COMPANY RESEARCH AND ANALYSIS REPORT

SymBio Pharmaceuticals Limited

4582

JASDAQ Growth Market

20-Dec.-2019

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https://www.symbiopharma.com/ir_e/

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Summary

Significant increase in growth potential from 2022 onward owing to expanded areas of indication for TREAKISYM® and the licensing-in of an antiviral drug candidate

Symbio Pharmaceuticals Limited <4582> (hereafter, also "the Company") is a bio-venture that is advancing developments in the fields of oncology, hematology, and rare diseases where there are few patients, but high medical needs. The main drugs in the development pipeline are TREAKISYM®, whose indications as a treatment for malignant lymphoma are expanding, and rigosertib, which is being developed for myelodysplastic syndrome (MDS). In September 2019, the antiviral drug brincidofovir (hereafter, "BCV") was added to the development pipeline. The Company is working to expand indications for TREAKISYM®, which is already commercially available. Concurrently, it is pushing ahead with development in order to switch TREAKISYM® from a lyophilized powder formulation to a liquid formulation. Moreover, the Company will transition to its own sales system when its marketing agreement with Eisai Co., Ltd. <4523> finishes at the end of 2020.

1. Stronger prospects for becoming profitable in FY12/21

In its Mid-Range Plan announced in February 2019, the Company set a goal of becoming profitable in FY12/21, with net sales of ¥9,132mn and operating profit of ¥1,225mn. The Company downwardly revised its initial forecast for its financial results for FY12/21 due to the impact of quality problems related to TREAKISYM® products that were imported at the beginning of 2019. However, steady progress is being made on the three strategies for becoming profitable in FY12/21. First, the Company announced (on November 5, 2019) that it has achieved the primary endpoint (overall response rate) in a phase III clinical trial of TREAKISYM® for relapsed and refractory diffuse large B-cell lymphoma (DLBCL) (in combination therapy with rituximab). The Company has been advancing these trials to expand the indications of TREAKISYM®. As a result, it is now highly likely that the Company will submit a new drug application (NDA) in Q2 FY12/20 and commence sales in 2021. Second, the Company has been working to switch TREAKISYM® to a ready-to-dilute (RTD) liquid formulation. It submitted an NDA for TREAKISYM® RTD liquid formulation in September 2019, and expects to commence sales of the RTD liquid formulation in Q1 FY12/21. Third, the Company has made steady progress on building its own nationwide sales system, completing the recruitment of 20 TREAKISYM® managers by July 2019. Notably, the shift to the RTD liquid formulation will improve profitability in comparison to that of the lyophilized powder formulation. Based on these factors, at FISCO we believe that the Company now offers stronger prospects for achieving profitability in FY12/21.

2. Addition of the antiviral drug brincidofovir (BCV)

The Company has licensed-in BCV from Chimerix Inc. <CMRX> (U.S.). BCV stands out for its ability to drastically suppress the proliferation of DNA viruses and for its superior safety profile. BCV is expected to be developed into an effective treatment against a wide spectrum of infectious diseases caused by DNA viruses. As the first step, the Company aims to begin clinical trials in Japan in 2020, targeting viral hemorrhagic cystitis (vHC) and HHV-6 encephalitis occurring after allogeneic hematopoietic stem cell transplantation. With high unmet medical needs, these areas represent critically underserved therapeutic areas for intravenous formulations. In addition, the Company has concluded an exclusive global license agreement with Chimerix, so it plans to target business expansion in Europe, the U.S, and the Asian region including China, which are large organ transplant markets, and to advance a partnership strategy that harnesses the regional characteristics of the targeted diseases. Under the terms of the agreement, the Company will pay the developer, Chimerix, an upfront payment of US$5mn (approximately ¥540mn) in Q3 FY12/19, future milestones of up to US$180mn (approximately ¥19.4bn) and a double-digit royalty on net sales of brincidofovir products. We believe that the addition of BCV to the development pipeline has increased the Company's growth potential further.

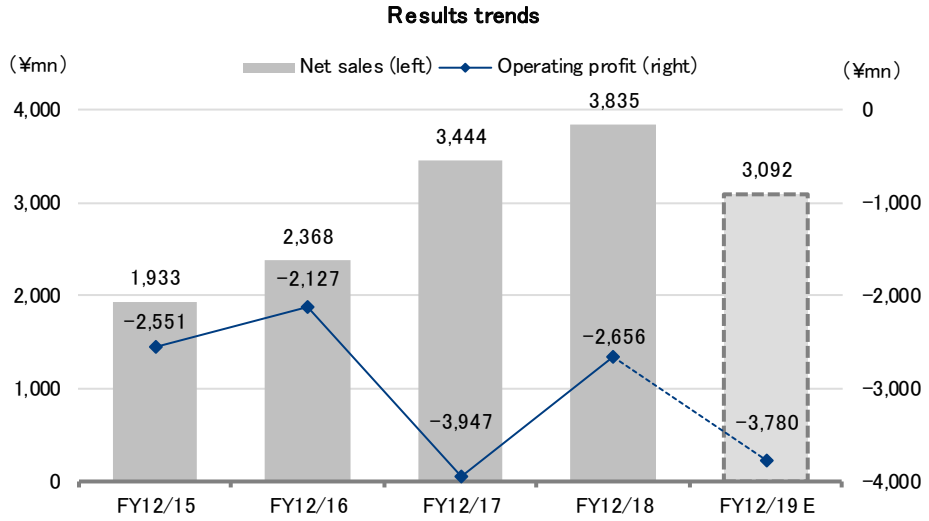
3. Results trend

In terms of results for Q3 FY12/19, the Company reported net sales of ¥2,008mn, down 33.8% year-on-year (YoY) and an operating loss of ¥3,536mn (compared with a loss of ¥1,907mn in same period last year). The main reason for the decrease in net sales was that sales of TREAKISYM® were halted temporarily due to quality issues. On the cost front, R&D expenses rose 52.5% to ¥1,971mn, partly due to the recording of an upfront payment for BCV. Other SG&A expenses rose 38.3% YoY to ¥2,127mn, due to higher expenses to build the Company's own sales system. The Company had revised its forecasts of FY12/19 results in August 2019, but has kept those forecasts unchanged, with net sales of ¥3,092mn, down 19.4% YoY, and an operating loss of ¥3,780mn (compared to a loss of ¥2,656mn in the previous fiscal year). The upfront payment for BCV is likely to cause profits to fall below forecast. That said, with a change in a supplier's manufacturing site for TREAKISYM®, net sales are expected to recover from Q4 FY12/19 onward.

