SymBio Pharmaceuticals Ltd.

(4582 JASDAQ) Issue date: August 21,2018

Therapies Using Treakisym Becoming Standard

Treakisym being used in standard therapies

The company's sales engine, Treakisym, has been the beneficiary of some ground-breaking news since February 2018. From a survey conducted on SymBio's behalf by an external entity it appears that, as of the end of March, the use of Treakisym in combination with rituximab (B-R therapy) for the treatment of untreated low-grade non-Hodgkin's lymphoma had achieved a market penetration rate in excess of 50%, thereby surpassing by a large margin the conventional R-CHOP therapy.

Further, in the 2018 edition of Guidelines for Clinical Practice in Hematopoietic Tumors, published by the Japan Society of Hematology on July 20, Treakisym was newly selected as a standard treatment option for all approved indications. According to SymBio, this is the first time in almost 20 years that a standard therapy has been so designated. This event means that Treakisym has established itself in theory and in fact as a standard therapy in the field of malignant lymphoma and has thereby moved a step closer to achieving a market penetration of 80% by the end of 2020.

Good progress in pipeline development

The company's pipeline is developing steadily. With Treakisym, of particular note is the Phase 3 clinical trial targeted at relapsed/refractory middle-high grade non-Hodgkin's lymphoma (r/r DLBCL). Of the 60 cases targeted for the trial, 20 patients have now completed registration and 48 more are expected to do so by year end. It would seem, therefore, that development is moving steadily toward a target application date in the first half of 2020 and an approval date some time in 2021. In terms of product life-cycle management the company began preparing application documents in June for the approval of the RTD preparation and expects approval to come in 2021. As for the RI preparation, using guidance from the Pharmaceuticals and Medical Devices Agency (PMDA) the company started drawing up plans for clinical trials in May with the expectation that trials (36 cases) will begin in 2019. Approval is expected in 2022.

Rigosertib development seems to be on a similarly steady path. The schedule is for the registration of subjects in Japan for the Phase 3 injection preparation to be completed in October. 4 subjects have already been registered for Phase 1 trials for the rigosertib oral preparation of rigosertib, and from next year the company intends to participate in the international collaborative Phase 3 trials being planned by Onconova Therapeutics, Inc.

Even with dilution from exercise of multi-year stock options, stock still undervalued

Treakisym is establishing itself as the crucial element in treating malignant lymphoma, rendering the forecast in our last report of a possible total market size of over JPY20 billion even more feasible. However, while the company's pipeline is going ahead, since our last report there has been no evolution to Phase 3 so our trial calculation of that pipeline remains unchanged. This means that, taking into account the company's possible development of its own sales structure and after allowing for costs associated with on-going drug search activities, the corporate value of SymBio, including end-June cash and cash equivalents, works out at JPY30.4 billion (discount rate 10%, pre-tax).

The development of its own sales structure and full-fledged clinical testing means that for the next three years (2018-2020) the company will continue to chalk up losses in excess of JPY3 billion. However, the issue in April 2018 of stock options with multi-year exercise rights (maximum proceeds JPY10 billion) has relieved concerns that the company's cash reserves might run out. Excluding the rights exercised up to the first half, the company's market value combined with an expected further financing valued at a maximum of around JPY8.5 billion comes to no more than JPY15.7 billion, as against a corporate value of JPY30.4 billion pre-tax, and JPY21 billion after tax. It therefore seems possible that SymBio stock, even allowing for a level of dilution, is being undervalued by the market.

