February 7, 2018
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582, JASDAQ Growth)

SymBio's Mid-Range Plan: FY 2018 to FY 2021 (Four Years)

I. Mid-Range Plan for the Next Four Years

(1) Overview of FY 2017 Business Results as of the Date of the Mid-Range Plan

Progress in the Company's business for FY 2017 (from January 1, 2017 to December 31, 2017) is as follows:

1. Domestic

[Anticancer agent: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (ready-to-dilute ("RTD") formulation), SyB L-1702 (rapid infusion ("RI") formulation) and SyB C-0501 (oral formulation) (generic name: bendamustine hydrochloride, trade name: TREAKISYM®)]
The Company markets TREAKISYM® in Japan through its business partner, Eisai Co., Ltd. ("Eisai"). The Company obtained marketing approval for first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in December 2016, and for chronic lymphocytic leukemia in August 2016. These are in addition to the approvals for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma which were obtained in October 2010. This indication expansion has resulted in a significant in-market sales increase of 60.9% year-on-year (NHI price basis). Net sales to Eisai also grew considerably, by 62.7% year-on-year.

In addition to the three already approved indications, the Company continues to work on obtaining approval for recurrent/refractory intermediate/high-grade non-Hodgkin's lymphoma (diffuse large B-cell lymphoma) to benefit patients in need of new therapies and to further maximize product value. For these indications, the Company has completed a Phase II clinical trial and in August 2017 began a Phase III clinical trial (designed in accordance with consultations with the Pharmaceuticals and Medical Devices Agency ("PMDA")) and completed the first patient enrollment in January 2018.

In addition to the ongoing label expansion initiatives, the Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) ("Eagle") in September 2017, under which Eagle licensed to the Company rights under Eagle's intellectual property to develop, market, and sell Eagle's RTD and RI liquid formulations ("TREAKISYM® liquid formulation") (Note 1) in Japan. This will further enable the Company to extend the product life until

2031 through patent protection and maximize the value of TREAKISYM®, while bringing significant benefits to patients and medical professionals. (See press release dated September 21, 2017 titled "Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited.")

In addition to the development and expansion of the intravenous formulation product, the Company is exploring the development of an oral formulation of TREAKISYM® with a focus on the treatment of solid tumors and autoimmune diseases and intends to further expand the business, with an aim to solidify its business through a platform of TREAKISYM® products. Amid such initiatives, the Company commenced a Phase I clinical trial for progressive solid tumors in January 2018, with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of TREAKISYM®, and narrowing down the types of potential target tumors.

(Note 1) RTD and RI are pre-dissolved liquid formulations that differ from currently available freeze-dried ("FD") powder injection. RTD (ready-to-dilute) will significantly reduce the preparation time and labor cost for healthcare providers, and RI (rapid infusion) will reduce infusion duration to 10 minutes from the current 60 minutes, providing significant benefit and value to both patients and healthcare providers.

[Anticancer agents: SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation), generic name: rigosertib]
U.S. Licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) ("Onconova") is conducting a global Phase III clinical trial (with trial sites in more than 20 countries) of the intravenous formulation of rigosertib sodium for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents ("primary HMA failure") or which relapse after treatment under the current standard of care. The Company is responsible for clinical development in Japan and in December 2015 started a domestic trial for which 30 patients are already enrolled. The Company completed the first patient enrollment in Japan in July 2016 and patient enrollment is proceeding favorably. Based on the results of the interim analysis completed in January 2018, the Company will continue the trial with an increase in patient enrollment in accordance with pre-determined statistical criteria.

Regarding the oral formulation of rigosertib, the domestic Phase I clinical trial for combination therapy with azacitidine (Note 2) for the target indication of HR-MDS began in December 2015. Although delays with the investigational drug by Onconova had delayed patient enrollment, Onconova has recently resumed provision of the investigational drug and the Company commenced a new domestic Phase I clinical trial in June 2017 to confirm the safety of high-dose oral rigosertib, which was added to the Phase II clinical trial being conducted by Onconova in the U.S. for first-line treatment and recurrent/refractory treatment of patients with HR-MDS. First patient enrollment was completed in October 2017. After safety is confirmed through this trial, the Company plans to conduct a domestic clinical trial for combination therapy with azacitidine, and to take part in Onconova's planned global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with HR-MDS.