Key Points

- Steady progress on measures to become profitable in 2021, despite quality issues with TREAKISYM® in FY12/19.
- Expansion of indications for TREAKISYM® as the standard treatment for malignant lymphoma, with the shift to the TREAKISYM® RTD liquid formulation expected to gain ground from 2021 onward
- The licensing-in of BCV will increase sales growth potential further

Summary



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

Company profile

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

1. History

SymBio Pharmaceuticals is a bio-venture founded by the current Representative Director 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 is that it 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 licensing-in development candidates for which *POC for humans has been obtained, and conducting development from the clinical trials 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 development candidate licensed-in first was the anti-cancer agent bendamustine hydrochloride (hereafter, Bendamustine hydrochloride) 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 2015. With the development code SyB L-0501, 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 (product name, TREAKISYM®). 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 as its marketing partner, it concluded licensing agreements for Japan in 2008 and for South Korea and Singapore in 2009. The Company has decided to dissolve the licensing agreements with Eisai at the end of 2020. For this reason, it plans to shift to its own sales system in Japan from 2021. At present, the Company is making preparations to establish sales and distribution systems.

TREAKISYM®, whose sales were launched in Japan in December 2010, continued to be subsequently developed in order to expand its indications, and in 2016, it acquired approval for indications for chronic lymphocytic leukemia (CLL) and untreated (first line of treatment) low-grade NHL/MCL, and its sales are growing. Also, in Asia, it sales began in Singapore in 2010, in South Korea in 2011, and in Taiwan in 2012. For Taiwan, in 2008, the Company concluded a licensing agreement with InnoPharmax Inc. (Taiwan), which is conducting sales through the Company.

Also, the second drug licensed-in was rigosertib (development code, SyB L-1101 (intravenous formulation)/SyB C-1101 (oral formulation)), which is a development candidate from Onconova Therapeutics, Inc. (U.S.) (hereafter, Onconova) indicated for myelodysplastic syndrome*1 for which the Company concluded an exclusive development and marketing rights agreement in 2011 for Japan and South Korea. Currently also, its development is being progressed. Further, in 2017 it concluded an exclusive development and marketing rights agreement for Japan with Eagle Pharmaceuticals, Inc. <EGRX> (U.S.) for the TREAKISYM® liquid formulation, ready-to-dilute (RTD) formulation / rapid infusion (RI) formulation (development code, SyB L-1701/SyB L-1702)*2, and in the same way, its development is being progressed.

*1 Myelodysplastic syndrome: a disease in which normal blood cells (red blood cells, white blood cells, and platelets) cannot be produced due to abnormalities in the hematopoietic stem cells in the bone marrow. It is known as a disease that has a high incidence in the elderly and that is likely to develop to become acute myeloid leukemia.

*2 Currently, TREAKISYM®, which has been approved in Japan, is a lyophilized powder formulation, which means it must be dissolved at the medical site when it is used. As this task is unnecessary for the liquid formulation, it greatly reduces the workload placed on healthcare workers. Also, the difference between the RTD formulation and the RI formulation is the intravenous injection time. The RTD formulation takes the same time, 60 minutes, as existing products, but the time for the RI formulation is as short as 10 minutes, so the burden on the patient is greatly reduced.

Moreover, in September 2019, the Company concluded an exclusive global license agreement with Chimerix that gives the Company the rights to develop, manufacture, and commercialize BCV in all viral diseases excluding small pox. BCV will be the third drug to be licensed-in and developed by the Company. The main features of BCV are that it has higher anti-viral activity and a superior safety profile in comparison with cidofovir (CDV: unapproved in Japan). Accordingly, BCV is expected to be an effective treatment against various infection diseases caused by DNA viruses. As the first step, the Company plans to conduct development in Japan for the indications of viral hemorrhagic cystitis (vHC) and HHV-6 encephalitis*2, conditions that can occur after allogeneic hematopoietic stem cell transplantation.

*1 Viral hemorrhagic cystitis (vHC): vHC is one type of viral infectious disease that frequently occurs following hematopoietic stem cell transplantation. In vHC, hemorrhagic cystitis is caused by the proliferation of adenovirus. In Japan, the incidence ratio of vHC for allogeneic stem cell transplantation is between 8.6% and 24.0%. There are also reports that the incidence ratio of vHC for cord blood stem cell transplantation is even higher. It is generally refractory, with patients showing primary symptoms such as frequent urination, abdominal pain, micturition pain and hematuria. In mild cases of vHC, patients often experience no symptoms. However, in severe cases, disseminated infection can be lethal. There are also reported cases where mortality occurs from renal impairment associated with adenovirus infection. Transplantation with unrelated donors including cord blood, of which there is a high proportion in Japan, is a potent risk factor. Since there are no approved drug therapies or definitive treatment in Japan, some physicians privately import cidofovir (CDV) and administer it to their patients. However, CDV has a strong nephrotoxicity with only limited efficacy, so an effective and safe drug therapy is eagerly awaited.

*2 HHV-6 encephalitis (Human herpesvirus 6): HHV-6 is the sixth human herpes virus to be identified. The reactivation of HHV-6 occurs in 30-70% of patients in cases of allogeneic hematopoietic stem cell transplantation, and can cause HHV-6 encephalitis. Typically, symptoms gradually progress from memory impairment to consciousness disorder and convulsions, which are the three major symptoms. The incidence ratio of convulsions has been reported to be 30% to 70%. In rapidly progressing cases, neurological symptoms worsen with time, and many cases require respirator management for repeated convulsions and respiratory depression. Early treatment is very important for patients with HHV-6 encephalitis, as the patient's condition often worsens rapidly in a short time. According to the Guidelines for hematopoietic cell transplantation edited and published by The Japan Society for Hematopoietic Cell Transplantation in February 2018, the first-line drug is foscarnet (FOS) or ganciclovir (GCV), and the second-line drug is cidofovir (CDV). CDV is defined as the second-line drug due to its strong nephrotoxicity and poor delivery of the drug into the cerebrospinal fluid (CSF). However, the clinical effects of these drugs, including FOS and GCV, have not actually been confirmed, and these drugs have only been shown to be effective on HHV-6 infection in vitro, so an effective and safe drug therapy is eagerly awaited.

