COMPANY RESEARCH AND ANALYSIS REPORT

SymBio Pharmaceuticals Limited

4582

JASDAQ Growth Market

17-Jan.-2022

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Summary

Will become profitable in FY12/21 for the first time since its foundation through the increase in sales of TREAKISYM®

SymBio Pharmaceuticals Limited <4582> (hereafter, also “the Company”) is a bio-venture progressing developments from the clinical trial stage, targeting indications for oncology, hematology, and rare diseases for which there are few patients but medical needs are high. The main development pipeline includes TREAKISYM®, for which it is expanding indications as a treatment for malignant lymphoma; rigosertib, which it in-licensed from OnconovaTherapeutics, Inc. <ONTX> (hereafter, Onconova) (U.S.); and the antiviral drug brincidofovir (BCV) in-licensed from Chimerix Inc. <CMRX> (U.S.).

1. Result trend of 3Q FY12/21

In the 3Q FY12/21 cumulative (January to September 2021) results, net sales increased 138.1% year-on-year (YoY) to ¥5,553mn and operating profit was ¥424mn (compared to a loss of ¥3,142mn in the same period in the previous fiscal year). The main reasons for the increase in sales were that from December 2020, the Company launched in-house sales of TREAKISYM® and then in March 2021, it greatly expanded the indication areas for TREAKISYM® by obtaining approval for the manufacturing and marketing authorization, allowing the product to be used in the bendamustine-rituximab (BR) therapy and in the polatuzumab vedotin plus bendamustine-rituximab (P+BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). Also, in addition to the shift to the in-house sales structure, from January 2021 it began sales of the RTD formulation (liquid type), which has a higher profit margin than the former FD formulation (lyophilized powder intravenous type). Due to the progress made in switching from the FD formulation, the gross profit margin increased greatly, rising from 29.0% in the same period in the previous fiscal year to 76.0%, which was a major factor behind the Company becoming profitable.

For the FY12/21 results, the Company has left the initial forecasts unchanged, of net sales to increase 206.4% YoY to ¥9,151mn and operating profit of ¥1,361mn (compared to a loss of ¥4,506mn in the previous period). It is possible that net sales will be slightly lower than forecast due to inventory on the market and people refraining from medical diagnoses because of the spread of the novel coronavirus (hereafter, COVID-19). However, both R&D expenses and other SG&A expenses are expected to be less than forecast, so the outlook is that the profit forecasts will be achieved. The switching rate from the FD formulation to the RTD formulation was a little behind schedule up to the 3Q, but by the 4Q it is forecast to reach around 90%, as was initially forecast.

2. Trends in the development pipeline

For TREAKISYM®, in May 2021 the Company applied for marketing approval for the RI formulation (reduces the intravenous administration time to 10 minutes from the previous 60 minutes), and if the review proceeds smoothly, it is expected to be approved within the year and sales to begin in the second half of 2022. As it contributes greatly not only to medical practitioners, but also to improving patients' QOL, sales are expected to further grow through the sales launch of this product. For rigosertib as well, the Company is working on joint research with academia to search for possibilities for combination therapies with existing drugs, including with TREAKISYM®, and its policy is to determine a new development strategy in 2022, including for indications. Also, for BCV (intravenous formulation), from the 3Q FY12/21 it started the global joint phase II clinical trial indicated for adenovirus infections (in infants) that develop after hematopoietic stem cell transplantation, and if smooth progress is made, it may advance to the phase III clinical trial in 2023. Moreover, in 2022 the Company intends to start a global joint clinical trial indicated for viral diseases after organ transplants, while it has also started efforts to expand the BCV development areas, including starting research with overseas universities and medical facilities for the oncology area. In order to more actively conduct development overseas, in October 2021 the Company appointed a manager with expertise and experience in clinical trials as vice president at the U.S. subsidiary, and it has started fully-fledged operations.

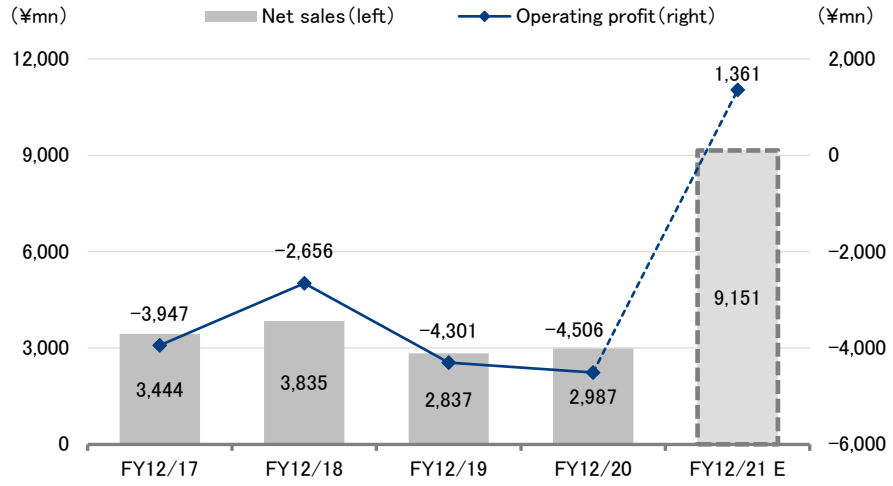
3. Mid-Range Plan

In the Mid-Range Plan, the Company has set results targets for FY12/23 of net sales of ¥12,369mn, operating profit of ¥2,099mn, and earnings per share of ¥46.5. Sales are expected to grow from the spread in the use of TREAKISYM® for relapsed and refractory DLBCL, and also, following the start of sales of the RI formulation, its further spread at medical institutions implementing multi-drug combination therapies. In profits, R&D expenses are forecast to increase, mainly BCV development expenses, but this will be absorbed by the growth of gross profit. The Company positioned 2021 as the first year of its "second foundation" with the aim of becoming a global specialty pharma, and its policy for 2022 onwards is to actively progress BCV development overseas and to increase the ratio of overseas sales to 50% by 2030 through the market launch of BCV, and thereby to evolve to become a global pharmaceutical company.

Key Points

- TREAKISYM® has the growth potential to approximately double sales through starting sales of the RTD formulation and expanding its indications to relapsed and refractory DLBCL
- Has started a global clinical trial for brincidofovir indicated for adenovirus infections after hematopoietic stem cell transplantation and is progressing research on its antitumor effects
- Operating profit is forecast to grow by more than 20% a year from 2022 onwards due to the increase in sales of TREAKISYM®

Results trends



Source: Prepared by FISCO from the Company's financial results

Company profile

A bio-venture that conducts developments from the clinical trial stage, targeting the fields of oncology, hematology, and rare diseases

SymBio Pharmaceuticals is a bio-venture founded by the current Representative Director and President Chief Executive Officer Fuminori Yoshida in March 2005. For its business strategy, its basic policy is to conduct drug discovery and development for underserved therapeutic areas in which development has not been progressed due to the small numbers of patients. One of its features has a business model that aims to achieve highly efficient and rapid drug discovery within the areas targeting oncology, hematology, and rare diseases, which are fields with high medical needs, by in-licensing development candidates for which POC* for humans has been obtained, and conducting development from the clinical trial stage.

* POC (proof of concept): when the usefulness and efficacy of a new drug candidate compound is recognized following its administration to animals or humans during research and development.

