February 4, 2021

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Three-Year Mid-Range Plan: FY 2021 to FY 2023

I. Three-Year Mid-Range Plan

(1) Overview of FY 2020 Business Results as of the Date of the Mid-Range Plan

Progress in the Company's business for FY 2020 (from January 1, 2020 to December 31, 2020) is as follows:

(i) Domestic business

[Establishment of the Company's own sales organization]

With its business partnership agreement with Eisai Co., Ltd. ("Eisai") set to expire in December 2020, SymBio began preparations to establish its own sales organization for the sale of TREAKISYM® in Japan in October 2018. In the fiscal year ended December 31, 2020 (hereafter "FY 2020"), the Company identified needs of each region and formulated detailed proposals to address these needs. In efforts to establish a salesforce with enhanced productivity, the Company assigned 53 medical representatives across the nation and nine hematology experts to each region of operation.

In September 2020, to establish a nationwide distribution system, the Company concluded basic agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. for the distribution of the Company's pharmaceutical products with these two companies as its sole wholesalers after the partnership agreement with Eisai expired. For the nationwide logistics system, the Company began collaborating with S.D. Collabo Co., Ltd and set up two logistics centers—one in Eastern and the other in Western Japan.

Through these efforts, the Company established its own sales organization, and following the expiration of its partnership agreement with Eisai, transitioned the sale of TREAKISYM® to its own sales system in December 2020. Achieving profitability in FY 2021 and sustaining earnings growth thereafter are important objectives for the Company, and with the transition to its own sales organization, its prospects for future growth have been solidified.

[Stable supply of products]

SymBio imports lyophilized powder formulation of TREAKISYM® from Astellas Deutschland GmbH ("Astellas Deutschland"), a subsidiary of Astellas Pharma Inc. In the first half of FY 2020, certain batches were found to contain impurities and appearance defects, resulting in TREAKISYM® inventories at Eisai to trend lower year-on-year. However, in the second half of the fiscal year, the Company conducted secondary packaging and quality tests for a number of imported batches, returning inventory to normal levels.

In the fourth quarter of FY 2020, the Company obtained manufacturing and marketing approval for the ready-to-dilute (RTD) liquid formulation of TREAKISYM®, for which it entered an exclusive license agreement with Eagle Pharmaceuticals Inc. (head office: New Jersey, U.S., "Eagle"), and began importing and delivering to wholesalers the RTD formulation scheduled for market launch in January 2021.

[Anticancer agents: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (ready-to-dilute ("RTD") formulation), SyB L-1702 (rapid infusion ("RI") formulation) (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM®)]

SymBio obtained manufacturing and marketing approval for TREAKISYM® for the indications of first-line treatment of low-grade non-Hodgkin's lymphoma (low-grade NHL) (Note 1) and mantle cell lymphoma (MCL) in December 2016, recurrent/refractory low-grade NHL and MCL in October 2010, and chronic lymphocytic leukemia (CLL) in August 2016. TREAKISYM® is thus being used to treat a wide array of malignant lymphoma. Further, the combination therapy of TREAKISYM® and rituximab (BR therapy) was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues edited and published by the Japanese Society of Hematology in July 2018, becoming recommended as a choice for standard treatment for all previously approved indications. With this development, TREAKISYM® has established its foothold as a standard treatment for malignant lymphoma.

In July 2018, the Company obtained approval of a partial change to the marketing authorization for TREAKISYM®, allowing the product to be used in combination with not only rituximab but also other new anti-CD20 antibodies for the treatment of CD-20 positive follicular lymphoma (FL), a typical histologic type of low-grade NHL. With this approval, TREAKISYM® is available to patients as a new treatment option in combination with obinutuzumab (Note 2). In March 2019, the Company obtained approval of another partial change which authorizing the use of TREAKISYM® as a pretreatment agent for tumor-specific T-cell infusion therapy (Note 3), enabling TREAKISYM® to be used as a pretreatment agent for Kymriah® intravenous infusion (Note 4), the first chimeric antigen receptor T-cell (CAR-T) therapy (Note 5) to be approved in Japan. The use of TREAKISYM® as a pretreatment agent for regenerative medicine and other pharmaceutical products has further solidified the status of TREAKISYM® as the standard treatment for malignant lymphoma.