(Note 2) About azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug (for injection) 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. MDS is a preleukemic state, and decrease in tumor suppressor gene due to excessive methylation of DNA is thought to be related to the disease. Hypomethylating agents such as azacitidine are thought to suppress progress to leukemia by restoring tumor suppressor gene with a deterrent effect against methylation of DNA.

[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 US-based The Medicines Company (Head Office: New Jersey, U.S.) for an exclusive license to develop and commercialize SyB P-1501 in Japan. 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, with enrollments accumulating. The Company, acting in the best interest of patients, determined on April 21, 2017 to temporarily suspend new patient enrollment due to its recently arising concern as to the continuity of The Medicines Company's business regarding the product. The license agreement with Incline Therapeutics, Inc. terminated effective November 30, 2017.

The Company initiated an arbitration against The Medicines Company on October 11, 2017, under the rules of the International Chamber of Commerce, seeking damages of 82 million U.S. dollar (approximately 9.0 billion yen) arising from The Medicines Company's repudiation of the license agreement. (See press releases "Initiation of an Arbitration against The Medicines Company," dated November 13, 2017, and "Termination of License Agreement between SymBio Pharmaceuticals Limited and The Medicines Company," dated November 30, 2017.)

In conjunction with the termination of the license agreement, the Company will terminate the development of SyB P-1501, a process that the Company expects to complete by March 31, 2018.

[New drug candidates]
The Company continues to actively seek new drug candidates and in-licensing opportunities globally, aiming to expand both profitability and growth potential over the medium-to-long-term, and discussions with multiple potential licensors are ongoing.

In May 2016, the Company established a wholly-owned subsidiary, SymBio Pharma USA, Inc. (Menlo Park, California, U.S., "SymBio Pharma USA"), as the Company's planned strategic base for overseas business development. Acquiring rights to new drug candidates through SymBio Pharma USA as the base of global business will be part of the Company's continued transformation into a global specialty biopharmaceutical company with capability to develop and commercialize new drugs in the U.S., Japan, Europe, and other major global markets.

2. Markets outside Japan

SyB L-0501 is also marketed in South Korea, Taiwan, and Singapore, and product sales of SyB L-0501 in these countries progressed favorably at a pace exceeding the Company's forecasts.

3. Business results

As a result of the above, net sales totaled 3,444,206 thousand yen for the fiscal year ended December 31, 2017, primarily reflecting product sales of TREAKISYM® in Japan. Product sales showed a year-on-year increase of 61.1%. Accordingly, overall net sales rose 45.4% year-on-year.

Selling, general and administrative expenses totaled 4,978,327 thousand yen (a year-on-year increase of 64.2%), including research and development ("R&D") expenses of 3,017,812 thousand yen (a year-on-year increase of 81.0%) primarily due to the upfront payment relating to the license agreement with Eagle Pharmaceuticals for TREAKISYM® liquid formulation (RTD and RI formulations) and 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 1,960,514 thousand yen (a year-on-year increase of 43.7%).

As a result, an operating loss of 3,947,061 thousand yen was recognized for the fiscal year ended December 31, 2017 (an operating loss of 2,127,049 thousand yen for the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 34,229 thousand yen primarily comprising stock issuance costs of 14,477 thousand yen, foreign exchange losses of 10,421 thousand yen, and commission fees of 9,090 thousand yen, and non-operating income totaling 4,506 thousand yen primarily due to interest income of 3,092 thousand yen and dividend income of 1,339 thousand yen. This resulted in an ordinary loss of 3,976,784 thousand yen (an ordinary loss of 2,316,806 thousand yen for the previous fiscal year) and net loss of 3,977,862 thousand yen (a net loss of 2,313,233 thousand yen for the previous fiscal year).

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

SymBio is the first Japanese "specialty pharma" specializing in the areas of 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 as large pharmaceutical companies avoid development due to concerns about operational efficiency and 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 (drugs with sales surpassing 100 billion yen). Capturing revenue opportunities through the development and sale of drugs in these therapeutic areas is at the core of the Company's business.

One significant aspect of the Company's business model is to in-license drug candidates with clinically confirmed efficacy and safety from pharmaceutical and bio venture companies in the U.S. and Europe after rigorous evaluation. This enables the Company to avoid having its own in-house research and manufacturing function and the associated large capital investments 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 (mainly through 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 to achieve profitability through the continuation of these efforts.