The first development candidate to be in-licensed was the anticancer agent bendamustine hydrochloride (hereafter, bendamustine hydrochloride; product name in Japan: TREAKISYM®) indicated for malignant lymphoma that was developed by Astellas Pharma GmbH (Germany), for which the Company concluded an exclusive development and marketing rights agreement for Japan in December 2005. With the development code SyB L-0501 (FD formulation), the Company began the phase I clinical trial in 2006 for indications for relapsed and refractory low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL), and in 2010, it acquired manufacturing and marketing approval. It progressed licensing activities during this time, and in 2007, it expanded the target areas for the exclusive development and marketing rights in China, South Korea, Taiwan, and Singapore. Then with Eisai Co., Ltd. <4523> it concluded licensing agreements for Japan in 2008 and for South Korea and Singapore in 2009. Due to changes in Eisai's business strategy, the domestic licensing agreement was terminated on the deadline of December 9, 2020, and the Company transitioned to its own sales system. It is also progressing discussions to terminate the agreements for South Korea and Singapore. For Taiwan, in 2012, it concluded a development and marketing agreement with InnoPharmax Inc. (Taiwan) for the FD formulation and it is conducting sales. However, its policy is to end by progressing the switch from the FD formulation to the RTD formulation.

TREAKISYM® was launched in the Japanese market in December 2010, and since then, the Company has progressed its development to expand its indications. In 2016, it acquired marketing approval for chronic lymphocytic leukemia (CLL) and untreated (first line of treatment) low-grade NHL/MCL, and then in March 2021, it acquired approval for relapsed and refractory DLBCL, so sales are expected to increase from the rise in the number of patients for which it is indicated. Also, in 2017, it concluded an exclusive development and marketing rights agreement for Japan with Eagle Pharmaceuticals, Inc. <EGRX> (U.S.) for the TREAKISYM® liquid type RTD/RI formulation (development codes: SyB L-1701/SyB L-1702)*.

> * The FD formulation, which the Company has purchased from Astellas Pharma up to the present time, has to be dissolved at a medical site at the time of use (which requires about 3 hours, including the adjustment time). But this work is not required with the liquid formulation, so it has the advantage of greatly reducing the burden placed on medical practitioners. Also, the only difference between the RTD formulation and the RI formulation is the volume of diluted physiological saline, which is diluted to 250ml in the RTD formulation and to 50ml in the RI formulation. Therefore, for the intravenous injection time, the RTD formulation takes the same time as the FD formulation, of 60 minutes, but the RI formulation reduces this to only 10 minutes, greatly reducing the burden on the patient.

Also, as the second in-licensed product, the Company concluded an exclusive development and marketing rights agreement in 2011 for Japan and South Korea with Onconova for rigosertib (development codes: SyB L-1101 (intravenous formulation) / SyB C-1101 (oral formulation)) as a development candidate indicated for myelodysplastic syndrome (MDS)*. Moreover, in September 2019, it concluded an exclusive global development, manufacturing, marketing, and licensing agreement with Chimerix for brincidofovir (BCV) for all viral diseases excluding smallpox. The features of BCV are that compared to cidofovir (CDV; unapproved in Japan), it has high antiviral efficacy and safety and is effective against multiple DNA viruses.

> * MDS is a disease in which the patient cannot produce normal blood cells due to abnormalities in the hematopoietic stem cells in their bone marrow, causing a decrease in normal blood cells and symptoms such as anemia, infection, and hemorrhage. It is also an intractable disease that is highly likely to transition to acute myeloid leukemia, and it frequently occurs in the elderly.

Technology in-licensing agreements

Name		TREAKISYM®		Rigosertib sodium	Brincidofovir
Development codes	SyB L-0501 (Lyophilized powder formulation) / SyB C-0501 (Oral formulation)	SyB L-0501 (Lyophilized powder formulation) / SyB C-0501 (Oral formulation)	SyB L-1701 (RTD formulation) / SyB L-1702 (RI formulation)	SyB L-1101 (Intravenous formulation) / C-1101 (Oral formulation)	SyB V-1901 (Intravenous formulation)
In-licensing partner	Astellas Pharma (Germany)	Astellas Deutschland (Germany)	Eagle Pharmaceuticals (U.S.)	Onconova (U.S.)	Chimerix (U.S.)
Date agreement was concluded / agreement period	December 2005 / 10-year period from the first product sales or the market-exclusive period in Japan, whichever is longer	March 2007 / 10-year period from the first product sales or the market-exclusive period, whichever is longer	September 2017 / Product patent period or the market-exclusive period, whichever is longer	July 2011 / 10-year period from the first product sales (7 years in South Korea), the market-exclusive period, or the patent validity period, whichever is longest, in each country	September 2019 / Each royalty period is 10 years from the start of sales, the patent period, or the market-exclusive period, whichever is longest, for each product's indication and for each country. The agreement deadline is when the final royalty period expires
Content of the main agreements	Exclusive development and marketing rights in Japan	Exclusive development rights and marketing rights in China (including Hong Kong), Taiwan, South Korea, and Singapore	Exclusive development rights and marketing rights in Japan	Exclusive development rights and marketing rights in Japan and South Korea	Exclusive global license agreement concerning the rights to develop, manufacture, and commercialize BCV in all DNA virus indications excluding smallpox

Source: Prepared by FISCO from the Company's securities report and news release

History

Date	Summary
March 2005	Established SymBio Pharmaceuticals Limited at Minato-ku, Tokyo
December 2005	Concluded a license agreement with Astellas Pharma GmbH (Germany) to acquire exclusive development and marketing rights in Japan for anti-cancer agent Bendamustine Hydrochloride
March 2006	Obtained manufacturer's license (packaging, labeling and storage) from Tokyo Metropolitan Government
March 2007	Concluded a license agreement with Astellas Deutschland GmbH (Germany) to acquire development and marketing rights in China, Taiwan, South Korea and Singapore for anti-cancer agent SyB L-0501
August 2008	Concluded a license agreement with Eisai Co., Ltd. to grant co-development and marketing rights in Japan for anti-cancer agent SyB L-0501
March 2009	Concluded sublicense agreement with Cephalon, Inc. (U.S.) to grant development and marketing rights in China for anti-cancer agent SyB L-0501
May 2009	Concluded a license agreement with Eisai to grant co-development and marketing rights in South Korea and Singapore for anti-cancer agent SyB L-0501
September 2010	Launched SYMBENDA® (generic name: bendamustine hydrochloride) in Singapore for the treatment of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia
October 2010	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan (launched in December 2010)
July 2011	Concluded a license agreement with Onconova Therapeutics, Inc. for anti-cancer agents SyB L-1101/SyB C-1101
October 2011	Launched SYMBENDA® (generic name: bendamustine hydrochloride) in South Korea for the treatment of chronic lymphocytic leukemia and multiple myeloma
October 2011	Listed on Osaka Securities Exchange JASDAQ Growth Market
February 2012	Launched INNOMUSTINE® in Taiwan for the treatment of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia
October 2015	Concluded a licensing agreement with The Medicines Company (U.S.) to acquire exclusive development and marketing rights in Japan for post-operative, self-administered pain-management medication, SyB P-1501 (the agreement ended in November 2017)
May 2016	Established SymBio Pharma USA, Inc. at Menlo Park, California, USA
August 2016	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan for the additional indication of chronic lymphocytic leukemia
December 2016	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan for the additional indication of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma
September 2017	Concluded a license agreement with Eagle Pharmaceuticals, Inc. to acquire development and marketing rights in Japan for bendamustine liquid formulations (RTD formulation and RI formulation) *RTD: Ready-to-dilute, RI: Rapid Infusion
October 2017	Filed for arbitration for damages against The Medicines Company (U.S.) due to the non-fulfillment of the licensing agreement
July 2018	TREAKISYM® was newly listed as the standard treatment for malignant lymphoma in the 2018 edition of the Japan Society of Hematology's Guidelines for the Treatment of Hematopoietic Tumors,