SymBio conducted a Phase III clinical trial of BR therapy targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), an additional indication for the combination therapy following the approved indications. After obtaining favorable results from the trial, with the overall response rate—the primary endpoint of the trial—exceeding expected levels, /the Company applied in May 2020 for a partial change to the manufacturing and marketing authorization. The Company is also conducting a follow-up study with overall survival as primary endpoint, since survival data (e.g., overall survival and progression-free survival) for the BR therapy is crucial in establishing TREAKISYM® as a DLBCL treatment. In June 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai Pharmaceutical") filed for manufacturing and marketing approval for polatuzumab vedotin

(Note 6) used in combination with BR therapy targeting r/r DLBCL. In response, in July 2020 the Company applied for approval to partially amend the manufacturing and marketing authorization for TREAKISYM® used in combination with polatuzumab vedotin and rituximab. Once polatuzumab vedotin is included in the NHI drug price list after the Company and Chugai Pharmaceutical obtain approval, TREAKISYM® can be used in the combination therapy of polatuzumab vedotin and BR therapy. As there is currently no effective treatment for r/r DLBCL, combination therapies comprising multiple anticancer drugs are currently used as rescue chemotherapy. There is therefore a significant need for development of highly effective and safe drugs. BR therapy is already used to treat patients with r/r DLBCL in Europe and the U.S. In Japan, patient organizations and relevant academic societies have submitted a request to the Ministry of Health, Labour and Welfare, asking to make BR therapy available as soon as possible. Once approval is granted, the Company expects TREAKISYM® to be widely available as a treatment option for many patients.

In September 2017, SymBio concluded a license agreement with Eagle and obtained exclusive rights to develop and market RTD and RI liquid formulations (Note 7) of TREAKISYM® in Japan. The Company obtained manufacturing and marketing approval for the RTD formulation on September 18, 2020, and launched the product in January 2021. For the RI formulation, clinical trials to confirm its safety are currently underway, and the Company plans to apply for approval in FY 2021. Unlike the current lyophilized powder formulation, RTD formulation of TREAKISYM® does not require the cumbersome manual work of dissolving the drug (i.e., drug reconstitution), shortening preparation time and substantially reducing the burden on healthcare providers. Further, the RI liquid formulation significantly reduces the infusion time to 10 minutes, down from the 60 minutes required by the currently available lyophilized powder and RTD formulations. This will greatly benefit patients and healthcare providers, enabling the Company to add substantial value. Further, with exclusive rights to manufacture these patent-protected liquid formulations, the Company is able to extend the life of these products until 2031 and further strengthen the foundation of its business growth.

(Note 1) Non-Hodgkin's lymphoma (NHL) refers to malignant lymphoma other than Hodgkin's lymphoma. Malignant lymphoma is a cancer of the lymphatic system in which lymphocytes develop malignant growths. The majority of Japanese malignant lymphoma patients are suffering from NHL.

(Note 2) Obinutuzumab (Gazyva®, marketed by Chugai Pharmaceutical Co., Ltd.): Like rituximab recommended by treatment guidelines for non-Hodgkin's lymphoma in Japan and overseas, obinutuzumab is a glycoengineered type II anti-20 monoclonal antibody that directly binds to CD20 (a protein expressed on B-cells other than stem cells or plasma cells) on target B-cells to attack and destroy them along with the body's immune system.

(Note 3) Tumor-specific T-cell infusion therapy is a treatment method in which tumor-specific T-cells (T-cells that specifically recognize cancer cells) taken from cancer patients are artificially bestowed with cancer specificity extracorporeally, amplified and then administered to the patient.

(Note 4) Kymriah® intravenous infusion (generic name: tisagenlecleucel, marketed by Novartis Pharma K.K.): Kymriah® intravenous infusion is the first chimeric antigen receptor T-cell (CAR-T) therapy approved within Japan. Novartis Pharma received manufacturing and marketing approval for Kymriah® for use in the treatment of CD19 positive recurrent/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive DLBCL in March 2019. Kymriah® intravenous infusion was included in NHI price listings in May 2019.

