○ In addition, while application for approval for the indication of frontline low-grade non-Hodgkin's lymphoma has been completed in Japan, approval status may be dependent upon the status of approval in Europe. Therefore, numerical assumptions were made based on two scenarios (approval obtained in Europe / approval not obtained in Europe) and presented as the maximum and minimum figures.

SymBio Pharmaceuticals Limited

III. Other Reference Information

Status of Development Portfolio and Performance Targets

Development product Therapeutic category	Indication	Phase I clinical trial	Phase II clinical trial	Phase III clinical trial	File for Marketing Approval	Marketing Approval
TREAKISYM® Anticancer drug	Refractory/relapsed low-grade non-Hodgkin's lymphoma; mantle cell lymphoma	Marketing Approval (October, 2010)				
	Frontline low-grade non-Hodgkin's lymphoma; mantle cell lymphoma					
	Chronic lymphocytic leukemia					
	Refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma			Phase II completed		
Rigosertib Anticancer drug (Intravenous formulation)	Refractory/relapsed higher risk MDS (myelodysplastic syndrome)					
Rigosertib Anticancer drug (Oral formulation)	Higher risk MDS (in combination with azacitidine)			Participation in global clinical trials is to be considered		
	Transfusion-dependent lower risk MDS			To be determined based on Onconova's development status		
SyB P-1501 Drug for patient-controlled analgesia	Short-term acute post-operative pain management during hospitalization					

Note 1. : The development plan

: Completed as of December 31, 2015 (FY 2015)

: FY 2016 target

: FY 2017 target

: FY 2018 target

2. With regard to the anti-cancer drug using the TTR1 nano-agonist molecule, the Company will carry out the joint research and development with Teikyo Heisei University in FY 2016 and evaluate the outcome for obtaining the global license.

Portfolio summary and issues for achieving plans are set out below.

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

Summary:

- Bendamustine hydrochloride was used in Germany for many years as an anticancer drug for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia (trade name: Ribomustin).
- From 2000, the efficacy and safety of this drug has been re-evaluated and it is now approved and sold in 76 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. Going forward, the Company will continue to collaborate closely with local business partners to maximize sales.
- In Japan, manufacturing and marketing approval was obtained in October, 2010, for refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, with sales initiated through Eisai, a businesspartner, in December, 2010. Since its launch in Japan, TREAKISYM® has been administered to approximately 15,000 patients (estimated by the Company) as of the end of FY 2015.
- In order to expand the value of TREAKISYM®, in December 2015, the Company filed an application for domestic marketing approval for indications of first-line low-grade non-Hodgkin's lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia. The Company will continue to discuss the future development plan for the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma.

Issues and Specific Measures:

- Promotion of Indication Expansion

  Although the application for approval has been already completed for the indication of first-linelow-grade non-Hodgkin's lymphoma and mantle cell lymphoma, approval status may be dependent upon the status of approval in Europe. Therefore, numerical assumptions were made based on two scenarios (approval obtained in Europe / approval not obtained in Europe) and presented as the maximum and minimum figures. The application for approval for the indication of chronic lymphocytic leukemia has also been completed. Since it is designated as an orphan drug, the Company will make every effort to receive approval as soon as possible by quickly addressing any questions the PMDA might have.

Regarding the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Phase II clinical trial 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 Long Range Plan.

- Maximizing Sales

  In Japan, our most significant market, sales of TREAKISYM® are generated through Eisai, our business partner. In order to further promote market penetration, the efficacy and safety of the drug supported by positive data in clinical trials needs to be more widely understood so that it is more often prescribed. To that end, the Company will work closely with Eisai and plan strategies vis-à-vis competing therapies, and tactically develop marketing strategies such as future collaborations with Eisai on academic conferences and study groups.