Date	Summary
September 2019	Concluded an exclusive global license agreement with Chimerix (U.S.) concerning the rights to develop, manufacture, and commercialize the antiviral drug, brincidofovir (excluding smallpox)
September 2020	In the final arbitration ruling for the claim for damages filed against the Medicines Company (U.S.) due to the non-fulfillment of a licensing agreement, the Company will receive from the Medicines Company 50% of its expenses relating to the arbitration proceedings, including attorneys' fees.
December 2020	Start of own sales of TREAKISYM®
January 2021	Concluded a joint research agreement with The Institute of Medical Science, The University of Tokyo to search for new indications for bendamustine and rigosertib
March 2021	Submitted an IND application to the FDA in the U.S. for a global joint clinical trial indicated for adenovirus infections (in infants) after hematopoietic stem cell transplantation
March 2021	Acquired marketing approval for a TREAKISYM® and rituximab combination therapy and TREAKISYM®, rituximab, and polatuzumab vedotin combination therapy indicated for relapsed and refractory diffuse large B-cell lymphoma

Source: Prepared by FISCO from the Company's securities report and website

Trends in the development pipeline

The sales growth potential of TREAKISYM® will approximately double by expanding its indications to relapsed and refractory DLBCL

1. TREAKISYM® (generic name: bendamustine hydrochloride)

TREAKISYM® is an anticancer agent for malignant lymphoma. Malignant lymphoma is a disease in which lymphocytes, which are a type of white blood cell, undergo canceration (tumorification) and lumps (masses) can grow in lymph nodes distributed throughout the body and organs other than lymph nodes (such as the stomach, intestines, thyroid, spinal cord, lung, liver, skin, and eyes). It is said to be the most common of the blood cancers, with approximately 10 out of every 100,000 people contracting it each year in Japan. Malignant lymphoma is mainly divided into Hodgkin's lymphoma (HL) and non-Hodgkin's lymphoma (NHL), with about 90% of cases in Japan being NHL. It is classified into low-grade, medium-grade, and high-grade according to the progression rate of the symptoms, and there are various disease types.

Types of non-Hodgkin's lymphoma

Type according to grade	Non-Hodgkin's lymphoma type (disease type)
Low grade: Indolent lymphoma (progresses yearly)	Follicular lymphoma (grade 1, 2), MALT lymphoma, lymphoplasmacytic lymphoma Mycosis fungoides, Sezary syndrome, chronic lymphocytic leukemia / small lymphocytic lymphoma, etc.
Medium grade: Aggressive lymphoma (progresses monthly)	Follicular lymphoma (grade 3), mantle cell lymphoma, diffuse large B-cell lymphoma Peripheral T cell lymphoma, extranodal NK / T cell lymphoma, adult T cell leukemia / lymphoma (chronic type), etc.
High grade: Highly aggressive lymphoma (progresses weekly)	Burkitt's lymphoma, acute lymphocytic leukemia / lymphoblastic lymphoma Adult T-cell leukemia / lymphoma (acute type, lymphoma type), etc.

Source: Prepared by FISCO from National Cancer Center Japan materials

(1) Expansion of indications

As its sales strategy for TREAKISYM®, the Company has been working to sequentially expand its indications. It acquired marketing approval for relapsed and refractory low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL) in October 2010, chronic lymphocytic leukemia (CLL) in August 2016 and untreated (first line of treatment) low-grade NHL/MCL in December 2016. Also, in July 2018, TREAKISYM® and rituximab combination therapy (BR therapy) was newly listed in the Japan Society of Hematology's Guidelines for the Treatment of Hematopoietic Tumors, and it has come to be recommended as the standard treatment option for all indications for which it has been approved. So TREAKISYM® has come to be positioned as the standard treatment for malignant lymphoma in both name and reality.

Other than the above, for CD20-positive follicular lymphoma (FL), which is a typical type of low-grade NHL, the Company acquired approval in July 2018 for partial changes relating to combination use with a new anti-CD20 antibody formulation, in addition to rituximab, and combination therapy with obinutuzumab*1 was added as a therapy option. Furthermore, in March 2019, it acquired approval for partial changes relating to pre-treatment with tumor-specific T-cell infusion therapy*2, and for the first time in Japan, TREAKISYM® can be used as a pre-treatment for the CAR T-cell therapy*3 Kymriah® intravenous drip*4. In such ways, its position as the standard therapy for malignant lymphoma is being further solidified.

*1 Obinutuzumab (GAZYVA®; sold by Chugai Pharmaceutical Co., Ltd.): similar to rituximab, which is recommended in the treatment guidelines domestically and overseas as a therapeutic drug for NHL, it is a glycosylated modified type II anti-CD20 monoclonal antibody that binds to CD20, a protein that expresses on B cells other than stem cells and plasma cells, and it directly attacks and destroys the B cells it targets together with the body's immune system.

*2 Tumor-specific T-cell infusion therapy: a therapy administered to patients after artificially applying and multiplying cancer specificity outside the body to the cancer patient's own T cells (a type of lymphocyte).

*3 CAR T-cell therapy (chimeric antigen receptor T-cell therapy): among tumor-specific T-cell infusion therapies, this is a therapy to introduce, amplify, and infuse into the gene-coding T cells the chimeric antigen receptors (CAR) that combine the antigen-binding site of the antibody that recognizes the membrane antigen on the tumor cell and the T-cell receptor's intracellular domain.

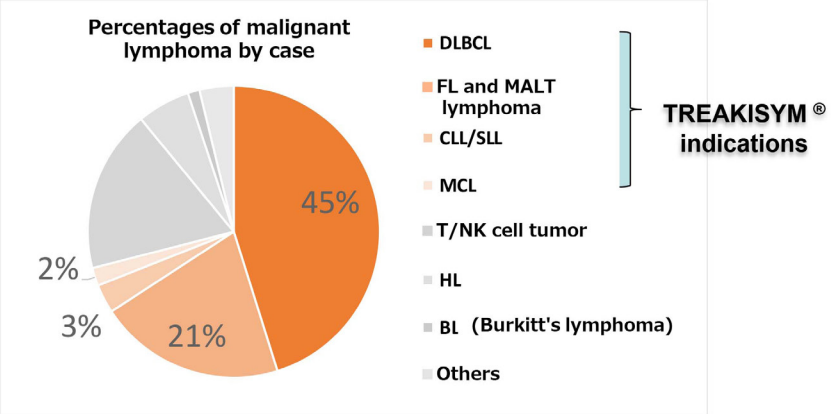
*4 Kymriah® intravenous drip (generic name: tisagenlecleucel; sold by Novartis Pharma KK as the first CAR-T therapy approved in Japan. In March 2019, it acquired manufacturing and marketing approval indicated for relapsed and refractory CD19-positive B cell acute lymphoblastic leukemia (B-ALL) and relapsed and refractory CD19 positive DLBCL.

Then on March 23, 2021, it was announced that it had acquired marketing approval for relapsed and refractory DLBCL, which is of the same scale in terms of the number of targeted patients as existing indications*1. In addition to the combination therapy (BR therapy) with rituximab developed by the Company, the combination therapy with polatuzumab vedotin (P-BR therapy)*2 developed by Chugai Pharmaceutical Co., Ltd. <4519> was also approved. Through these marketing approvals, the number of patients TREAKISYM® is indicated for has approximately doubled compared to previously, so its market value has risen significantly. Actual sales started from 2Q FY12/21.