(Note 5) Chimeric antigen receptor T-cell (CAR-T) therapy is a type of tumor-specific T-cell infusion therapy that introduces genes that code chimeric antigen receptors (CARs) into T-cells, amplifies these cells and then infuses them. These chimeric antigen receptors are produced by combining the intracellular domains of T-cell receptors with the antigen binding sites of antibodies capable of recognizing membrane antigens attached to tumor cells. In clinical trials using CARs to target CD19 that expresses on B-cells, CD19-targeting CARs were introduced into T-cells that were later administered to patients with B-cell tumors. These modified cells produced clear clinical effects.

(Note 6) Developed by Roche using Seattle Genetics' antibody-drug conjugate (ADC) technology, polatuzumab vedotin is a first-in-class anti-CD79b ADC (targeting CD79b) built by conjugating humanized monoclonal antibody targeting CD79b to a tubulin polymerization inhibitor. CD79b protein is specifically expressed on the surface of many B-cells, and is expected to be a promising target in new drug development. Polatuzumab vedotin selectively binds to CD79b while minimally affecting normal cells, and destroys B-cells with the chemotherapeutic agent it contains.

(Note 7) Ready-to-dilute (RTD) and rapid infusion (RI) are pre-dissolved liquid formulations that differ from currently available lyophilized (freeze-dried) powder injection. RTD will significantly reduce the preparation time and labor cost for healthcare providers, and RI 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 sodium)]

The Company's U.S. licensor for rigosertib, Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S., "Onconova") is conducting global Phase III clinical trials (with trial sites in more than 20 countries; INSPIRE study) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which failed to respond to the current standard treatment with hypomethylating agents, relapsed after treatment under the current standard of care, or were intolerant to hypomethylating agents; the primary endpoint of the study is overall survival. In August 2020, Onconova announced that the primary endpoint—improved survival compared to physician's choice of treatment—was not met. The Company is responsible for clinical development in Japan, and is reviewing ways to utilize the findings from the additional analysis of the INSPIRE study in the future development of rigosertib.

As for the oral formulation of rigosertib, Onconova completed a Phase I/II clinical trial of the investigational drug (in combination with azacitidine (Note 8)) in the U.S. in first-line HR-MDS patients, and the results suggested that the oral formulation of rigosertib and azacitidine used in combination were safe and effective. In June 2017, the Company initiated a Phase I clinical trial in Japan to confirm the safety and tolerability of high-dose monotherapy and tolerance in Japanese patients, and completed patient enrollment in June 2019.

With the aim of maximizing the business value of TREAKISYM® and rigosertib, the Company intends to conduct joint research with the Institute of Medical Science, the University of Tokyo, to investigate the efficacy of the drugs used in combination as well as in combination with other existing drugs, and to identify new indications.

(Note 8) Azacitidine (Vidaza®, marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (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.

[Antiviral drug: SyB V-1901 (generic name: brincidofovir)]

On September 30, 2019, the Company concluded an exclusive global licensing agreement for intravenous and oral formulation of antiviral drug brincidofovir (Note 9) (SyB V-1901; "BCV IV" and "BCV Oral," respectively) with Chimerix Inc. (head office: North Carolina, U.S., "Chimerix"). Under this agreement, the Company acquired exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding smallpox.

As a result of the review at the Global Advisory Board meeting in February 2020, the Company decided to prioritize the global development of BCV IV targeting adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, an area with high unmet medical needs as there currently exists no effective treatment. The global study will primarily be in Japan, the U.S., and Europe. Leveraging its knowledge of the efficacy and safety of BCV obtained from clinical trials, the Company plans to investigate the efficacy of BCV against a range of dsDNA(Note 10) viral infections and expand target indications to include multiple viral infections occurring after hematopoietic stem cell transplantation. It also intends to pursue the possibility of expanding target indications of the drug to viral infections after kidney or other organ transplantation. Through these efforts, the Company aims to expand the market for BCV and maximize its business value. Currently, the Company is preparing to start clinical trials of BCV IV targeting AdV infections in children scheduled for FY 2021.