Technology licensing-in agreements

Name		TREAKISYM®		Rigosertib sodium	Brincidofovir
Development code	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) SyB C-1101 (Oral formulation)	SyB V-1901 (Intravenous formulation)
Licensing-in partner	Astellas Pharma (Germany)	Astellas Deutschland (Germany)	Eagle Pharmaceuticals, Inc. (U.S.)	Onconova Therapeutics, Inc. (U.S.)	Chimerix Inc. (U.S.)
Date agreement was concluded / agreement period	December 2005 / Whichever is longer; the 10-year period from the first product sales, or the market-exclusive period in Japan	March 2007 / Whichever longer; the 10-year period from the first product sales or the market-exclusive period	September 2017 / Whichever longer; the product-patent period or the market-exclusive period	July 2011 / Whichever longer; the 10-year period from the first product sales (7 years in South Korea), the market-exclusive period, or the patent-validity period, in each country	September 2019
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

Technology licensing-out agreements

	SyB L-0501 (Lyophilized powder formulation)			
Licensing-out partner	InnoPharmax Inc. (Taiwan)	Eisai Co., Ltd. (Japan)		Cephalon, Inc. (U.S.)
Date agreement was concluded / agreement period	March 2008 / 10 years from the first product sales in Taiwan	From August 2008 to December 2020	From May 2009 to December 2020	March 2009 / 10 years from the first product sales in China
Content of the main agreements	Exclusive development rights and marketing rights in Taiwan	Joint development rights and exclusive marketing rights in Japan	Exclusive development rights and marketing rights in South Korea and Singapore	Exclusive development rights and marketing rights in China (including Hong Kong)

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

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,
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)

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

Expansion of indications for TREAKISYM® as the standard treatment for malignant lymphoma, with the shift to the TREAKISYM® RTD liquid formulation expected to gain ground from 2021 onward

2. Trends in the development pipeline

(1) TREAKISYM® (generic name: bendamustine hydrochloride)

TREAKISYM® is an anti-cancer 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 and organs other than lymph nodes (such as the stomach, intestines, thyroid, spinal cord, lung, liver, skin, and eyes) distributed throughout the body. 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

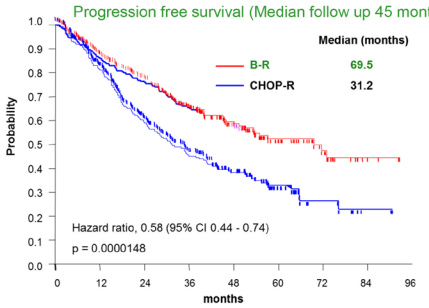
Type according to grade	Non-Hodgkin's lymphoma type (disease type)
Low grade: Indolent lymphoma (progresses yearly)	Follicular lymphoma (grade 1, 2), MALT lymphoma, lymphoplasmacytic lymphoma Mycosis fungoides, Sezary syndrome, chronic lymphocytic leukemia / small lymphocytic lymphoma, etc.
Medium grade: 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.

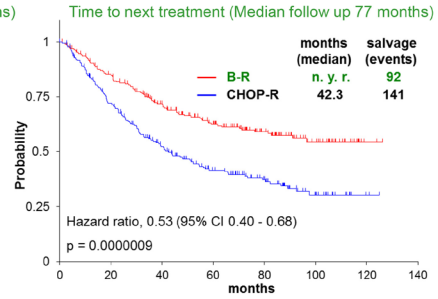
Source: Prepared by FISCO from National Cancer Center Hospital materials

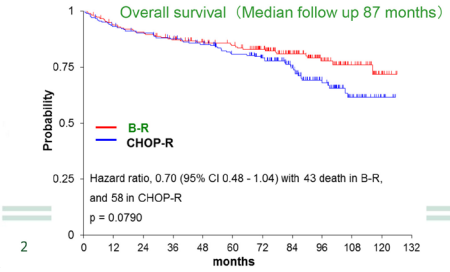
Among these, currently the Company has acquired marketing approval for indications for relapsed and refractory low-grade non-Hodgkin's lymphoma (NHL), mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), and untreated (first line of treatment) low-grade NHL/MCL. In particular, in 2016 its use in this field started to spread following the acquisition of marketing approval for untreated low-grade NHL/MCL, and then in July 2018, in its treatment guidelines, the Japan Society of Hematology recommended TREAKISYM® and Rituximab® combination therapy (BR therapy) as the standard treatment, and it is becoming established as the standard treatment in both name and reality. In the field of untreated (first line of treatment) low-grade NHL, previously the standard treatment was R-CHOP therapy*, but on looking at the market penetration rates, in Q4 FY12/17 (October to December 2017), BR therapy had overtaken it, and as of Q2 FY12/19 (April to June), BR therapy had a 55% share of the market as a whole. In light of the high efficacy of BR therapy, the Company expects that the market penetration rate will increase to nearly 70% in 2020 in the untreated area, with the possibility of increasing the market penetration rate to at least around 75% thereafter.

* R-CHOP therapy: a multi-drug combination therapy combining Rituximab® and 4 other drugs

BR therapy It is superior to R-CHOP for both efficacy and safety



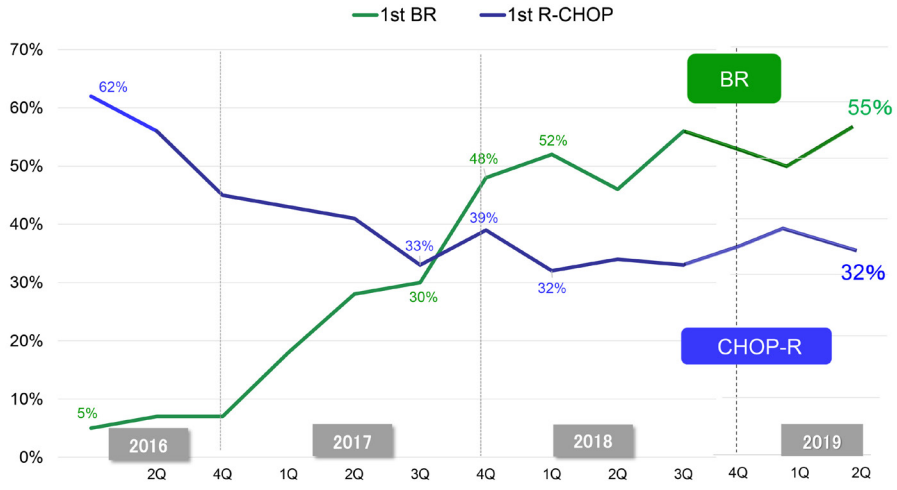




Safety comparison	B-R (n=260) (no. of pts)	CHOP-R (n=253) (no. of pts)	P value
Alopecia	-	+++	< 0.0001
Paresthesias	18	73	< 0.0001
Stomatitis	16	47	< 0.0001
Skin (erythema)	42	23	= 0.0122
Allergic reaction (skin)	40	15	= 0.0003
Infectious complications	96	127	= 0.0025
Sepsis	1	8	= 0.0190