SymBio's Mid-Range Plan (FY 2018 to FY 2021) sets out to achieve profitability in FY 2021 as the top-priority management goal. Under this plan, which covers a four year period, the Company has formulated sales structure plans, including development of the Company's own salesforce, and a pipeline development plan. An outline of the plan is as follows.

- Maximize the commercial value of TREAKISYM® and to ensure sustainable profitability and growth potential, through:
  - Increasing sales from already approved indications: increasing market share by further promoting penetration of first-line treatment of low-grade non-Hodgkin's lymphoma.
  - Expansion through additional indications: complete the Phase III study for the indication of relapsed/refractory diffuse large B-cell lymphoma as planned, with the aim of filing a new drug application by the first half of 2020.
  - Product lifecycle management: launch RTD formulation in the first half of 2021 (and the RI formulation at a subsequent date), and proceed to switch from the current lyophilized powder formulation to a liquid formulation as soon as practicable.
  - Development of oral TREAKISYM®: advance the Phase I study of an oral formulation for progressive solid tumors and engage in commercialization of an oral formulation to provide a new treatment option in the future.
- Proceed with clinical trials to obtain approval for intravenous and oral formulations of rigosertib, as new drug candidates following TREAKISYM®, thereby enhancing the

Company's growth potential and expanding revenue opportunities.

- Establish the Company's own salesforce to maximize profit, giving appropriate consideration to the expiration of the business partnership agreement with Eisai in December 2020 and the timing of marketing approval for rigosertib intravenous formulation.
- Search for and evaluate new drug candidates for development and continue to explore in-licensing opportunities, giving due consideration to the impact on achieving profitability in FY 2021.

(3) Business Status, Outlook and Other Assumptions

○ SyB L-0501 (lyophilized powder formulation), SyB L-1701 (RTD formulation), SyB L-1702 (RI formulation) and SyB C-0501 (oral formulation) (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)

- Domestic sales of TREAKISYM® began with the drug's launch in December 2010 for relapsed/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. TREAKISYM® is marketed through our marketing partner, Eisai Co., Ltd., ("Eisai"). Sales have increased steadily and the market share among patients with relapsed/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma reached a new high point in 2017.
- 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. As a result of steady progress in market penetration including for first-line treatment of low-grade non-Hodgkin's lymphoma, net sales for FY 2017 totaled 7.6 billion yen, an increase of 60.9% year-on-year (NHI price basis).
- Going forward, in order to further increase sales of TREAKISYM®, the Company in collaboration with Eisai will reinforce marketing to promote and encourage the full and proper use of TREAKISYM®, especially as first-line treatment for low-grade non-Hodgkin's lymphoma, establishing TREAKISYM® as the initial drug of choice in 2018, with the aim of achieving a 60% market share.
- Regarding the additional indication of relapsed/refractory diffuse large B-cell lymphoma (DLBCL), after completing the Phase II study for bendamustine-rituximab (BR) therapy and achieving promising clinical trial results, the Company commenced a Phase III study in August 2017 with a view toward confirming the efficacy and safety of the Phase II study. The Company will complete this trial as planned, aiming to file a new drug application in the first half of 2020.
- The Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. ("Eagle") on September 20, 2017, under which Eagle licensed to the Company rights under Eagle's intellectual property to develop, market and sell Eagle's liquid formulation injection products in Japan (to be marketed as TREAKISYM® RTD and TREAKISYM® RI). Taking countermeasures against the probable launch of generics in Japan was a key consideration as the marketing exclusivity period for the current FD formulation in Japan will expire in late 2020. Patent protected through 2031, the RTD and RI liquid formulations will significantly extend the product life of TREAKISYM®. The Company will aim to obtain approval for RTD in the first half of 2021 (and for RI at a subsequent date). The Company will aim to achieve a

complete transition from the current lyophilized powder formulation to the liquid formulation as soon as possible after the launch of RTD.

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

- Rigosertib intravenous: the interim analysis 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") was completed in January 2018. The independent Data Monitoring Committee (DMC) (Note 3) recommended that the INSPIRE trial continue with enrollment increased from then current 225 patients to 360 patients. Onconova announced it would follow the DMC's recommendation. The enrollment criteria for the expanded study will be identical to that of the original study. Patients with HR-MDS who are refractory to HMAs have limited treatment options and there is extremely high unmet medical need with existing therapies. Based on the DMC's recommendation, the Company will continue in collaboration with Onconova to move forward with the trial with an increase in the total enrollment of patients in Japan up to 40 patients. The Company aims to file a new drug application for manufacturing and marketing approval for indications of relapsed/refractory HR-MDS in 2021.