BCV Oral demonstrated highly active antiviral effects in clinical trials conducted in Europe and the U.S. by Chimerix. These trials also confirmed that BCV Oral had broad-spectrum antiviral effects. Based on these extensive antiviral effects of BCV Oral against various dsDNA viruses, the Company expects BCV IV to be also effective and safe in the treatment and prevention of various viral infections occurring after hematopoietic stem cell transplantation.

In December 2020, Chimerix announced that the U.S. Food and Drug Administration (FDA) accepted its filing of a New Drug Application (NDA) for BCV as a medical countermeasure for smallpox. The FDA granted BCV a priority review designation and based on the Prescription Drug User Fee Act (PDUFA), set the PDUFA date for April 7, 2021.

(Note 9) Brincidofovir (BCV) has a structure in which cidofovir (an antiviral drug already approved and marketed in the U.S. and Europe, but unapproved in Japan; "CDV") is bound to a lipid chain

(hexadecyloxypropyl; "HDP"). It is quickly absorbed into the lipid bilayer membrane and efficiently transferred into cells, and the bound lipid chain is metabolized and separated from the structure by intracellular phospholipases. This process generates an activator (CDV-PP; CDV diphosphate) that is retained in the cells for a long period of time, dramatically raising the compound's antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, since HDP conjugation prevents the accumulation of the compound in renal tubular epithelial cells through organic anion transporter 1 (OAT1) and CDV is released at low levels in the bloodstream.

(Note 10) Double-stranded DNA (dsDNA) viruses include herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as CMV, AdV, HHV-6, BK virus, HSV1/2, VZV, HPV, JCV, and small pox virus

[Patient-controlled analgesia SyB P-1501]

On October 11, 2017, SymBio initiated an arbitration against The Medicines Company (head office: New Jersey, U.S., "MDCO")—from whom the Company in-licensed SyB P-1501 (IONSYS in the U.S.) in October 2015—under the rules of the International Chamber of Commerce, seeking damages of 82 million US dollars arising from MDCO's decision to discontinue and withdraw IONSYS from the U.S. and European markets and failure to provide adequate assurances of MDCO's performance under the license agreement. On September 1, 2020, the Company announced that the arbitral tribunal did not agree with the Company's claim that MDCO failed to provide adequate assurances of performance under the license agreement and denied the Company's claim for damages. However, the arbitral tribunal awarded the Company 4,950,000 US dollars representing 50% of its legal fees and expenses that it sought to recover in the arbitration.

(ii) Business outside Japan

SyB L-0501 is also marketed in South Korea, Taiwan, and Singapore, and sales of SyB L-0501 in these countries were in line with the Company's forecasts.

(iii) Licensing of new drug candidates

SymBio plans to focus on formulating and executing plans for the global development of the antiviral drug brincidofovir in-licensed in September 2019 for the time being. However, the Company will continue working on its existing initiatives of reviewing multiple licensing projects at all times and searching and evaluating new drug candidates for potential in-licensing. Through these efforts, it aims to create long-term business value as a profitable biopharmaceutical company with growth potential.

(iv) Business results

As a result of the above, net sales totaled 2,987,051 thousand yen for FY 2020, primarily reflecting product sales of TREAKISYM®, and overall net sales increased 5.3% year on year.

Selling, general and administrative expenses totaled 5,373,073 thousand yen (+4.0% year on year). This included research and development ("R&D") expenses of 2,266,556 thousand yen (-7.2% year on year), reflecting expenses associated with clinical trials for the intravenous formulation of TREAKISYM® and the intravenous formulation of rigosertib, as well as other selling, general and administrative expenses of 3,106,517 thousand yen (+14.0% year on year), reflecting upfront spending for establishing the internal sales organization.

As a result, an operating loss of 4,506,220 thousand yen was recognized for FY 2020 (an operating loss of 4,301,615 thousand yen in the previous fiscal year). In addition, non-operating income was 2,585 thousand yen, primarily consisting of dividend income of insurance of 2,324 thousand yen. Meanwhile, non-operating expenses were 112,268 thousand yen and primarily comprised commission expenses of 43,958 thousand yen, foreign exchange losses of 41,287 thousand yen, and share issuance cost of 27,021 thousand yen. Consequently, ordinary loss totaled 4,615,903 thousand yen (an ordinary loss of 4,376,655 thousand yen in the previous fiscal year) and bottom-line loss in FY 2020 totaled 4,090,216 thousand yen (a loss of 4,376,258 thousand yen in the previous fiscal year), partially offset by the recording of settlement received of 525,124 thousand yen.