Source: From the Company's results briefing material

Treatments for untreated (first line of treatment), low-grade NHL patients



Source: From the Company's results briefing material

The Company is currently progressing five drugs in the development pipeline. Of these, in the phase III clinical trial for the expansion of the indication of the existing lyophilized powder formulation TREAKISYM® for relapsed and refractory DLBCL, the observation periods of all test subjects were completed in September 2019. On November 5, 2019, the Company announced favorable results, with the overall response rate, which was the primary endpoint of the trial, exceeding the expected response rate. Going forward, the Company plans to make preparations to submit a new drug application (NDA) in Q2 FY12/20. If steady progress is made, it is expected that approval could be granted and sales commence in the second half of FY12/21. If relapsed and refractory DLBCL is approved as an indication, the potential market size for TREAKISYM® will grow to more than double the size of the existing market. This is because the number of relapsed and refractory DLBCL patients is currently nearly 10,000 for all three areas covered by existing indications, but will increase by 1.5 times if the new indication is approved. Patient advocacy groups and relevant academic societies have also filed petitions urging the authorities to make BR therapy available as early as possible. As soon as sales begin, TREAKISYM® is expected to rapidly penetrate the market in the field of relapsed and refractory DLBCL.

In September 2019, the Company applied for marketing approval for RTD formulation, which is the TREAKISYM® liquid formulation, and the application is currently under review. If steady progress is made, the Company expects to obtain approval in Q4 FY12/20 and to launch sales in Q1 FY12/21. The Company also started clinical trials of the RI formulation in November 2018 with the main aim of confirming its safety (planned number of cases, 36), and the registration of 26 cases has been completed as of the end of October 2019. If steady progress is made, the Company can expect to complete the clinical trials in Q1 FY12/20, apply for marketing approval at an early stage, and launch sales in the first half of FY12/22. The indications for both the RTD/RI formulations include all those for which TREAKISYM® has already been approved as well as relapsed and refractory DLBCL.

Teva Pharmaceuctical Industries Ltd. (U.S.) has already commercialized the RTD/RI formulations as BENDEKA® on the U.S. market. With the acquisition of a 97% share of the bendamustine market as of 2017, it appears that most patients have already switched to the liquid formulation. In addition to eliminating the need for dissolving work, the administration time is short for the RI formulation, so the burden on patients is greatly reduced. Therefore, there are strong calls for its early marketing approval in Japan. As the exclusive sales period for the existing, lyophilized powder formulation type ends in 2020 in Japan, generics may be developed for it. But if the RTD/RI formulations are launched, there will be major differences in terms of their functions, so this would effectively extend the exclusive marketing period until 2031. If the RTD/RI formulations are launched, the drug prices will be the same level as the previous products, but the supplier will be changed to Eagle Pharmaceuticals so at FISCO, we think that it is highly likely that the profit margin will improve compared to the existing products.

For the treatment of malignant lymphoma, TREAKISYM® obtained approval for use as a pretreatment agent for the chimeric antigen receptor T-cell (CAR-T) therapy, KYMRIAH®, which has obtained NHI Price Listing in May 2019. TREAKISYM® is also currently used as a drug in combination therapy in the development of immune checkpoint inhibitors. TREAKISYM® now has an even more solid strategic position as a standard treatment for the future.

In addition, the phase I clinical trial of the TREAKISYM® oral formulation (development code: SyB C-0501) for the indication of advanced solid tumors, has been conducted since January 2018. Based on considerations of tolerance and safety, the Company plans to narrow down the indicated tumors. Moreover, the Company has concluded a joint research agreement with Keio University to explore possibilities for immune system diseases. The pre-clinical trial for an indication for systemic lupus erythematosus (SLE)*, for which there are extremely strong needs in the area of autoimmune diseases, has been conducted since July 2018. Looking ahead, in light of an assessment of the results of this trial, the Company plans to determine future policies, including whether to conduct clinical trials.

* An autoimmune disease in which the patient's own immune system mistakenly attacks normal cells. It is designated as an intractable disease because it causes inflammation and tissue damage in various organs throughout the body. There are approximately 60,000 to 100,000 patients in Japan.

TREAKISYM®

Drug	Indication	Progress
SyB L-0501 (FD lyophilized powder formulation)	r/r lowLow-grade NHL/MCL	Approved October 2010
	CLL	Approved August 2016
	1st line Low-grade NHL/MCL	Approved December 2016
	r/r DLBCL	P3 completed, scheduled to apply for marketing approval in Q2 FY12/20
SyB L-1701 (RTD liquid formulation)	All indications	Applied for marketing approval in September 2019, targeting launch in the first half of FY12/21
SyB L-1702 (RI liquid formulation)	All indications	Currently undergoing clinical trials, complete trials in Q2 FY12/20, targeting launch in the first half of FY12/22
SyB C-0501 (Oral formulation)	Advanced solid tumors	P1 initiated January 2018
	SLE	Pre-clinical study initiated July 2018

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

(2) Rigosertib (intravenous formulation/oral formulation)

Rigosertib is an anti-cancer agent that has a 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 development is being progressed indicated for high-risk myelodysplastic syndrome (MDS)*.

* MDS is a disease in which the patient cannot produce normal blood cells due to abnormalities in the hematopoietic stem cells in the bone marrow, causing a decrease in normal blood cells and symptoms such as anemia, infection and hemorrhage. It is also known to transition to become acute myeloid leukemia. The condition of the bone marrow is examined, the leukemia transition period is determined, and it is classified into four stages, such as according to the length of the period. The high-risk type has a 25% leukemia transition period of 0.2 of year, and the 50% survival period median value is 0.4 of a year. There are approximately 11,000 patients in Japan. The only treatment of the root cause is hematopoietic stem cell transplantation. In chemical therapy, azacitidine is used as the drug of first choice. In Japan, Nippon Shinyaku Co., Ltd.'s Vidaza® is on the market, and it has annual sales on a scale of ¥15 to ¥16bn on a drug-price basis.