(Note 3) Data Monitoring Committee (DMC): The DMC is a committee of clinical research experts with expertise to conduct an independent review of the results of the interim analysis and to provide a recommendation to the sponsor on the appropriateness of continuing the trial and on any needed changes to the trial.

- Rigosertib oral formulation: the Company started the Phase I study as a single agent in HR-MDS in June 2017, and completed the first patient enrollment in October 2017. The Company will promptly conduct an oral rigosertib/azacitidine combination trial in Japan after demonstrating the safety of oral rigosertib, and intends to participate in the global Phase III study in untreated HR-MDS patients that Onconova is now planning.
- Additionally, regarding the indication of transfusion-dependent lower-risk MDS, the Company will continue to consider its clinical development plans in view of the status of the development by Onconova.

○ SyB P-1501 patient-controlled pain management drug

- In conjunction with the termination (effective November 30, 2017) of the license agreement entered into between the Company and The Medicines Company (Head Office: New Jersey, U.S.) on October 5, 2015 for the exclusive rights to develop and commercialize the patient-controlled pain management drug SyB P-1501 in Japan, the Company has terminated the development of SyB P-1501 and will complete the process of terminating development by March 31, 2018.

○ Establishment of the Company's own salesforce

- Although TREAKISYM® is currently marketed in Japan through Eisai, the Company considers shifting sales to the Company's own salesforce to raise profitability to be a top priority. The Company considers it beneficial to establish its own salesforce so that the Company can respond to market needs more quickly and accurately to further benefit both healthcare professionals and patients. This will also lead to further enhancement of product value and the ability to provide more specialized information to healthcare professionals, furthering the Company's contribution to society.
- Under this Mid-Range Plan, the Company expects to engage in the sale of TREAKISYM® on its own from 2021 following the expiration of the business partnership agreement with Eisai in December 2020, aiming to achieve profitability in FY 2021 as the top-priority of management. However, the Company regards it essential to carefully consider the timing of the establishment of the salesforce and its optimal structure, 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 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 2018 in a timely manner.

○ New drug candidates and global business expansion

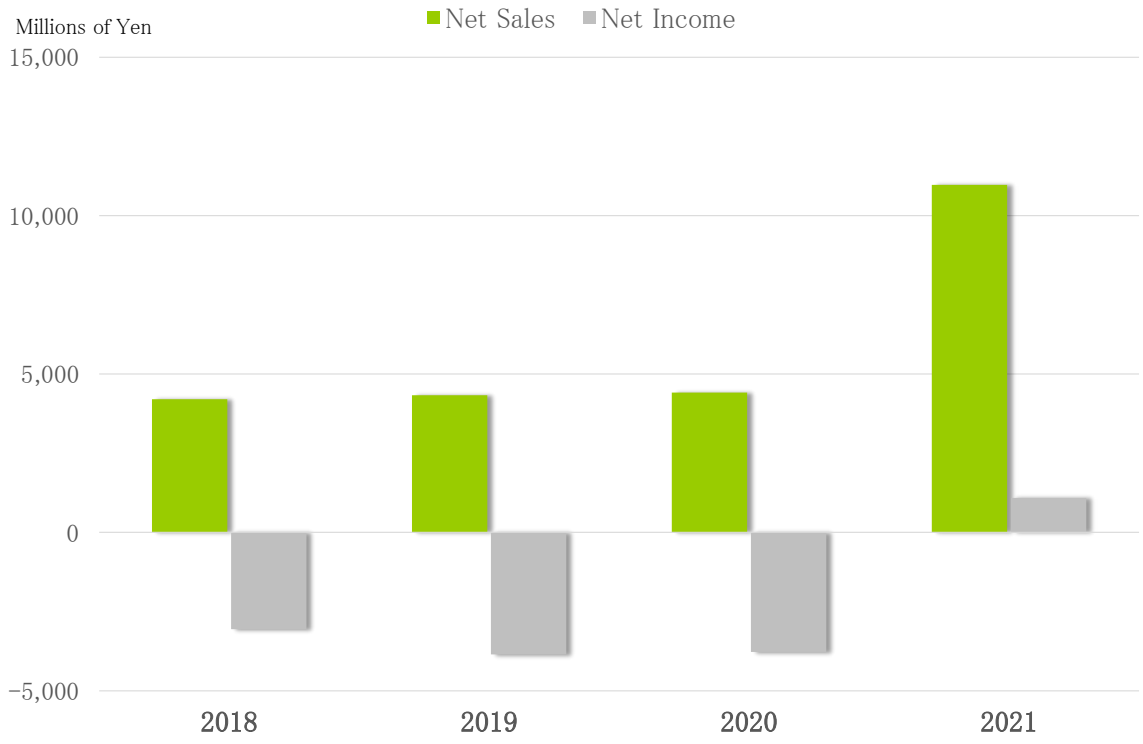
- The Company is continually evaluating new drug candidates for development. The Company will continue to consider in-licensing drug candidates that will increase corporate value, giving appropriate consideration to the impact on profits for FY 2021. When searching for, evaluating, and negotiating new drug candidates for in-licensing and development, the Company may do so with a view to commercializing on a global basis.