Segment information has been omitted since the Company operates within a single segment, which includes the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities.

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

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

The Company recognizes underserved therapeutic areas with significant medical needs as a business opportunity and remains focused on the areas of oncology and hematology, where high entry barriers exist due to the high degree of specialization required. In this sense, SymBio is the first specialty pharmaceutical company in Japan. Rather than exploring opportunities to in-license and develop new "blockbuster" drugs (drugs with sales exceeding 100 billion yen), the Company channels its resources into the development of drugs in underserved markets where medical needs are high despite limited patient numbers. Holding multiple drug approvals and new drug candidates in these key therapeutic areas, the Company aims to build a solid pipeline portfolio, achieve high profitability with high-value products and services, and operate sustainable businesses.

SymBio's Mid-Range Plan spans three years from FY 2021 through FY 2023. In FY 2021, with its in-house salesforce in full operation from the outset of the fiscal year, the Company aims to rapidly convert the current lyophilized powder formulation of TREAKISYM® to the newly launched RTD formulation. SymBio looks to expand TREAKISYM®'s market share with the additional indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). The Company aims to quickly achieve annual NHI price based sales of 10 billion yen for TREAKISYM® to realize its core management objectives of achieving profitability in FY 2021 and sustaining growth from FY 2022 onward. With respect to the pipelines, SymBio aims to maintain progress with existing development projects and embark on domestic and global development of the newly in-licensed antiviral drug brincidofovir. The Company looks to continue the transformation into a global specialty pharmaceutical company. An outline of the plan is as follows:

- To achieve profitability in FY 2021 and maintain sustainable growth thereafter, the Company launched full operation of its own salesforce following the expiration of the business partnership agreement with Eisai in December 2020.

  - The Company established a nationwide in-house salesforce in FY 2020, comprising a team of knowledgeable, experienced, and highly productive hematologic cancer specialists. The sales team began full operation in the beginning of FY 2021 after taking over sales operations from Eisai.

  - The Company established the necessary logistics and distribution infrastructure and systems to support a nationwide sales expansion in FY 2020. It aims to lay the foundation for a stable product supply under a robust in-house sales and logistics system excelling both in efficient logistics and risk management.

- To maximize the business value of TREAKISYM®, ensure sustainable profitability and growth potential, and achieve sales of 11.3 billion yen (NHI price basis; same applies below) in FY 2021 by the following initiatives:
  - Increasing sales from approved indications: maintain an earnings base of TREAKISYM® indicated for first-line low-grade non-Hodgkin's lymphoma patients, and aim for sales of 4.1 billion yen.
  - Expanding indications: launch TREAKISYM® in the second quarter of 2021 for the indication of r/r

DLBCL, for which the Company filed for approval in May 2020, and aim for sales of 2.6 billion yen.

- Target total sales for other indications to be 4.6 billion yen.
- Product lifecycle management: launch the RTD formulation in the first quarter of 2021 and switch 91% of TREAKISYM® from the current lyophilized powder formulation to the liquid (RTD) formulation by the end of 2021. Launch the RI formulation in the first half of 2022 to further maximize product value of TREAKISYM®.

➢ In regard to the newly in-licensed antiviral drug brincidofovir, SymBio decided to prioritize global development of the drug primarily in Japan, the U.S., and Europe as a treatment for adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation, a niche area with a high unmet medical need. The Company is preparing to commence a clinical trial of the liquid (IV) formulation of BCV targeting AdV infections in children in the first half of 2021. It is also considering to launch global clinical trials aimed at expanding the business to Europe, the U.S., and Asia (including China), which have larger organ transplant markets than Japan and where an injection agent is likely to be widely used. SymBio seeks to deliver brincidofovir to as many patients as possible at the earliest possible stage while maximizing its business value. To achieve this goal, SymBio will pursue a development, production, and commercialization program that utilizes strategic partnerships.