Follow-up Report

Fair Research Inc.
Tsuyoshi Suzuki

Company Information	
Location	Tokyo
President	Fuminori Yoshida
Established	March 2005
Capital	JPY 11,834 mil.
Listed	October, 2011
URL	www.symbiopharma.com
Industry	Pharmaceuticals
No. of employees	82

Key Indicators as of Aug.17, 2018	
Share Price	120
Year High	268
Year Low	116
Shares outstanding	62,353 thousand
Trading Unit	100 shares
Market Cap	7,482 million
Dividend (est)	0
EPS	JPY-50.62
Forecast PER	na
BPS (actual)	JPY46.22
PBR (actual)	2.60X

Note: EPS, PER,BPS,PBR are on basis of shares outstanding, excl. treasury shares

Results	Revenues JPY mil	YoY %	OP Income JPY mil	YoY %	RP JPY mil	YoY %	Net Income JPY mil	YoY %	EPS JPY	Share Price High	Share Price Low
2015/12 Actual	1,933	-1.1	-2,551	NA	-2,630	NA	-2,632	NA	-81.3	383	177
2016/12 Actual	2,368	22.5	-2,127	NA	-2,316	NA	-2,313	NA	-58.82	509	173
2017/12 Actual	3,444	45.4	-3,947	NA	-3,976	NA	-3,977	NA	-79.78	311	200
2017/12 2Q Actual	1,786	47.5	-1,235	NA	-1,268	NA	-1,266	NA	-26.09	311	200
2018/12 2Q Actual	1,928	8.0	-1,324	NA	-1,377	NA	-1,388	NA	-23.79	247	144
2018/12 Forecast	4,201	22.0	-2,981	NA	-3,044	NA	-3,056	NA	-50.62		

Company outline and philosophy

Business Model	SymBio Pharmaceuticals Ltd. is regarded as a bio-venture but has the following special characteristics:
Requiring neither labs nor factories SymBio is a pharmaceuticals venture with none of the risks assumed by drug discovery firms, operating a niche strategy focused on maximizing profits.	1. Controls risk and maximises earnings with a "lableless" and "fabless" strategy. In terms of business model, the company does not itself conduct basic research on new drugs. Rather, it seeks out and carefully investigates new drug candidates developed by drug discovery ventures and pharmaceutical companies around the world. A new drug selected as a result of this process is the subject of a licensing agreement and, following development in Japan, is either licensed out to another company for commercialization or commercialized by SymBio itself. (Since the company itself conducts drug development in Japan it should be recognized as not simply a technology trader but as a bio-drug company). 2. Targets large market share and high earnings using a niche strategy. The company focuses its development efforts on drugs for relatively rare conditions in, for example, oncology, hematology and pain management which, despite strong medical needs, the major pharmaceutical companies have mostly avoided. It seeks to maximize market share and profits using this niche strategy. 3. Post-POC (proof of concept) strategy In most cases proof of concept has already been established. By insisting on prior evidence of efficacy and safety in human subjects, the company reduces the development risks of new drug candidates.
The determinants of commercial success are interactions with a network of drug discovery companies and the ability to discern and evaluate.	The success or failure of this business model is dependent on having a network of drug discovery companies worldwide and a keenly discerning eye. This business model is one which seeks to control the risk inherent in drug discovery and, at the same time, secure good returns from pharmaceuticals.
The company is a bio-venture in the rare position of having a product which was approved and brought to market within five years of being adopted	Evidence of this ability is provided by the company's track record. Normally, it takes some 10-20 years to bring a drug from basic research to the market. In terms of the probability of success, some estimates suggest that, counting from the chemical compound stage, it is less than 1/30,000, and even from the POC stage, around 7 to 8%. But SymBio managed to get its first product, Treakisym, from adoption to manufacturing and commercial approval in around five years, and in the three years following launch captured 57% of the market. In the eleven or so years since founding, the company has screened 1,500 drug candidates, of which over 600 have been formally investigated in-house. And of these, five products have been adopted and two are currently under development.
Company structure and staff quality are key	We believe this track record has been made possible by the expertise of the company's staff and by the way the company is organized. SymBio has a workforce of 82, of whom more than 40 are involved in research and development. The drug search function is supported by a Scientific Advisory Board (SAB) of specialists (including Nobel Prize candidates) who support drug search activities. Needless to say, the presence of the company's founder and CEO, Fuminori Yoshida, is of great value in terms of both the experience h brings and his extensive personal network (for CV's of the SAB members and of Fuminori Yoshida please see our previous report released on February 19, 2018).