II. Earnings Forecast and Performance Targets

Unit: millions of yen

	FY 2018 (forecast)	FY 2019 (target)	FY 2020 (target)	FY 2021 (target)
Net Sales	4,201	4,238	4,413	11,624 ~ 10,325
Operating Income (loss)	(2,981)	(3,786)	(3,709)	1,777 ~ 878
Ordinary Income (loss)	(3,044)	(3,849)	(3,772)	1,724 ~ 825
Net Income (loss)	(3,056)	(3,853)	(3,776)	1,467 ~ 702

[Trends of Net Sales and Net Income]



* The median values of the maximum and minimum values are used for 2021.

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. As for 2021, the sales amounts are accounted for based on sales of TREAKISYM® made through the Company's own sales force.
Net sales of TREAKISYM® are expected to further expand from 2021 due to the additional indication of relapsed/refractory diffuse large B-cell lymphoma (DLBCL), for which approval is planned to be obtained in the first half of 2021. Net sales are calculated and target figures are presented based on the expected market share range for this indication.

○ Cost of sales is estimated based on the provisions of the licensing and supply agreements with Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., and Eagle Pharmaceuticals, Inc.

○ Selling and general administrative expenses mainly consist of research and development 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." Newly planned matters under this Mid-Range Plan are as follows.
  - Expenses related to a Phase III study for relapsed/refractory diffuse large B-cell lymphoma (due to commence in August 2017).
  - Expenses related to the filing of a new drug application for approval and development of TREAKISYM® liquid formulations (RTD and RI) (in-licensed from Eagle Pharmaceuticals, Inc. in September 2017).
  - Expenses related to a Phase I study of oral TREAKISYM® for progressive solid tumors (due to commence in January 2018).
- With regard to SyB L-1101 (rigosertib intravenous formulation), milestone payments to the licensors triggered at the time approval is obtained have not been included in the forecasts, given that the Company will continue to move forward with the trial with an increase in the total enrollment of patients in Japan, based on the results of the interim analysis conducted in January 2018.
- With regard to new drug candidates for development, in-licensing and development costs are not accounted for, although the Company continues to evaluate candidates for potential in-licensing.
- Other selling and general administrative expenses mainly consist of expenses incurred from TREAKISYM® marketing, production & distribution, business development and administrative operations. Expenses related to the establishment and operation of the Company's own salesforce are accounted for from 2019, due to expected sales of TREAKISYM® by the Company itself from 2021 following the expiration of the business partnership agreement with Eisai in December 2020.

○ In terms of personnel planning, there were 78 employees as of December 31, 2017, and the Company plans to maintain the minimum number of staff required to develop TREAKISYM® (the current lyophilized powder formulation, as well as RTD and RI formulations), oral TREAKISYM®, rigosertib intravenous formulation and rigosertib oral formulation. A certain increase in staff, especially medical representatives, will be required from 2019 when the Company establishes its own salesforce. Personnel costs for the establishment of such salesforce have been accounted for in the projections.