For the current development situation, an international joint phase III clinical trial is being conducted by the licensor Onconova for the intravenous formulation indicated for relapsed and refractory high-risk MDS (target number of cases, 360). According to an announcement in October 2019, nearly 90% of the target number of cases were registered. In Japan, the Company's assigned area, the Company has registered subjects for 48 of the target number of 50 cases as of the end of October 2019. In the first half of FY12/20, Onconova plans to announce the primary endpoint results. Based on the results of the trial, Onconova plans to apply for marketing approval in Japan at the same time as in Europe and the U.S., with the aim of launching sales in 2022.

For the oral formulation, the phase I clinical trial was completed for the single drug indicated for relapsed and refractory high-risk MDS in June 2019, while in the future, the plan is to switch to development for its joint use with azacitidine. As a result of consultations with the FDA on SPA*, Onconova has announced that in clinical trials for combination use of azacitidine for untreated high-risk MDS, it will consider conducting a phase II clinical trial to establish a comparison with azacitidine as a single drug. If an international joint phase III clinical trial is initiated, the Company plans to assume responsibility for development in Japan. Apart from this, the Company plans to consider participating in development activities for a target indication of transfusion dependent low-risk MDS in Japan, while closely monitoring the status of development at Onconova.

* SPA (Special Protocol Assessment): a system in which, after the phase II clinical trial, for the phase III clinical trial, agreement is obtained in advance from the FDA for aspects such as the indicated disease, purpose, study design, endpoints (primary and secondary evaluation items), and analysis method, and after the trial has been completed, it is recognized as meeting the approval requirements in the approval review as it is, without changing the contents of the agreement. By using this system, if the endpoints are achieved for the evaluation and review of the trial results, it increases the likelihood of approval with shorter review process and time.

Rigosertib

Drug	Indication	Progress
SyB L-1101 (Intravenous formulation)	Relapsed and refractory high-risk MDS	P3 global clinical trials ongoing Plans to report topline (primary endpoint) results in the first half of 2020
SyB C-1101 (Oral formulation)	Relapsed and refractory high-risk MDS single drug	P1 completed
	Untreated high-risk MDS (AZA combination use)	P3 global clinical trial under preparation
	Transfusion dependent low-risk MDS single drug	Clinical trial under preparation

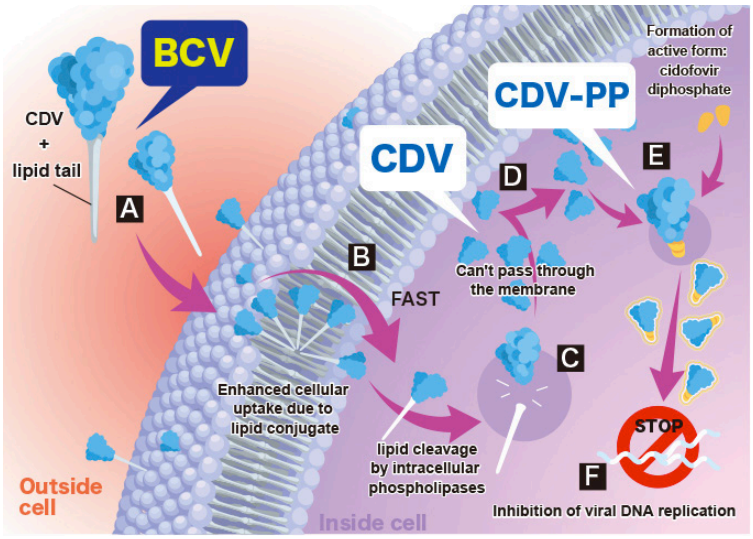
Source: Prepared by FISCO from the Company's results briefing material and website

(3) Brincidofovir (Intravenous formulation)

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 that has higher anti-viral activity and a superior safety profile in comparison with CDV. Lipid conjugatation 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. For this reason, data showing that BCV has a much higher anti-viral replication effect than CDV and other anti-viral drugs have been obtained from in vivo tests and other studies. In terms of the safety profile, CDV has the side effect risk of strong nephrotoxicity, including the risk of renal dysfunction, through 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.

Chimerix had developed an oral formulation of BCV, but it had discontinued development because it did not obtain favorable results in Phase III clinical trials. Currently, Chimerix is concentrating its business resources on the anti-cancer agent field. It had been looking for a partner to whom it could license out BCV, while the Company was searching for new drug agents to license in. The timing was right for both companies, and they decided to conclude a global license agreement. One of the main factors behind the Company's decision was that it had determined that an injection formulation of BCV would have a high probability to be successfully developed, because of its lower exposure to the gastrointestinal tract and higher transfer rate to the brain than an oral formulation. Another factor was that the Company could expect to capture synergies with its existing businesses in the hematologic disease field. 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.

How BCV works



Source: Reprinted from the Company's website

The Company will develop BCV as part of its strategic pipeline for the future. The Company has set its sights on developing BCV into an antiviral drug not only for after hematopoietic stem cell transplants, but also for after organ transplants such as kidney transplants. Considering that these fields are Underserved Therapeutic Areas that do not have effective and safe drug therapies, it is very meaningful that the Company is advancing development in these fields. Moreover, this agreement features worldwide coverage, including Japan, the U.S. and Europe, and is an exclusive global license agreement including manufacturing rights. TREAKISYM® has been marketed in South Korea, Taiwan, and Singapore through partners. However, these sales were small and had only a negligible impact on the Company's business performance. The agreement on BCV covers the whole world. Therefore, if development succeeds, the Company's growth potential will increase tremendously.