Main Points in First Half Results

While first half sales growth was on the surface a restrained 8.0% due to a number of one-off factors, the more realistic picture shows that a growth trajectory of more than 20% has been maintained

SG&A expenses will rise as the company takes on more staff to strengthen its marketing activities

First half performance

Revenues in the first half of 2018 (January-June 2018) derived entirely from sales of Treakisym. Sales revenues grew 8.0% to JPY1.93 billion. Domestic sales were up 6.4% YoY to JPY1.76 billion. This appears superficially to represent a major slowdown, given sales growth of 47.5% in the first half of 2017 and 43.2% in the second half, and given the company's target of 22% for 2018. But in fact, sales of Treakisym on the basis of approved drug prices rose 22.3% YoY to JPY4.07 billion. The company has explained that the difference was due to the shift to the second half of one drug lot which Symbio was due to ship to Eisai in June. By adding that back in we can see that the sales growth trajectory is still at around the 20% level.

The cost of sales ratio stood at 70.3%, an improvement of 1.2% over the same period of the previous year. SG&A expenses came in at JPY1.9 billion, up 8.7% on the same period of the previous year, but within this, R&D expenses contributed JPY840 million, on a par with the same period of the previous year. SG&A minus R&D expenses rose to JPY1.06 billion, a significant 16.9% jump on the same period of the previous year due to costs associated with taking on more staff to strengthen marketing activities.

The final result was a loss on sales revenue of JPY1.32 billion, compared to a loss of JPY1.24 billion in the same period of the previous year, and a loss on net profit, partly due to currency losses, of JPY1.38 billion, compared to a loss of JPY1.27 billion in the same period of the previous year.

Profit & Loss in the first half of 2018

(JPY mil)

	1H2018	1H2017
Revenues	1,928	1,786
Growth	8.0%	47.5%
Unit cost	1,355	1,276
Pct	70.3%	71.4%
Sales-SG&A	1,897	1,745
Of which, R&D	838	839
Non-R&D costs	1,059	906
Op. profts	-1,324	-1,235
Net profits	-1,388	-1,266

Source: Fair Research Inc. using short-form results report

Losses may continue over the medium term, but because of multi-year exercise of option rights there is little fear that funds to finance development will run out

On the other hand cash and cash equivalents on the balance sheet now stand at JPY3 billion, about the same level as December 2017. Of the stock option issue announced in April (maximum proceeds of JPY10 billion over 3 years) there has been some progress in exercising the 2018 portion, such that, by the end of June, cash of JPY1.5 billion was raised (by end of July the figure was JPY2.14 billion). Of note also is the fact that SymBio's medium term management plan (dated February 2018) reveals that in the three years (2018-2020) prior to turning profitable in 2021 the company will accumulate losses of around JPY10.7 billion. However, concerns about running short of cash have been dispelled by this multi-year stock option issue.

Assets & Liabilities

(JPY mil)

	End Dec. 2017	End June 2018
Liquid Assets	4,036	4,645
Cash	2,947	3,049
Fixed Assets	215	200
Total Assets	4,252	4,845
Liquid Liabilities	1,011	1,364
Fixed Liabilites	1	1
Net ssets	3,239	3,479
Equity ratio	63.6%	59.5%

Source: Fair Research Inc. using SymBio short form report

Reference: Medium term management plan

Unit: millions of yen

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

Source: SymBio, released Feb 7, 2018

No change in the company's own results forecast for 2018. Losses will shrink because new product introduction costs in the previous year will be absent

The company has not changed its forecast for full-year 2018 results. Using official drug prices Treakisym sales in Japan retain a target level of JPY10.1 billion, and Symbio sales are forecast at JPY4.2 billion (up 22% on the year before). As noted later, Treakisym sales are supported by the occurrence of a number of developments, such as achieving standard treatment status, so there is little need for concern that sales will fall precipitously. R&D activities continue to be actively pursued, but due to the fall-off of costs associated with the previous year's introduction of the RTD and RI preparations R&D expenditures are expected to decline by as much as JPY700 million on the previous year, reducing SG&A expenditures by JPY630 million (SG&A expenditures minus R&D expenditures will rise as a result of increased spending on marketing). The end result of higher revenues and lower SG&A expenditures will mean a significant decrease in losses at both the operating level and the net earnings level.