○ With regard to the Company's financial plan, the Company makes it a basic policy to maintain 18 months' worth of funding to ensure business continuity. Anticipated funding requirements include funding for the development of in-licensed drugs, for investments for new in-licensing and potential M&A to ensure long-term growth opportunities, and for the establishment of the Company's own salesforce. 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.

III. Other Reference Information

Status of the Development Portfolio and Performance Targets

Development product/ Therapeutic categories	Indications	Phase I	Phase 2	Phase 3	Filing of NDA for approval	Approval
TREAKISYM® FD 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 diffuse large B-cell lymphoma					
TREAKISYM® RTD Anticancer Drug	All approved indications					
TREAKISYM® RI Anticancer Drug	All approved indications					
TREAKISYM® Oral Anticancer Drug	Progressive solid tumors		Details are under review			
Rigosertib Intravenous Anticancer Drug	Relapsed/refractory higher-risk MDS (myelodysplastic syndromes)					
Rigosertib Oral Anticancer Drug	Higher-risk MDS in combination (mono therapy)		Plan to begin a Phase 1 study in combination with azacitidine after completing this phase 1 study.			
	1st line higher-risk MDS in combination with azacitidine			Plan to participate in the global Phase 3 study that is being planned by Onconova after completing this Phase 1 study.		

Note

The above table shows the development plan.

- Completed as of December 31, 2017
- FY 2018 target
- FY 2019 target
- FY 2020 target
- FY 2021 target

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

○ SyB L-0501 (lyophilized powder formulation), SyB L-1701 (RTD liquid formulation), SyB L-1702 (RI liquid formulation) and SyB C-0501 (oral formulation) (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 set forth below. Since its launch in Japan, TREAKISYM® has been administered to approximately 24,000 patients cumulatively (estimated by the Company) as of the end of FY 2017:

•	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 maximize the product value of TREAKISYM® through the following initiatives, in order to meet underserved medical needs. It will also take the initiative to ensure both sustainable profitability and growth potential.

- **Increasing sales from already approved indications**
  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, by ever-strengthening its collaboration with Eisai to further increase sales. The Company will establish its position as the initial drug of choice in 2018, with the aim of achieving a 60% market share, and pursues further market penetration.

- **Expansion through additional indications**

Diffuse large B-cell lymphoma (DLBCL) accounts for about one-third of malignant lymphoma, with patient numbers following an upward trend. However, a standard chemotherapy for treatment of relapsed/refractory DLBCL is currently not available. Instead, multiple drug therapies are administered which tend to have strong adverse effects placing a burden on patients. Accordingly, r/r DLBCL is a disease with high unmet medical need. The need for development of bendamustine-rituximab (BR) therapy has been expressed by both patient and academic associations.

SymBio's earlier completed Phase 2 study for BR therapy showed very positive results for the treatment of patients with r/r DLBCL. The NCCN Guidelines, which are the standard for clinical policy in oncology in the U.S. and have recommended BR therapy since 2012, cite the results of this clinical study. Having started a Phase III study in August 2017 for the indication of relapsed/refractory DLBCL, the Company aims to file a new drug application in the first half of 2020.

- **Product lifecycle management**

The Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. (Head Office: New Jersey, U.S.) ("Eagle") on September 20, 2017, under which Eagle licensed to the Company rights under Eagle's intellectual property to develop, market and sell Eagle's bendamustine hydrochloride ready-to-dilute ("RTD") and rapid infusion ("RI") injection products in Japan.