*1 The standard treatment for untreated DLBCL is to provide a combination therapy of rituximab and chemotherapy, but recurrence is seen in approximately 40% of patients. Also, autologous stem cell transplantation (ASCT) is recommended as one treatment for relapsed and refractory DLBCL, but for approximately half of patients, the relief chemotherapy provided prior to ASCT is not successful and ASCT cannot be provided. Moreover, there are many patients for whom ASCT is not suitable as a treatment, such as due to their age or complications, and it has yet to be established as the standard treatment.

*2 Polatuzumab vedotin: an anti-CD79b antibody drug compound developed by Roche using the antibody drug conjugate technologies of Seattle Genetics Inc., in which humanized anti-CD79b monoclonal antibodies and tubulin polymerization inhibitors are combined with a linker. CD79b proteins are expressed specifically on many B cells, and this is a promising target in terms of developing new therapies. It is considered that polatuzumab vedotin binds with CD79b while suppressing the effects on normal cells and destroys B cells through the delivered chemotherapy agent.

Details of malignant lymphomas



Source: Prepared by SymBio Pharmaceuticals based on Chihara D, et al. Br J Haematol 164:536-545,2014

Source: Reprinted from the business plan and items relating to growth potential

The results of the phase III clinical trial for BR combination therapy indicated for relapsed and refractory DLBCL announced by the Company were excellent, with a complete response rate of 47.4% and an overall response rate of 76.3%. In particular, it seems that medical specialists were surprised by the level of the complete response rate for persons aged 76 years and older, which was 36.4%. There is currently no effective treatment for relapsed and refractory DLBCL, and a multi-drug combination therapy that combines multiple anticancer agents (3 to 6 types) is administered as relief chemotherapy. However, it has strong side effects, so there are hopes for the development of new highly effective therapeutic drugs and treatments that have few side effects. With the recent approval of BR therapy and P-BR therapy, it is highly likely that their use will spread as the standard therapies. There have also been request documents submitted by patient groups and related academic societies to be able to use BR therapy at an early stage, so sales of TREAKISYM® are forecast to further increase in the future with the spread of the use of BR therapy and P-BR therapy at medical facilities adopting multi-drug combination therapies. The choice of whether to use BR therapy or P-BR therapy depends on the doctor's decision, based on factors such as the patient's symptoms and gene type*.

* In BR therapy, TREAKISYM® 120mg/m^2 (body surface area) is administered once a day for 2 consecutive days, and then not administered for 19 days. This constitutes one cycle, and it is administered for a maximum of six cycles while observing the patient's condition. In P-BR therapy, the dosage is 90mg/m^2.

(2) RTD/RI formulation

Sales of the RTD formulation, which is the TREAKISYM® liquid type, began in January 2021. The situation is that steady progress is being made in switching to it from the FD formulation, as the switching rate had increased from approximately 20% at the end of March 2021 to slightly less than 50% by June. But the rate as of September was slightly less than 60%, so the speed of the switching slowed down (in the plan, the forecast was for a rate of more than 80%). This is because even if doctors want to use the RTD formulation, they cannot switch to it without obtaining the approval of the relevant department, so it seems this adjustment took some time. As a result, demand for the FD formulation has been higher than expected and there were concerns that a shortage of it could occur, so in September the Company announced that it has started adjusting shipments of the FD formulation. As a result, the speed of the switching to the RTD formulation has recovered and as of December, the outlook is that the switching rate will reach around 90%, as was initially forecast. Sales were started initially for existing indications except for relapsed and refractory DLBCL, but it acquired marketing approval for relapsed and refractory DLBCL in April 2021 and it is currently being sold for all existing indications.

The Company also applied for marketing approval for the RI formulation in May 2021, and if the review proceeds smoothly, it is expected to acquire approval within one year and to start sales in the second half of 2022. The RI formulation reduces the intravenous administration time to 10 minutes from the previous 60 minutes, so contributes greatly not only to medical practitioners, but also to improving patients' QOL. In particular, reducing the administration time is a major advantage for outpatients. Therefore, at FISCO we think that it is highly likely that the use of the RI formulation will spread even more at medical facilities conducting multi-drug combination therapy.

Furthermore, the exclusive market period for the FD formulation in Japan ended in 2020, so generics may be developed. However, due to major differences in terms of functionality compared to the RTD/RI formulation, it is expected that the exclusive marketing period of TREAKISYM® will actually continue until 2031, which is when the RTD/ RI formulation patent expires. Also, drug price revisions for FD formulation implemented in April 2021 and for the RTD formulation from next fiscal year will slightly lower prices, but the impact of that is expected to be limited. On the other hand, there are differences in contract conditions for purchase prices, and it seems that the prices for the RTD/RI formulation have been set low compared to the FD formulation, so switching from the FD formulation to the RTD/RI formulation will be a factor causing the profit margin to rise.

Alongside the switch from the FD formulation to the RTD formulation, the Company ended purchases of the FD formulation at the end of 2020 (it has already completed purchases for sales of the FD formulation from 2021 onwards), while it has also completed processing all of its debts and credits with Astellas Pharma. Therefore, it also plans to end sales of the FD formulation in Asia, and it is concentrating on sales of TREAKISYM® in Japan.

Sales progress of TREAKISYM®

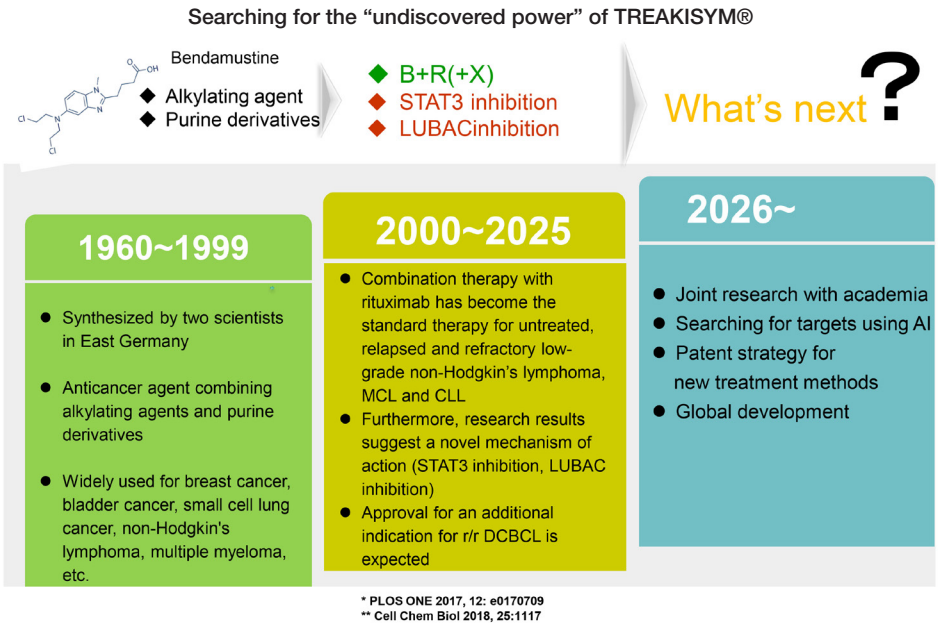
Drug	Indication	Progress
SyB L-0501 (FD lyophilized powder formulation)	r/r low-grade NHL/MCL CLL First-line low-grade NHL/MCL r/r DLBCL	Approved for sale in October 2010 Approved for sale in August 2016 Approved for sale in December 2016 Approved for sale in March 2021
SyB L-1701 (RTD liquid formulation)	Already approved indications	Marketing approval in September 2020 (Marketing approval for relapsed and refractory DLBCL in April 2021)
SyB L-1702 (RI liquid formulation)	Already approved indications	Applied for marketing approval in May 2021

Source: Prepared by FISCO from the Company's results briefing materials and website

(3) Future development plans

For TREAKISYM®, going forward the Company will progress joint research with academia to search for new indications, and its policy is to work to further increase business value. Specifically, in January 2021 it concluded a joint research agreement with The Institute of Medical Science, The University of Tokyo, and they plan to progress research into new treatments through possible developments not only for blood cancer, but also for solid cancers and other types of cancer, and also through combinations with other drugs, while utilizing AI technologies. In addition, in August of the same year it concluded a joint research agreement with Kyoto University, and they are progressing research into its inhibitory effect on LUBAC, which it has been suggested is involved in refractory activated B cell type (ABC) DLBCL.