➢ Regarding rigosertib, an investigational drug for which Onconova is conducting global Phase III clinical trials (INSPIRE study), SymBio is in charge of clinical development in Japan. The Company is considering ways to utilize findings from the genomic analysis of the INSPIRE study for the future development of rigosertib.

➢ To secure long-term growth opportunities, SymBio will proactively search for and evaluate new drug candidates for development after brincidofovir, and further explore in-licensing opportunities.

(3) Business Status, Outlook, and Other Assumptions

○ Establishment of the Company's own salesforce

➢ With its business partnership agreement with Eisai set to expire in December 2020, the Company began preparations to establish its own sales organization for the sale of TREAKISYM® in Japan in October 2018. Under this Mid-Range Plan, the Company's core management objectives are achieving profitability in FY 2021 and sustaining growth thereafter. The Company began selling TREAKISYM® through its own salesforce starting in 2021, following the expiration of the Company's agreement with Eisai in December 2020. Selling through the in-house salesforces will enable the Company to more accurately understand and more swiftly respond to market needs, thereby benefiting patients and maximizing the business value of TREAKISYM®. Furthermore, through building a sales and marketing force highly specialized in hematological diseases, the Company aims to further enhance business efficiency, ensure sustainable earnings growth, and maximize shareholder gains.

○ Anticancer agents: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (RTD formulation), SyB L-1702 (RI formulation) (generic name: bendamustine hydrochloride, trade name: TREAKISYM®)

- Since the start of sales of TREAKISYM® by Eisai in December 2010, sales have been stable for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Sales have grown substantially since the addition of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma as an indication in December 2016 and the addition of chronic lymphocytic leukemia in August 2016. The product has gained a foothold as a first-line treatment of low-grade non-Hodgkin's lymphoma. Further, the combination treatment of TREAKISYM® and rituximab (BR therapy) was added to the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 published by the Japanese Society of Hematology in July 2018, recommending BR therapy as an option for standard treatment, establishing a foothold as the standard treatment.

- Regarding the additional indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), in November 2019, SymBio announced favorable results from the Phase III study, in which the overall response rate—the primary endpoint—exceeded expectations. Based on this, the Company applied for approval to partially revise the manufacturing and marketing authorization of TREAKISYM® in May 2020, and expects to launch the product for the additional indication in the second quarter of 2021.

- With regard to TREAKISYM® liquid formulations, the Company aims to substantially extend the product's life cycle through further patent protection, thereby maximizing profit. SymBio launched the RTD formulation in January 2021. It aims to convert 91% of TREAKISYM® from the current lyophilized powder formulation to the liquid formulation by the end of 2021, and switch 95% by the end of 2022. The Company will work to further maximize the product value of TREAKISYM® with the launch of the RI formulation in the first half of 2022.

- In collaboration with Eisai, SymBio was able to smoothly transition the sales and logistics operations from Eisai to its own salesforce by the end of 2020 and began in-house sales from 2021. With the launch of in-house sales in 2021, SymBio aims to quickly achieve annual sales of 10 billion yen (NHI price basis) for TREAKISYM®, through the aforementioned addition of r/r DLBCL indication and measures to extend the product life cycle by launching liquid formulations of TREAKISYM®.

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

- For the rigosertib intravenous formulation, the Company collaborated with Onconova in conducting the global Phase III clinical trials (INSPIRE study) targeting the recurrent/refractory higher-risk myelodysplastic syndromes (MDS). However, in August 2020, Onconova announced that the primary endpoint of the study—improved overall survival compared to physician's choice of treatment—had not been met. The Company is in charge of clinical development in Japan, and is reviewing ways to utilize findings from the genomic analysis of the INSPIRE study for the future development of rigosertib.

○ Antiviral drug SyB V-1901 (generic name: brincidofovir)

- The Company decided to prioritize the global development of the intravenous formulation of brincidofovir (BCV IV) primarily in Japan, the U.S., and Europe for the treatment of adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation. The Company is preparing to commence a clinical

trial of the liquid (IV) formulation of BCV targeting AdV infections in children in the first half of 2021. Further, it plans to launch global clinical trials after formulating clinical trial plans and reviewing target indications, with the aim of expanding the business to Europe, the U.S., and Asia (including China), which in comparison with Japan have larger organ transplant markets where BCV IV is likely to be widely used. As for BCV oral formulation, the Company will consider its development plan including efforts to improve the formulation. By pursuing a development, production, and commercialization program that incorporates strategic utilization of partnerships, SymBio seeks to deliver brincidofovir to as many patients as possible at the earliest possible stage while maximizing business value.