Looking at the number of hematopoietic stem cell transplants (allogeneic), Europe and the U.S. perform roughly seven times more of these transplants than Japan does per year, with 25,000 transplants in Europe and the U.S. compared with 3,700 in Japan. With regard to kidney transplants, Europe and the U.S. perform more than 20 times more of these transplants than Japan does, with around 40,000 kidney transplants in Europe and the U.S. compared with 1,648 in Japan. Looking at the incidence ratio for viral infectious diseases after hematopoietic stem cell transplants, in Japan, the incidence ratio for viral hemorrhagic cystitis (vHC) is between 8.6% and 24% (even higher for cord blood stem cell transplantation). With regard to the prevention of HHV-6 encephalitis, the reactivation of HHV-6 occurs in 30-70% of patients in cases of allogeneic hematopoietic stem cell transplantation. There are reports that the reactivation of HHV-6 can cause HHV-6 encephalitis. The Company has estimated the number of patients who will be affected by viral infectious diseases in 2027 based on this data and other information. Around 2,600 people in Japan and around 14,000 people in Europe and the U.S. will need vHC (treatment) and HHV-6 encephalitis (prevention) after allogeneic hematopoietic stem cell transplantation. In addition, around 550 people in Japan and around 15,000 people in Europe and the U.S. will need BK virus (treatment) and cytomegalovirus (prevention) after kidney transplantation. Considering that kidney transplants are actively performed in China and other regions, the number of patients will increase further on a global basis. Based on these factors, if the Company successfully develops BCV, its potential market size could increase to several ten billion yen.

Number of allogeneic hematopoietic stem cell transplants and kidney plants, and estimates of number of viral infectious disease patients after transplants

(Number of cases, people)

Region (population)	U.S. (320 million)	EU (550 million)	Japan (130 million)	Other	Total
Hematopoietic stem cell transplants (allogeneic)	8,700	16,400	3,700	6,454	35,254
Kidney transplants	19,860	20,000	1,648	39,052	80,560

Number of viral infectious disease patients (2027)	U.S. + EU 5 countries	Japan
vHC, HHV-6 encephalitis (after hematopoietic stem cell transplants)	14,189	2,592
BK virus, cytomegalovirus (after kidney transplants)	15,386	558

Source: Prepared by FISCO, based on the Company's materials prepared according to Chimerix's materials (January 2019)

In terms of its development policy for an injection formulation of BCV, the Company first plans to advance development activities targeting the diseases of viral hemorrhagic cystitis (vHC) (treatment) and HHV-6 encephalitis (prevention) after hematopoietic stem cell transplantation, for which there are high medical needs. Given that Chimerix has already completed a phase I clinical trial for BCV, it appears that the Company is seeking to advance development starting from the phase II clinical trial stage by citing data from Chimerix's phase I clinical trial. In addition, the Company is considering making use of the SAKIGAKE system, which can reduce the reviewing time needed for drug approval. Because the agreement with Chimerix encompasses manufacturing rights, the Company must choose a manufacturing contractor in the near future. Since BCV does not require any special manufacturing technologies, the Company should be able to find a contractor at an early stage. Accordingly, the Company aims to start clinical trials within 2020 and launch sales around 2024. As for overseas business expansion, the Company plans to implement a partnership strategy that harnesses the regional characteristics of the targeted diseases.

Looking at the contract conditions with Chimerix, the contract requires the Company to pay an upfront payment of US$5mn (approximately ¥540mn) in Q3 FY12/19, future milestones of up to US$180mn (approximately ¥19.4bn) and a double-digit royalty on net sales of brincidofovir products.

BCV's first development and commercialization target

Disease field	Disease	Current status	Problems
Hematopoietic stem cell transplants	Viral hemorrhagic cystitis (vHC)	• With no approved drug therapies in Japan, some physicians privately import cidofovir (CDV) and administer it to their patients. • Bladder perfusion is the only treatment for symptoms. • Patients suffer from urinary problems and pain, and disseminated infections can be lethal.	• CDV has a strong nephrotoxicity with only limited efficacy • No definitive treatments
	HHV-6 encephalitis	• Onset of the disease leads to a rapid progression of consciousness disorders and can be lethal. Severe aftereffects remain in surviving patients. • Foscarnet, the drug of first choice, was approved for the treatment of encephalitis through a public knowledge-based application, but cannot suppress the onset of encephalitis.	• Foscarnet has nephrotoxicity. • Japan has a high percentage of transplantations from non-blood relatives, increasing the probability of the onset of encephalitis
Kidney transplants	Viral infectious diseases (BKV, CMV, etc.)	• No effective drugs have been approved for BKV infection. Renal impairment occurs in roughly half of the patients who contract BKV infection, hindering engraftment of transplanted kidneys. • Ganciclovir agents in general use for CMV infections have the side effect of bone marrow suppression, and the incidence of resistant viruses has become a clinical problem.	• Problems are more serious in Europe and the U.S. than in Japan. • Mutation in the UL97 gene leads to frequent cases of drug resistance. (BCV avoids drug resistance along with bone marrow toxicity.)

Source: Prepared by FISCO from Company material

Results trends

Steady progress on measures to become profitable in FY12/21, despite quality issues with TREAKISYM® in FY12/19.

1. Overview of Q3 FY12/19 results

For Q3 FY12/19, net sales decreased 33.8% YoY to ¥2,008mn, the operating loss was ¥3,536mn (compared to a loss of ¥1,907mn in the same period last year), the ordinary loss was ¥3,641mn (compared to a loss of ¥1,937mn in the same period last year) and the loss was ¥3,640mn (compared to a loss of ¥1,940mn in the same period last year). The main reason for the lower net sales was that the Company temporarily halted imports and sales of TREAKISYM® products that were imported in Q2 FY12/19, because problems such as contaminants and appearance defects were found in these products. The Company procures TREAKISYM® products from suppliers with factories in Belgium and Germany. It looks like there were problems with the manufacturing process and quality control at the factory in Germany, which had been the Company's supplier. Due to this impact, net sales for Q3 (July-September) had decreased sharply to ¥3mn. With the recent start of procurement from the Belgium factory, net sales are expected to return to a recovery path from Q4 FY12/19 onward.

On the cost front, research and development expenses rose 52.5% YoY to ¥1,971mn. The aforementioned upfront payment for BCV accounted for ¥540mn of these expenses. Other SG&A expenses increased 38.3% YoY to ¥2,127mn. This increase was mainly due to higher preparation costs recorded to build the Company's own sales system for TREAKISYM®. The Company has recruited 20 sales managers for TREAKISYM® as initially planned. It is now setting up a framework that divides Japan into six blocks. The framework will provide a sales system, logistics and information system that covers 400 priority medical facilities in the six blocks across the country.