Trends in the development pipeline



Source: From the Company’s results briefing materials

Is exploring the possibilities of developing rigosertib through combinations with other drugs, including TREAKISYM®

2. Rigosertib (intravenous formulation/oral formulation)

Rigosertib is an anticancer agent candidate that has unique multi-kinase inhibitory action (which causes cancer cells to die by inhibiting the multiple kinases involved in cancer cell proliferation, invasion, and metastasis). Its licensor, Onconova, has progressed the global joint phase III clinical trials (INSPIRE trial) with the overall survival period as the primary endpoint for high-risk myelodysplastic syndrome (MDS), for which sufficient treatment efficacy cannot be obtained through the current standard treatment of hypomethylating drugs, which recurs after treatment, and which shows resistance to hypomethylating drugs. In August 2020, it was announced that the primary endpoint had not been achieved in comparison to the doctor-selected therapy.

The Company is responsible for clinical development in Japan, and its policy is to search for new disease targets, including from the findings obtained from the INSPIRE trial’s additional analysis. Specifically, through the joint research agreements concluded with the Institute of Medical Science, The University of Tokyo, and Gunma University, they are creating new treatments through combination therapies for bendamustine and rigosertib and their combined use with other existing drugs, and searching for new disease targets, including in treatment areas other than the oncology area, while utilizing AI technologies. When using a treatment with multiple anticancer agents, there is the risk that the impact of the side effects will be amplified through drugs that have the same side effects. But the side effects of bendamustine and rigosertib are different, so it seems that their combination therapy is possible. Based on the above research, the Company intends to formulate a new rigosertib development plan in 2022.

Also, for the development of the rigosertib oral formulation, in September 2021 Onconova announced the interim results for the doctor-led phase 1/2a clinical trial (combined used with immune checkpoint inhibitors) for progressive KRAS* mutated NSCLC (non-small cell lung cancer, stage IV). Positive results were obtained showing antitumor activity in the combination therapy, which suggest the possibility that the effectiveness of immune checkpoint inhibitors is increased by their combination use with the rigosertib oral formulation, and development trends from now on will be closely watched. The Company has completed the phase I clinical trial in Japan in 2019 to confirm the safety of a high dosage of a single drug and its tolerability among Japanese people.

* KRAS is a cancer gene. The KRAS gene usually inhibits the replication of cells, but when a mutation of the KRAS gene occurs, a signal for cells to replicate is continually sent out, which causes cancerous cells to actively replicate. Patients with mutated KRAS genes have been identified in a considerable percentage of patients with certain forms of cancer, including colorectal cancer and lung cancer.

State of progress of rigosertib's development

Drug	Indication	Progress
SyB L-1101 (Intravenous formulation)	Relapsed and refractory high-risk MDS single drug	Global joint phase III clinical trial Currently conducting additional analysis
SyB L-1101 (Oral formulation)	Relapsed and refractory high-risk MDS single drug	Completed the phase I clinical trial in Japan
	Untreated high-risk MDS (combined use with azacitidine)	Completed the global joint phase I/II clinical trial

Source: Prepared by FISCO from the Company's results briefing materials and website

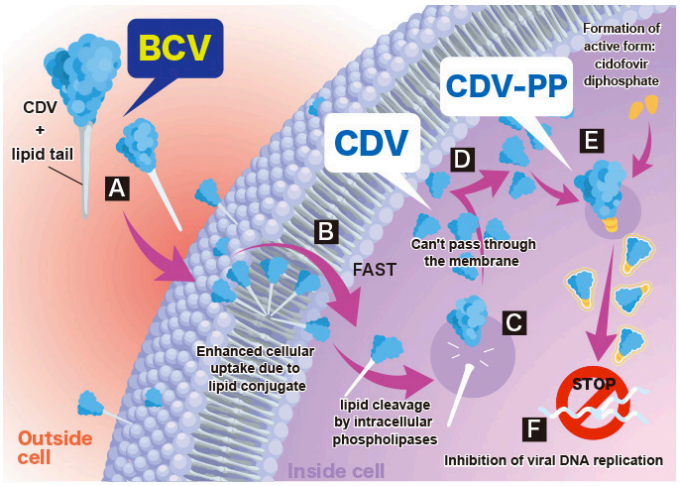
Has started a global clinical trial for brincidofovir indicated for adenovirus infections after hematopoietic stem cell transplantation and is progressing research on its antitumor effects

3. Brincidofovir (intravenous formulation/oral formulation)

(1) Overview and licensing agreement

Brincidofovir (BCV) is a lipid conjugate of cidofovir (CDV), which is known as a treatment of cytomegalovirus (CMV) retinitis. BCV is an antiviral drug candidate whose features are that it has higher antiviral activity, exhibits antiviral activity against a wider range of viruses, and has a superior safety profile compared to CDV. BCV has a structure that conjugates a lipid chain into CDV, which allows for more efficient uptake of BCV into cells than CDV alone. Once inside target cells, the lipid chain is cleaved, releasing CDV, which is then converted to its active form of cidofovir diphosphate (CDV-PP), which fulfills the role of inhibiting viral DNA replication. Data obtained from in vivo tests and other studies shows that BCV has a much higher antiviral replication effect than CDV and other antiviral drugs through these action mechanisms. In terms of the safety profile, CDV has risks for side effects such as strong nephrotoxicity, including renal dysfunction caused by the accumulation of CDV in renal tubular epithelial cells. However, because the lipid conjugation of BCV brings no accumulation of CDV in renal tubular epithelial cells, BCV has the outstanding feature of reducing the risk of nephrotoxicity associated with CDV. CDV has been granted fast-track designation by the FDA (the U.S. Food and Drug Administration) for the prevention of cytomegalovirus and the treatment of adenovirus and smallpox, while in Europe, the EMA has granted orphan drug designation for the same viruses.

How BCV works



Source: Reprinted from the Company's website

Chimerix had been developing an oral formulation of BCV, but it discontinued development because it did not obtain statistically significant results in the phase III clinical trials, and as there were some side effects, including diarrhea. Subsequently, Chimerix was looking for a partner to whom it could out-license BCV to concentrate its management resources in the anticancer agent field, while the Company was searching for new drug agents to in-license. The timing was right for both companies, and in September 2019, they concluded a licensing agreement for the global manufacture, marketing and development (excluding smallpox) of BCV. The key point for the Company's decision to in-license BCV was that it has excellent safety and functionality (high antiviral activity against a wide range of viruses), and it judged that its development was highly likely to be a success. Also its target diseases are "rare diseases" and "underserved therapeutic areas," which are not only consistent with the Company's development targets, but are also the same blood disease areas targeted by TREAKISYM®, so it judged that synergies for sales would be great.