○ New drug candidates and global business expansion

- The Company is continually evaluating new drug candidates for development. The Company will search for drug candidates that will increase corporate value and negotiate in-licensing of those candidates at the appropriate time. When searching for, evaluating, and negotiating new drug candidates, the Company will consider obtaining global licenses in addition to commercialization in the domestic market.

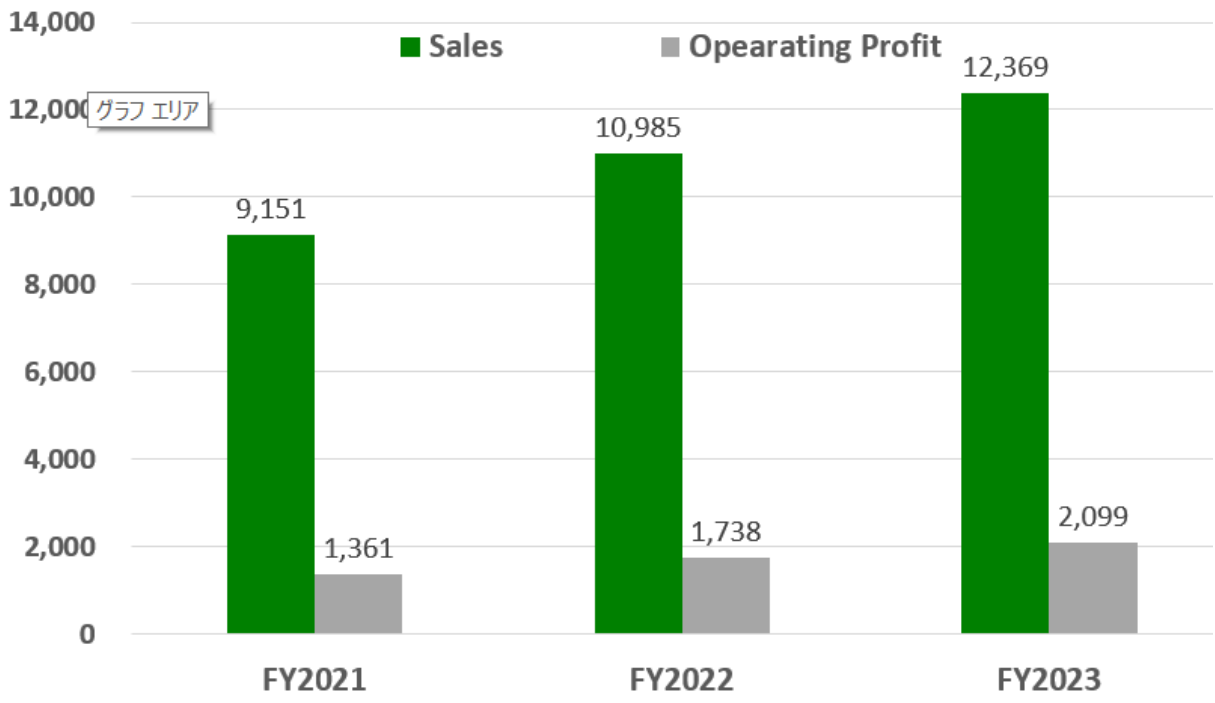
II. Earnings Forecast and Performance Targets

Unit: millions of yen

	FY2021 Forecast	FY2022 Target	FY2023 Target
Net Sales	9,151	10,985	12,369
Operating Profit	1,361	1,738	2,099
Operating Profit %	14.9%	15.8%	17.0%
Ordinary Profit	1,350	1,727	2,088
Net Profit	1,149	1,470	1,778
EPS（JPY）	30.1	38.5	46.5

[Trends of Net Sales and Net Income]

Unit: millions of yen



[Status of R&D pipeline]