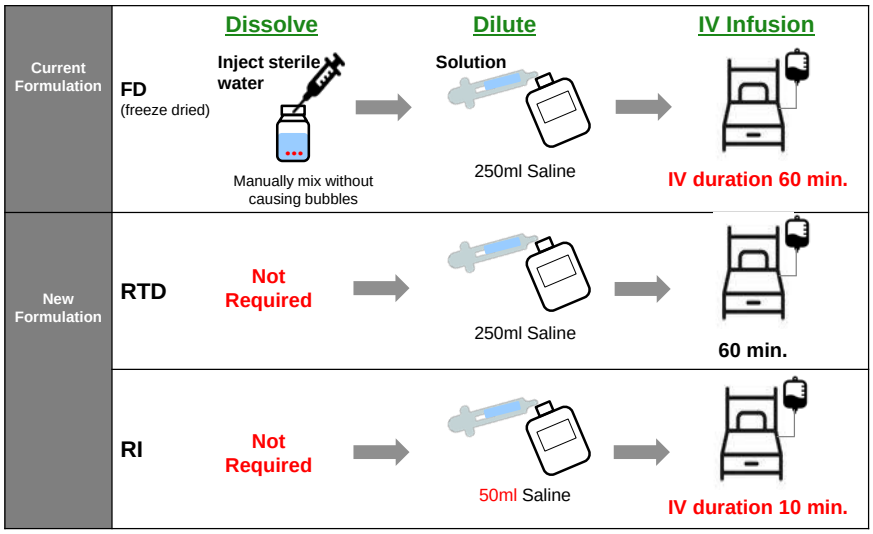
Switching from the existing lyophilized powder formulation to the ready-to-dilute (RTD) liquid formulation will significantly reduce the preparation time. The rapid infusion (RI) injection product will also shorten the infusion time from the current 60 minutes to 10 minutes, substantially reducing the burden on patients compared to the lyophilized powder formulation and providing significant benefits to both patients and healthcare providers. Taking countermeasures against the probable launch of generics in Japan was a key consideration as the marketing exclusivity period for the current FD formulation in Japan will expire in late 2020. The Company aims to obtain approval for the RTD formulation in the first half of 2021 (and the RI formulation at a subsequent date). These liquid formulations, patent protected through 2031, will significantly extend the product life of TREAKISYM®. The Company will aim to achieve a complete transition from the current lyophilized powder formulation to liquid formulation as soon as possible after the launch of RTD.

[About RTD and RI injection products]

The ready-to-dilute (RTD) injection product eliminates the cumbersome manual dissolution process,

significantly reducing the workload of healthcare providers. In addition, the rapid infusion (RI) injection product shortens the infusion time from 60 minutes to 10 minutes, substantially reducing the burden on patients.

<Comparison with current formulation>



➢ **Development of oral TREAKISYM®**

Since obtaining 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 in October 2010, the Company has pursued the expansion of indications for malignant lymphoma. To further enhance the value of TREAKISYM®, the Company plans to proceed with the development of an oral formulation for progressive solid tumors. In January 2018, the Company started the Phase I study of oral TREAKISYM® for progressive solid tumors. Based on the results of this trial, the Company plans to evaluate the recommended dose, dosage regimen, the tolerability and the safety of oral TREAKISYM®, identify types of solid tumors that show promise for treatment, and determine the subsequent clinical trial plan.

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

Summary:

➢ Rigosertib is a small molecule inhibitor that has a new mechanism of action: it inhibits the activation of Ras as an oncogene-related product, thereby blocking the action of multikinases, including PI3K, and inhibits cellular signaling in cancer cells necessary for their survival and proliferation, thus killing cancer 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 formulation, 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 20 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 interim analysis was conducted in January 2018, and the independent DMC has recommended that the INSPIRE trial continue with enrollment increased from the current 225 patients to reach a total enrollment of 360 patients. Onconova decided to follow the recommendation. The expanded study enrollment criteria will be identical to the original study.

- With regard to rigosertib oral formulation, Onconova is currently in the process of determining the plans for the global Phase III study for the first-line treatment of HR-MDS patients using the oral formulation of rigosertib in combination with azacitidine. Meanwhile, the Company started its domestic Phase I study as a single agent in HR-MDS in June 2017, and completed the first patient enrollment in October 2017.
- 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 and oral as a new drug candidate in addition to the already marketed TREAKISYM®.
- With regard to rigosertib intravenous formulation, patients with HR-MDS who are refractory to HMAs have limited treatment options and there is extremely high unmet medical need for patients who respond inadequately to existing therapies. Based on the DMC's recommendation, the Company will continue in collaboration with Onconova to move forward with the trial with an increase in the total enrollment of patients in Japan up to 40, and aims to file a new drug application for manufacturing and marketing approval for the indications of relapsed/refractory HR-MDS in 2021.
- With regard to rigosertib oral formulation, the Company will promptly conduct an oral rigosertib/azacitidine combination trial in Japan after demonstrating the safety of oral rigosertib in the Phase I study as a single agent, which is currently underway, and intends to participate in the global Phase III study in untreated HR-MDS patients that Onconova is now planning.
- Additionally, regarding the indication of transfusion-dependent lower-risk MDS, the Company will continue to consider clinical development plans in view of the status of the development by Onconova.

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.