In terms of the reason why Chimerix failed to develop an oral formulation, the Company thinks that as the drug absorption rate from the digestive organs was low, it was necessary to administer a large dosage. The Company believes that an intravenous formulation could have the same effect as an oral formulation at just 10% of the dosage, so it thinks there is a lower risk of side effects and a higher probability of success. This agreement covers both the intravenous formulation and the oral formulation, as the Company believes that going forward, there is a possibility that it can resolve these issues through new improvements to the drug. Of the viral infectious diseases, the reason why smallpox alone is excluded from the agreement is that the U.S. government needs to maintain its ability to manufacture and stockpile a smallpox treatment independently within the country as a measure to counter bioterrorism. In June 2021, Chimerix announced that the U.S. FDA approved its New Drug Application (NDA) for BCV Oral as a medical countermeasure for smallpox.

What is notable about this agreement is that it is a global license and also that it includes manufacturing rights. This drug will be used including to treat viral diseases that occur following hematopoietic stem cell transplantation and organ transplants. In particular, there are a large number of organ transplant cases not only in the U.S. and Europe, but also in Asia, and the potential organ transplant market is huge. The Company had previously sold TREAKISYM® in South Korea, Taiwan and Singapore through sales partners, but the sales volumes were small and their impact on results was negligible. It plans to actively progress the development of BCV overseas and is targeting expanding sales in the overseas markets and growing to become a global specialty pharmaceutical company.

Also, the quality issue for TREAKISYM® that arose in 2019 impacted the decision to have the agreement include manufacturing rights. The Company understands that controlling manufacturing on its own and building a system to suppress business risks to the fullest extent is critical in order to benefit all stakeholders, including patients, and aim for growth. In conjunction with the conclusion of the BCV licensing agreement, the Company paid developer Chimerix an upfront payment of US$5mn (approximately ¥540mn) in FY12/19, and it will pay future milestones of up to US$180mn (approximately ¥19.4bn), as well as double-digit royalties on net sales of brincidofovir products.

(2) Future development plans

As its development strategy for BCV (intravenous formulation), at the Global Advisory Board meeting convened in February 2020, the Company decided the following three points: progress development utilizing the multi-virus activity of BCV, which is its strength; target multiple viral infections, including adenoviruses* for which there are no treatments and medical needs are high; and conduct development as the highest priority for the infant transplant area, for which medical needs are high.

> * Adenoviruses are viruses existing in nature that can cause infections, such as pharyngitis, tonsillitis, conjunctivitis, gastro-enteritis, and hemorrhagic cystitis by infecting the respiratory organs, eyes, intestine, and urinary organs. Serious cases are rare among infections in healthy people, but the risk of severe complications increase in infections in patients whose immune systems have been weakened following a hematopoietic stem cell transplantation. As yet there is no treatment, so there are strong hopes for the developments of treatments and prophylactic drugs.

For the initial development target of adenovirus infections after hematopoietic stem cell transplantation indicated for infants, a phase II global joint clinical trial has begun and in August 2021 it reached First Patient In (FPI). In this trial, aspects such as safety, tolerability, and efficacy will be evaluated and the recommended dosage for the next trial will be determined. The scheduled number of patients is 24 cases and if it progresses smoothly, it will be completed in the second half of 2022 and may progress to the phase III clinical trial in 2023. Trials are being conducted at multiple medical facilities in the U.S. and the UK, but it seems that the pace of registrations is slightly behind schedule due to the impact of COVID-19. In order to smoothly progress the clinical trials, the Company appointed a manager with expertise and experience in clinical trials as vice president at the U.S. subsidiary and it has started fully-fledged operations in October 2021. It will conduct partner negotiations in parallel with the trials, and it is thought that specific discussions will be progressed after seeing the results of the clinical trials.

Moreover, in 2022 the Company intends to start a global joint clinical trial indicated for viral diseases after organ transplants. Globally, there are 35,000 hematopoietic stem cell transplantation (allogeneic transplantation) cases a year, while the market for organ transplants is more than 110,000 cases. So BCV's growth potential as a viral disease therapeutic drug and prophylactic drug is enormous, and we shall be paying attention to how development trends in the future. Conversely, the planned development in Japan indicated for viral hemorrhagic cystitis after hematopoietic stem cell transplantation has been postponed, because development overseas is being given priority.

Other than above, research has been started overseas to search for the antitumor effects of BCV (intravenous formulation). Specifically, in September 2021 the Company concluded a joint research agreement with the National Cancer Center Singapore (NCCS) into its antitumor effects and its mechanism of action for EB virus positive lymphoma. NCCS's Medical Oncology Department has commented that "To clarify BCV's mechanism of action against EB virus positive lymphoma, based on the findings obtained from this research, we want to progress clinical trials for malignant lymphoma patients for who BCV can be expected to have treatment effects." Also, in September of the same year, the Brain Tumor Center, the Department of Neurological Surgery, the University of California San Francisco, announced that it had started a pre-clinical trial to investigate its antitumor effects on brain tumors. This Center is progressing research into new treatments for intractable brain tumors and is focusing on BCV's antitumor effects. If the above research expands the possibilities for BCV's development to the oncology area, its market value is expected to increase even more.

Results trends

In the 3Q FY12/21 results, become profitable through the increase in sales of TREAKISYM®

1. Overview of the 3Q FY12/21 results

In the 3Q FY12/21 cumulative results, net sales increased 138.1% YoY to ¥5,553mn, operating profit was ¥424mn (compared to a loss of ¥3,142mn in the same period in the previous fiscal year), ordinary profit was ¥414mn (a loss of ¥3,220mn), and profit was ¥324mn (a loss of ¥2,694mn), and the Company become profitable for the first time since its foundation.

3Q FY12/21 results (cumulative)

(¥mn)

	3Q FY12/20	3Q FY12/21	YoY	YoY (%)
Net sales	2,332	5,553	3,220	138.1%
Gross profit	610	4,045	3,435	562.4%
SG&A expenses	3,753	3,621	-131	-3.5%
R&D expenses	1,754	1,286	-468	-26.7%
Other SG&A expenses	1,998	2,335	336	16.8%
Operating profit (loss)	-3,142	424	3,566	-
Ordinary profit (loss)	-3,220	414	3,635	-
Extraordinary profit (loss)	529	0	-529	-
Profit (loss)	-2,694	324	3,019	-

Source: Prepared by FISCO from the Company's financial results

Net sales increased significantly, mainly because in December 2020 the Company transitioned to an in-house structure for sales of TREAKISYM®* and as its indications were expanded to relapsed and refractory DLBCL, for which there are many patients. The gross profit margin also rose greatly, from 26.2% in the same period in the previous fiscal year to 72.9%, including due to the transition to the in-house sales structure and the progress made in switching from the FD formulation to the RTD formulation. As a result, gross profit increased 562.4% YoY to ¥4,045mn.

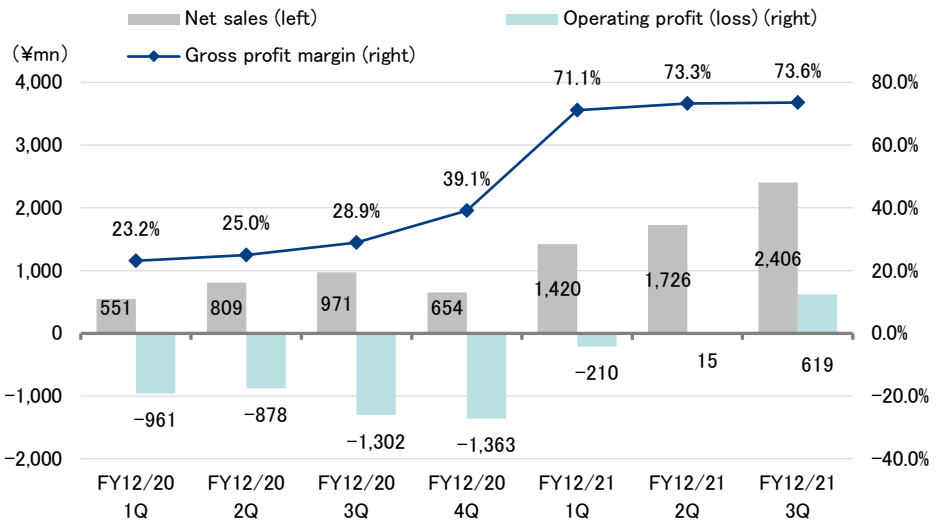
* For its distribution system, in September 2020 the Company concluded agreements with Suzuken Co., Ltd. <9987> and TOHO PHARMACEUTICAL CO., LTD., a consolidated subsidiary of Toho Holdings Co., Ltd. <8129>, and it became their general agent. It is also outsourcing logistics to S.D Collabo Co., Ltd., which is a subsidiary of Suzuken (one logistics base in both eastern and western Japan).