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

Summary:

- Rigosertib is an anticancer drug which functions as a unique multi-kinase inhibitor. Since obtaining exclusive rights to develop and commercialize the drug in Japan and South Korea from Onconova in July, 2011, the Company has been actively developing this drug. The Company has obtained rights for both the intravenous and oral formulations.
- With regard to development of this drug, currently, Onconova is pursuing development in the U.S. and Europe mainly for the indications of myelodysplastic syndromes ("MDS"). With regard to the intravenous formulation for refractory/relapsed higher risk MDS, Onconova is carrying out the a global Phase III clinical trial for patients who do not respond to treatment with the current standard of care, hypomethylating agents ("Primary HMA Failure") or high risk MDS patients who relapse after treatment. With regard to the oral formulation, the Phase II clinical trial for the indication of transfusion-dependent lower risk MDS is underway, and a Phase I/II clinical trial (in combination with azacitidine) for the indication of first-line higher risk MDS is also underway.
- Currently, the Company is conducting a clinical trial in Japan as part of the global Phase III clinical trial using the intravenous formulation for the indication of refractory/relapsed higher risk MDS, as well as a Phase I clinical trial using the oral formulation for the indication of higher risk MDS (in combination with azacitidine).

Issues and Specific Measures:

- Accelerating Various Clinical Trials for Marketing Approvals

  With regard to the intravenous formulation, the Company is conducting a clinical trial in Japan as part of Onconova's global Phase III clinical trial for the indication of refractory/relapsed higher risk MDS. The Company aims to complete the trials swiftly in order to file application for approval in FY 2018, the same year as the expected filings in Europe and the U.S.

  With regard to the oral formulation, a domestic clinical trial will be conducted after taking into consideration two trials: (i) first-line higher risk MDS in combination with azacitidine and (ii) transfusion-dependent lower risk MDS which are currently underway in Europe and the U.S. The Company prioritizes the domestic Phase I clinical trial (in combination with azacitidine) for higher risk MDS. Regarding the clinical trial for the indication of transfusion-dependent lower risk MDS, the Company will discuss its plan, taking Onconova's development status into account.

- Use of Overseas Data

  In order to reduce costs and shorten development timelines, the future development of drug candidates in the Company's pipeline will include participation in global clinical trials whenever possible. The Company will thoroughly review clinical data generated from overseas clinical trials to ensure the quality of domestic marketing approval applications.

○ **SyB P-1501 (a drug for patient-controlled analgesia)**

Summary:

- SyB P-1501 is a drug for short-term self-management of acute post-operative pain in adult patients during hospitalization. The Company acquired the exclusive development and distribution right for SyB P-1501 in Japan from U.S.-based The Medicines Company (New Jersey) in October 2015.
- SyB P-1501 is a 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.
- In addition to providing convenience to patients, SyB P-1501 is also a very innovative drug for patient-controlled analgesia that requires substantially reduced costs and labor for medical institutions when compared to the current PCA method using an electrical pump.
- SyB P-1501 has been approved in the US and Europe and sales have commenced. In

Japan, the Phase I clinical trial targeting healthy volunteers has been completed.

Issues and Specific Measures:

- Early Application for Marketing Approvals

  The Company expects to be able to submit an application for approval upon completion of the Phase III clinical trial in Japan since the Phase I clinical trial has been completed and the Company can utilize the data from clinical trials carried out in the US and Europe for its approval. Thus, the Company plans to start the Phase III clinical trial in FY 2016 and submit an application for approval in FY 2018.

○ **Anti-cancer Drug using the TTR1 Nano-agonist Molecule**

Summary:

The team led by Dr. Isao Ishida, Professor of the Faculty of Pharmaceutical Sciences, Teikyo Heisei University, discovered an antibody against TRAIL-R1 that is expressed on the surface of cancer cells or cancer stem cells, and modified its form to impart more efficient anti-cancer activity (TTR1 nanoagonist). A drug delivery technique using an expression system in Bifidobacterium was developed which enables the TTR1 nano-agonist to act selectively on hypoxic cancer tissue, with confirmation of the anti-cancer activity and safety of this new anti-cancer drug in animal models.

Issues and Specific Measures:

- Promotion of Joint Research and Development

  The Company will collaborate on research and development with Teikyo Heisei University and evaluate the outcome for obtaining a global license.