Q3 FY12/18 (cumulative)

(¥mn)

	Q3 FY12/18 (cumulative)	Q3 FY12/19 (cumulative)	Change	% change
Net sales	3,032	2,008	-1,024	-33.8%
Gross profit	924	562	-361	-39.1%
Selling, general and administrative expenses	2,831	4,099	1,267	44.8%
Research and development expenses	1,293	1,971	678	52.5%
Other selling, general and administrative expenses	1,538	2,127	588	38.3%
Operating profit (loss)	-1,907	-3,536	-1,628	-
Ordinary profit (loss)	-1,937	-3,641	-1,704	-
Profit (loss)	-1,940	-3,640	-1,699	-

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

2. Outlook for FY12/19

The Company has not changed its outlook for FY12/19 results, which was revised in August 2019. For FY12/19, the Company forecasts net sales of ¥3,092mn, a decrease of 19.4% YoY, an operating loss of ¥3,780mn (compared to a loss of ¥2,656mn in FY12/18), an ordinary loss of ¥3,856mn (compared to a loss of ¥2,748mn in FY12/18), and a loss of ¥3,859mn (compared to a loss of ¥2,752mn in FY12/18). Net sales for Q4 FY12/19 are projected to recover to around ¥1.0bn, the level before the quality issues arose. On the cost front, the recording of the upfront payment for BCV could result in higher costs than planned. However, the upfront payment is only a temporary factor, so it is not expected to affect the Company's prospects for becoming profitable in FY12/21.

Outlook for FY12/19

(¥mn)

	FY12/18 results	FY12/19 company forecast	Change	% change
Net sales	3,835	3,092	-742	-19.4%
Operating profit (loss)	-2,656	-3,780	-1,124	-
Ordinary profit (loss)	-2,748	-3,856	-1,107	-
Profit (loss)	-2,752	-3,859	-1,106	-

Note: Company forecasts represent the forecasts announced in August 2019.
Source: Prepared by FISCO from the Company's financial results

Mid-Range Plan

Aiming to become profitable in FY12/21 Higher growth potential based on the introduction of new pipeline drugs

1. Mid-Range Plan

In February 2019, the Company announced its four-year Mid-Range Plan, with FY12/22 as its final fiscal year. In this plan, it sets the target of becoming profitable in FY12/21 and moreover, doubling profit growth from FY12/22 onwards. As noted earlier, the Company is currently revising its Mid-Range Plan in light of the downward revisions to its outlook for FY12/19 results. That said, at FISCO we believe that the Company now offers stronger prospects for achieving profitability in FY12/21.

Mid-Range Plan

(¥mn)

	FY12/19		FY12/20	FY12/21	FY12/22
	Initial forecast	Revised forecast			
Net sales	4,465	3,092	3,282	9,132	11,282~11,809
Operating profit (loss)	-3,587	-3,780	-5,180	1,225	2,084~2,464
Ordinary profit (loss)	-3,612	-3,856	-5,224	1,181	2,040~2,420
Profit (loss)	-3,616	-3,859	-5,228	1,005	1,736~2,060

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

In FY12/21, the Company's net sales are forecast to rapidly increase to ¥9,132mn. To a large extent this will reflect the transition to the Company's own sales of TREAKISYM®. Looking at net sales on a drug-price basis, net sales will have likely increased from ¥8.5bn in FY12/18 to around ¥12.0bn in FY12/21. If provisionally calculated based on the previous sales standard (sales to Eisai), the amount of sales would be around ¥5.4bn. The market launch of the liquid RTD formulation is expected during Q1 FY12/21, and it is estimated that the annual average penetration rate will be 60% for switching from the lyophilized powder formulation. In addition, sales forecasts include almost no sales for relapsed and refractory DLBCL because the market launch will not be until Q3 FY12/21 or later. Sales growth will be driven mainly by expanded market share for existing indications. On the profit front, while SG&A expenses will increase, in addition to the positive effect of higher sales, there will be significant positive effects from the transition to the Company's own sales and the improvement in the gross profit margin from the switch to the liquid RTD formulation. Therefore, the Company is expected to become profitable at the operating profit level for the first time since it was listed. Research and development expenses for the new pipeline drug BCV are projected to remain in the order of around several ¥100mn.

The forecast for net sales in FY12/22 is in the range of ¥11,282mn to ¥11,809mn. The majority of the higher sales will be from the contribution of sales for relapsed and refractory DLBCL, and the range allows for the market penetration rate. The operating profit margin is expected to rise to a level of around 20%, as it seems that the gross profit margin improvement trend will continue from the progress made in switching to the liquid RTD/RI formulations.

In 2015, the Company concluded a licensing-in agreement with The Medicines Company (U.S.) for the self-administered pain-management medication (SyB P-1501). In October 2017, it filed for arbitration seeking a payment of US$82mn (around ¥9bn) as compensation for damages for the non-fulfillment of the licensing agreement, and this agreement was terminated in November of the same year. This arbitration procedure is still ongoing, but from the viewpoint that reflects the conservative earnings targets in the current Mid-Range Plan, the effects of this have not been included in the targets. As for the current situation, interviews with both companies have been completed, and all that remains is for the three arbitrators to make a final decision. At FISCO, we believe that the outcome of the case could be decided at the end of 2019 at the earliest, but no later than early 2020.

2. Key factors for achieving the plan

The Company has identified the following five Key Success Factors (KSFs) for the Mid-Range Plan. We believe that achievement of these KSFs will enable the Company to become profitable in FY12/21 and attain sustained growth thereafter.

(1) Establish its own sales system

For its sales system, the Company intends to establish a 30-person salesforce by adding 10 more core TREAKISYM® managers in 2019. This recruitment will be carried out in order to cover 400 priority medical facilities throughout the country, based on a local community-centered approach. Currently, TREAKISYM® is sold to approximately 900 facilities. Covering the priority facilities (400 facilities) will enable the Company to generate about 90% of net sales. Normally, the major pharmaceutical companies cover the country with a personnel system of 300 to 400 MRs. The Company plans to increase sales through efficient marketing activities undertaken by a small but highly skilled salesforce. It will make up for any shortfalls in sales personnel by utilizing external resources, such as cancer-specialist contract MRs (CSO).

(2) Achieve TREAKISYM® annual net sales of ¥10bn (on a drug-price basis)

The Company aims to achieve annual net sales of ¥10bn for TREAKISYM®. There will be a downturn in sales in FY12/19 due to a temporary factor. However, as previously explained, the inclusion of TREAKISYM® in the Japan Society of Hematology's treatment guidelines as the standard treatment for malignant lymphoma will have a considerable positive impact on sales. By raising the market penetration rate for BR therapy in the untreated area from around 55% at present to nearly 70%, FISCO believes that the Company can achieve its sales target for TREAKISYM® by FY12/20.