Conversely, SG&A expenses decreased 3.5% YoY to ¥3,621mn, mainly due to the decline in R&D expenses. R&D expenses declined ¥468mn YoY, but this was because a RTD formulation milestone payment of approximately ¥500mn that was recorded in the same period in the previous fiscal year was not recorded in the current period, and on excluding this factor, R&D expenses were basically unchanged YoY. Other SG&A expenses increased ¥336mn due to the rise in sales costs following the transition to the in-house sales system. As a result of the above, operating profit increased ¥3,566mn YoY.

Results trends

Looking at how net sales trended on a quarterly basis, the increase pace accelerated from the 2Q FY12/21 to the 3Q, but this was largely due to the effects of the start of sales for relapsed and refractory DLBCL. Also, the reason why the gross profit margin rose from 71.1% in the 1Q FY12/21 to 73.6% in the 3Q was the progress made in switching from the FD formulation to the RTD formulation. As previously stated, the pace of the switching rate in the 3Q was slower than initially forecast, so the gross profit margin rose only moderately.

Result trends



Source: Prepared by FISCO from the Company's financial results

Has entered a phase for achieving profitability in FY12/21, and fundraising is expected to be mainly borrowings from financial institutions

2. Financial condition

At the of end of 3Q FY12/21, total assets were down ¥75mn on the end of the previous fiscal period to ¥6,199mn. Looking at the main change factors, in current assets, there were increases of accounts receivable-trade of ¥1,430mn and merchandise and finished goods of ¥229mn, but there were decreases of cash and deposits of ¥1,235mn, semi-finished goods of ¥206mn, and accrued consumption taxes of ¥314mn. In non-current assets, software decreased ¥30mn.

Total liabilities were down ¥427mn on the end of the previous fiscal period to ¥1,189mn. The main change factors were increases in accrued consumption taxes of ¥291mn, and income taxes payable of ¥53mn, but decreases in accounts payable-trade of ¥582mn, and accounts payable of ¥90mn. Net assets increased ¥352mn to ¥5,009mn. Due to the exercise of stock acquisition rights, share capital and the capital surplus both increased ¥107mn, while due to the recording of profit, retained earnings increased ¥324mn. As a result, the equity ratio rose 8.5 percentage points, from 64.3% at the end of the previous period to 72.8%.

In December 2020, the Company concluded a commitment line agreement with two banks with an upper limit of ¥3bn. It had previously raised funds for business activities, mainly for R&D expenses, through equity financing by issuing stock acquisition rights. But as it is expected to become profitable from FY12/21, it has become able to borrow from financial institutions. Therefore, its policy going forward is to pay for business activities through fiscal-period earnings and borrowings from financial institutions.

Balance sheet and management indicator

(¥mn)

	End of FY12/18	End of FY12/19	End of FY12/20	End of 3Q FY12/21	Change
Current assets	6,038	4,887	5,815	5,764	-50
(Cash and deposits)	4,821	3,910	3,848	2,613	-1,235
Non-current assets	200	386	459	434	-25
Total assets	6,239	5,273	6,274	6,199	-75
Total liabilities	1,337	873	1,617	1,189	-427
(Interest-bearing debt)	-	-	-	-	-
Net assets	4,901	4,400	4,657	5,009	352
Management indicator					
Equity ratio	70.1%	71.7%	64.3%	72.8%	8.5pt

Source: Prepared by FISCO from the Company's financial results

In the FY12/21 results, net sales may be slightly lower than forecast, but the outlook is for every profit item to achieve their forecasts

3. Outlook for FY12/21

For the FY12/21 results, the Company has left the initial forecasts unchanged, of net sales to increase 206.4% on the end of the previous period to ¥9,151mn, operating profit of ¥1,361mn (compared to a loss of ¥4,506mn in the previous period), ordinary profit of ¥1,350mn (a loss of ¥4,615mn), and profit of ¥1,149mn (a loss of ¥4,090mn). So the outlook is for the Company to become profitable for a fiscal year for the first time since its foundation. It has achieved all of the conditions it cited to become profitable, of constructing the in-house sales structure, starting sales of the RTD formulation and switching to it from the FD formulation, and acquiring marketing approval for relapsed and refractory DLBCL, and these will be the main factors behind the significant increases in net sales and gross profit.

Outlook for FY12/21

(¥mn)

	FY12/20		FY12/21		Change	% change	3Q progress rate
	Results	vs. net sales	Company forecast	vs. net sales			
Net sales	2,987	-	9,151	-	6,163	206.4%	60.7%
Gross profit	866	29.0%	6,957	76.0%	6,090	702.6%	58.2%
SG&A expenses	5,373	179.9%	5,596	61.2%	222	4.1%	64.7%
R&D expenses	2,266	75.9%	2,019	22.1%	-247	-10.9%	63.7%
Other SG&A expenses	3,106	104.0%	3,577	39.1%	470	15.1%	65.3%
Operating profit (loss)	-4,506	-	1,361	14.9%	5,867	-	31.2%
Ordinary profit (loss)	-4,615	-	1,350	14.8%	5,965	-	30.7%
Profit (loss)	-4,090	-	1,149	12.6%	5,239	-	28.3%

Source: Prepared by FISCO from the Company's financial results

Looking at the progress rate for the full fiscal year forecasts up to the 3Q, net sales were slightly below forecast at 60.7%. This was because on entering FY12/21, inventory on the market worth ¥300mn to ¥400mn of the FD formulation sold by Eisai up to December 2020 was extinguished, that people refrained from medical diagnoses or postponed treatment due to the prolonging of COVID-19, and also because of the impact of restrictions on sales activities at medical facilities. Therefore, it is possible that full fiscal year net sales will be slightly lower than forecast. The gross profit margin may also be slightly lower than the full fiscal year forecast of 76.0%, because the switching from the FD formulation to the RTD formulation slowed down in the 3Q. But in terms of the sales conditions on entering the 4Q, sales for relapsed and refractory DLBCL are steadily growing and the switching to the RTD formulation is also progressing as forecast.

However, costs are progressing at a pace lower than initially forecast. The progress rate up to the 3Q was 63.7% for R&D expenses. This was mainly due to the delay in the BCV clinical trial because of the impact of COVID-19. The Company's policy is to aim to recover the lost time in the future while increasing the number of clinical trial facilities. The progress rate for other SG&A expenses was also less than forecast, at 65.3%, as overseas business trips were not possible because of COVID-19, and costs within Japan as well, such as transportation costs and sales-activity costs, were less than forecast. As a result, both net sales and gross profit may be slightly less than forecast, but as SG&A expenses will also be similarly less than forecast, the outlook is for operating profit to achieve its initial forecast.