- Anticancer agents: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (ready-to-dilute (“RTD”) formulation), and SyB L-1702 (rapid infusion (“RI”) formulation) (generic name: bendamustine hydrochloride, trade name: TREAKISYM®)
- Antiviral drug: SyB V-1901 (generic name: brincidofovir)

Drug	Indication	Phase I	Phase II	NDA	MA
TREAKISYM® (Freeze-dried)	r/r Low-grade NHL/MCL	Approved October 2010			
	CLL	Approved August 2016			
	1st line Low-grade NHL/MCL	Approved December 2016			
	r/r DLBCL	Primary objective achieved ➡ NDA filed May 2020 Follow-up study for evaluating overall survival is ongoing			
Liquid TREAKISYM® (RTD)	All	Approved September 2020			
Liquid TREAKISYM® (RI)	All	Completed the observation period for all patients (LPLV)			
Brincidofovir IV	Adenovirus infection after allogeneic hematopoietic stem cell transplantation (Global)	Preparing for global study			
Brincidofovir ORAL	Formulation development (Global)	Beginning in 2020			

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

  Rigosertib IV global phase III study did not meet its primary endpoint comparing IV plus best supportive care to physician's choice. Additional analysis and collaborative research with the Institute of Medical Science, the University of Tokyo, to explore new indications will be conducted.

Drug	Indication	Phase I	Phase II	Phase III	NDA	Approval
Rigosertib IV	Relapse/ refractory high risk MDS monotherapy	Global phase III study additional analysis				
Rigosertib Oral	Relapse/ refractory high risk MDS	Japan study completed				
	1st line high risk MDS Combination with AZA	Global phase I/II study completed				

Assumptions and Statistics for Projections and Performance Targets

○ Net sales (approximately 9.1 billion yen) are mainly composed of product sales for TREAKISYM®. The sales targets are based on a revised assumption for sales growth during the period covered by the Plan, taking into account recent sales trends and progress in market penetration.

Until 2020, the Company's sales were based on product shipments to sales partner, Eisai. From 2021, sales will be based on shipments to pharmaceutical wholesalers in the supply chain supporting the Company's in-house salesforce.

Sales targets for 2021 and beyond presume that the sales of TREAKISYM® will expand further owing the additional indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), for which approval is expected in the second quarter of 2021.

○ Selling, general and administrative expenses mainly consist of research and development expenses or other selling, general and administrative expenses.

- Research and development expenses (approximately 2.0 billion yen) are estimated based on the Company's latest development plan for its existing pipeline, comprising TREAKISYM®, rigosertib, and the antiviral drug brincidofovir.

- With regard to new drug candidates for development outside the existing pipeline, any upfront expenses for in-licensing are not accounted for, although the Company continues to evaluate and consider candidates for potential in-licensing, to follow on from the antiviral drug brincidofovir.

- Other selling, general and administrative expenses mainly consist of expenses involved in TREAKISYM® sales and marketing activities, logistics, business development, and administrations. Expenses related to the operation of the Company's own salesforce for the sale of TREAKISYM® are accounted for from 2021. The main cost increases are expected to stem from personnel and associated expenses resulting primarily from the addition of medical representatives.

○ Regarding net profit, based on its expectation of achieving profitability in FY 2021 and sustaining growth thereafter, the Company had initially accounted for the effect of progress in eliminating loss carried forward on estimates for income taxes deferred for FY 2021 and FY 2022 in the mid-range plan announced on February 6, 2020. However, considering the opinions of accounting auditors on FY 2020 earnings results, the Company has decided to leave out any projections for income taxes deferred for FY 2021 and subsequent fiscal years in the mid-range plan.

○ In regard to personnel, the Company established a 62-person nationwide sales organization in 2020. The budget for personnel expenses takes into account the Company's plan to dispatch a sufficient number of employees to each division other than the nationwide salesforce as well as its plan to increase personnel in line with the global expansion of antiviral drug brincidofovir.

○ Regarding financing, the Company will make every effort to further strengthen its financial base by considering diversified funding methods and promoting disciplined budget control. The Company will respond with flexibility

and agility to funding needs in accordance with future business development.

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.