(3) Approval and early switch to the TREAKISYM® liquid formulation (RTD/RI formulations)

With regard to the approval and switch to the TREAKISYM® liquid formulation (RTD/RI formulations), FISCO expects that the switch to the liquid formulation will proceed at an early stage once sales of the RTD formulation begin in 2021. This outlook is based on several factors. First, the application for marketing approval of the RTD formulation and the clinical trials for the RI formulation are proceeding on schedule. Second, in the U.S., the switch to the liquid formulation is already nearly 100% complete. Third, there are strong calls for the liquid formulation from healthcare professionals at medical sites.

(4) Approval and penetration of TREAKISYM® for the indication of relapsed and refractory DLBCL

Looking at prospects for the approval of TREAKISYM® for the indication of relapsed and refractory DLBCL, the Company has announced that it has obtained favorable results from its clinical trial in terms of the overall response rate, which was the primary endpoint of the trial. Accordingly, there now appears to be a higher likelihood that the Company will submit an application for marketing approval in Q2 FY12/20 and obtain approval in the second half of FY12/21. Therefore, the approval of TREAKISYM® for the indication of relapsed and refractory DLBCL is expected to contribute in earnest to sales growth from FY12/22 onward.

(5) Secure excellent human resources

The important point for the transition to the in-house sales system is securing excellent human resources in the salesforce who have high levels of expertise, an abundance of experience, and who are highly productive. For the time being, the Company seems to be working to secure 20 people who meet the conditions to be TREAKISYM managers, and their sales activities can be expected to produce results going forward.

The licensing-in of BCV will increase sales growth potential further

3. Sales growth potential

Looking at sales growth potential, if marketing approval of TREAKISYM® for the indication of relapsed and refractory DLBCL is obtained, the number of potential patients in Japan will roughly double all at once. Estimates of potential sales will vary depending on what percentage is set for the market penetration rate. Excluding DLBCL, potential sales are estimated at around ¥12bn to ¥13bn on a drug-price basis. If simply calculated, potential sales are expected to approximately double to ¥24bn to ¥26bn by adding patients with relapsed and refractory DLBCL.

Moreover, if rigosertib is approved for a combination therapy with azacitidine for untreated high-risk MDS, it can be expected to achieve sales of around the same scale of azacitidine (approximately ¥15bn). The sales growth potential for both drugs will increase from ¥8.5bn in 2018 to around ¥40bn on a drug-price basis, while the Company's net sales will amount to more than ¥30bn. The addition of the injection formulation of BCV as a new pipeline drug has increased the sales growth potential even more.

Intends to raise business funds up to FY12/20 through the exercise of stock acquisition rights

4. Financial condition

Looking at the financial condition at the end of Q3 FY12/19, total assets stood at ¥5,665mn, a decrease of ¥573mn from the end of the previous fiscal year. The main factors behind this change were decreases of ¥365mn in accounts receivable-trade, ¥196mn in cash and deposits, and ¥224mn in merchandise and finished goods under current assets. These decreases were partly offset by a combined increase of ¥144mn in software and software in progress under non-current assets.

Total liabilities stood at ¥1,796mn, an increase of ¥459mn from the end of the previous fiscal year. The main factor behind this change was an increase of ¥1,000mn in accounts payable-other, which was partly offset by a decrease of ¥502mn in accounts payable-trade. In addition, total net assets stood at ¥3,869mn, a decrease of ¥1,032mn from the end of the previous fiscal year. While capital stock increased ¥1,271mn and capital surplus rose ¥1,273mn following the exercise of stock acquisition rights, retained earnings decreased ¥3,640mn due to the recording of a loss. Consequently, the equity ratio decreased from 70.1% at the end of the previous fiscal year to 57.7%.

The Company issued the 45th through the 47th Stock Acquisition Rights (with Exercise Price Revision Clauses) from an allocation to EVO FUND in April 2018, in order to stably raise funds for business activities through FY12/20. The exercise of the 45th and 46th tranches have already been completed, with the Company raising a total of ¥5.1bn. The exercise period for the 47th tranche begins on November 14, 2019, with the number of common shares corresponding to the stock acquisition rights equal to 3.75 million shares. Assuming an exercise price of ¥600, the Company can still raise approximately ¥2.2bn. The Company is targeting profit between ¥1,736mn and ¥2,060mn for FY12/22, the final fiscal year of the Mid-Range Plan. EPS, calculated assuming all of the 47th Stock Acquisition Rights are exercised, will be in the range of ¥61.8 to ¥73.3.

Balance sheet and management indicators

(¥mn)

	End- FY12/15	End- FY12/16	End- FY12/17	End- FY12/18	End- Q3 FY12/19	Change
Current assets	4,826	6,685	4,036	6,038	5,322	-716
(Cash and deposits)	4,261	5,719	2,947	4,821	4,625	-196
Non-current assets	157	193	215	200	343	142
Total assets	4,984	6,878	4,252	6,239	5,665	-573
Total liabilities	552	1,393	1,012	1,337	1,796	459
(Interest-bearing debt)	-	450	-	-	-	-
Net assets	4,431	5,484	3,239	4,901	3,869	-1,032
(Stability)						
Equity ratio	82.9%	73.5%	63.6%	70.1%	57.7%	
Interest-bearing debt ratio	-	8.9%	-	-	-	

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

Overview on the issuance of acquisition rights by third-party allotment

	45th	46th	47th
Number of stock acquisition rights issued	20,000	15,000	3,750
Exercise period	April 26, 2018 to October 23, 2018	April 26, 2019 to September 17, 2019	From November 14, 2019
Exercise status	100%	100%	-
Amount funded	2,579	2,522	-
Minimum exercise price	113	113	452

Note: The Company conducted a 4-for-1 stock consolidation effective July 1, 2019.
Source: Prepared by FISCO from the Company's news release

Uses of the funds

	Amount (¥mn)	Expected timing of expenditure
Development of in-licensed drugs	4,700	April 2018 to December 2020
Creation of an independent sales structure	3,300	
Investment in new in-licensing, M&A, and other	2,413	
Total	10,413	

Source: Prepared by FISCO from Company material

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