Looking at the net sales of TREAKISYM® on a drugs-price basis, they are expected to increase approximately 40%, from the previous period's result of ¥8.1bn to ¥11.3bn. Breaking down this amount, the forecasts are for sales for untreated low grade NHL of ¥4.1bn, for other existing indications of ¥4.6bn, and for relapsed and refractory DLBCL of ¥2.6bn. The reasons why sales for existing indications will increase from ¥8.1bn in the previous period to ¥8.7bn are that in the previous period, sales of the FD formulation were restricted due to a defective-product problem, and also as it seems that the BR therapy penetration rate will further rise due to the switching to the RTD formulation.

Mid and Long- Range Outlook

From 2022 onwards, operating profit is expected to grow by more than 20% a year from the increase in sales of TREAKISYM®

1. Mid-Range Plan

In the three-year Mid-Range Plan that the Company announced in February 2021, the numerical results targets for the Plan's final fiscal year of FY12/23 are net sales of ¥12,369mn, operating profit of ¥2,099mn, ordinary profit of ¥2,088mn, profit of ¥1,778mn, and Earnings per share of ¥46.5. It plans to continuously achieve double digit increases in sales and profits from FY12/22 onwards.

Mid-Range Plan

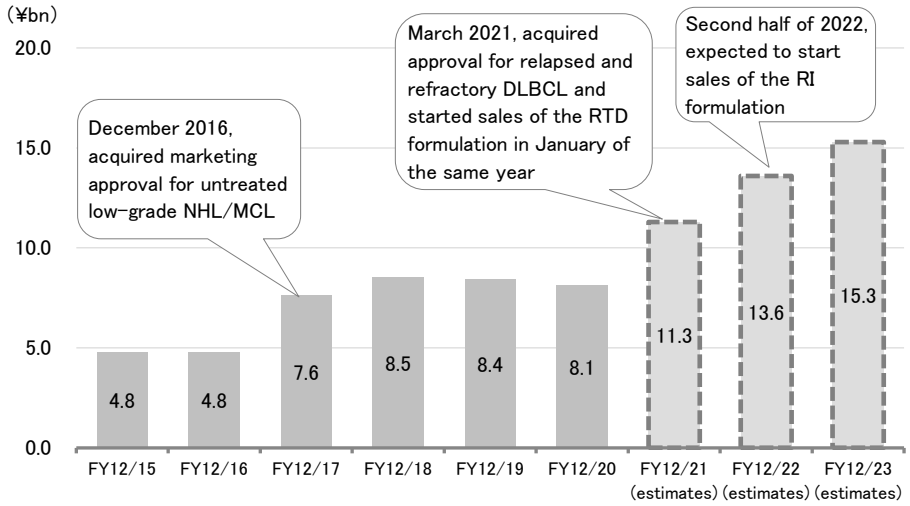
(¥mn)

	FY12/21 Company forecast	FY12/22 targets	Growth rate	FY12/23 targets	Growth rate
Net sales	9,151	10,985	20.0%	12,369	12.6%
Operating profit (loss)	1,361	1,738	27.7%	2,099	20.8%
Ordinary profit (loss)	1,350	1,727	27.9%	2,088	20.9%
Profit (loss)	1,149	1,470	27.9%	1,778	21.0%
Earnings per share (¥)	30.1	38.5	-	46.5	-

Source: Prepared by FISCO from the Company's results briefing materials

For net sales, sales will continue to increase for relapsed and refractory DLBCL, and in addition, sales of the RI formulation will start from the second half of 2022, while it seems the use of TREAKISYM® is progressing in medical facilities using multi-drug combination therapies, which will also lead to higher sales. On a drug-price basis, sales are forecast to increase from ¥8.1bn in FY12/20 to ¥15.3bn in FY12/23. Also, currently multiple pharmaceutical companies are progressing clinical trials for multi-drug combination therapies that include TREAKISYM®. So in the future, it is fully possible that treatments for existing indications and new indications using TREAKISYM® will increase, leading to sales growth from FY12/24 onwards. Within Japan, the situation in which in actuality the Company has exclusive marketing rights is likely to continue until 2031, which is when the patent expires for the RTD/RI formulation, and TREAKISYM® will be the driver of earnings.

TREAKISYM® net sales (drug-price basis)



Sources: the results are from interviews with the Company and from the results briefing materials for FY12/21, while the figures for FY12/22 onwards are estimates prepared by FISCO based on the FY12/21 figures

The gross profit margin is forecast to rise from 76.0% in FY12/21 to 79% in FY12/22, and to 80% in FY12/23. The profit margin is expected to increase from the progress made in switching from the FD formulation to the RTD/RI formulation. By the end of 2022, the percentage of sales from the RTD/RI formulation is forecast to be around 95%. This assumes that going forward, some medical facilities will continue to use the FD formulation, but when considering the superiority of its functions, it is anticipated that close to 100% of medical facilities will switch to the RTD/RI formulation.

SG&A expenses are forecast to continue to trend upward, increasing from ¥5,596mn in FY12/21 to ¥6,940mn in FY12/22, and to ¥7,796mn in FY12/23. Within this amount, R&D expenses are expected to increase from ¥2,019mn in FY12/21 to approximately ¥3.1bn in FY12/22 (of which, milestone payments of around ¥500mn), and to approximately ¥3.8bn in FY12/23 (of which, milestone payments of around ¥500mn). After excluding the milestone payments, they will continue to trend upwards, but this is mainly due to the increase in BCV development expenses. Conversely, other SG&A expenses are forecast to increase only slightly, from ¥3,577mn in FY12/21 to approximately ¥3.7bn in FY12/22, and to around ¥3.9bn in FY12/23. In TREAKISYM® operating expenses, logistics expenses will increase somewhat, while the Company plans to maintain the current situation for the personnel system. On the other hand, the Company plans to hire a small number of new employees at the U.S. subsidiary and personnel expenses are forecast to increase toward BCV's global deployment. An important issue for the Company is continuing to grow after 2032, which is when the patent for the RTD/RI formulation expires. So it is searching for new development candidates to follow-on from BCV, but the current results forecasts do not incorporate any one-off payments relating to in-licensing.

With 2021 as the first year of the second foundation, is aiming to be a global specialty pharma

2. Long-term targets

Since it was founded in 2005, the Company has continuously worked to develop TREAKISYM® as a bio-venture, arriving at its current situation in FY12/21 when it can become profitable for the first time, and in 2021, it is transitioning from a development stage to an earnings-growth stage. Therefore, the Company has positioned 2021 as the first year of its second foundation, and it is aiming to grow as a global specialty pharma by working continuously to increase and to create business value, and at the same time, to actively promote overseas business development through BCV.

Specifically, the Company is aiming for sustainable earnings growth by maximizing earnings from TREAKISYM®, and in addition, by targeting the market launches of rigosertib and BCV. Moreover, with an aim of maximizing its business value, the Company will work on discovering the fundamental value in each pipeline while moving ahead on joint research with academia and others. At the same time, it will conduct activities such as in-licensing of new pipeline drugs.

The Company has set "Local & Global" and "50 and 50 in 30" as the management keywords. Their meaning is to take a dramatic leap forward as a global pharmaceutical company by successfully guiding the development of BCV with the aim of increasing the percentage of total sales from overseas sales to 50% by 2030. BCV is expected to be an effective treatment for various viral infectious diseases after hematopoietic stem cell transplantation, while it is also possible that developments will be progressed for viral infectious diseases after organ transplants, viral infectious diseases in other areas (dermatology and ophthalmology), and for the oncology area. So it has enormous growth potential, and we shall be paying attention to development trends in the future.

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