FY 2018 earnings forecast

(JPY mil)

	FY2017 (Actual)	FY2018 (Forecast)
Revenues	3,444	4,201
Growth	45.4%	22.0%
Unit cost	2,412	2,833
change	70.0%	67.4%
Sales-SG&A	4,978	4,350
Of which, R&D	3,017	2,311
Non-R&D costs	1,961	2,039
Op. profits	-3,947	-2,981
Net profits	-3,977	-3,056

Source: From SymBio results meeting materials

Treakisym achieves standard therapy status

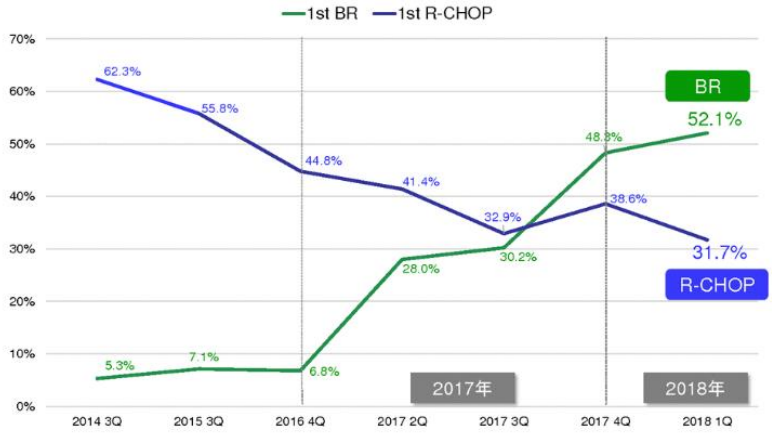
In July 2018, the B-R treatment using Treakisym was listed in clinical practice guidelines as a standard treatment

Rapid increase in market share to above 50%

Considerable effort is now going into the development of new combined drug therapies in which Treakisym is the basic component, and Treakisym has established itself as the backbone of various therapies to treat malignant lymphomas

Since February 2018 the company's revenues driver, Treakisym, has been the subject of some significant developments. In March, SymBio arranged for an external consultant to conduct a survey of 200 internal medicine physicians specialising in hematology. The survey found that the use of Treakisym in combination with rituximab (B-R therapy) for the treatment of untreated low-grade non-Hodgkins lymphoma had achieved a market penetration rate in excess of 50%, thereby surpassing by a large margin the conventional R-CHOP therapy. Next, in the 2018 edition of Guidelines for Clinical Practice in Hematopoietic Tumours, edited by the Japan Society of Hematology and published on July 20, Treakisym was newly listed as an additional standard treatment option for all approved indications. According to SymBio, this is the first time in almost 20 years that a standard therapy has been so designated. This development means that Treakisym has established itself in theory and in fact as a standard therapy in the field of malignant lymphomas and has thereby moved a step closer to achieving a market penetration rate of 80% by the end of 2020.

Comparison of market penetration trend: B-R therapy and R-Chop therapy

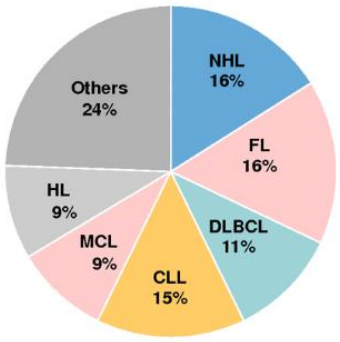


Note: Target indication: untreated low-grade NHL
Source: SymBio IR meeting materials

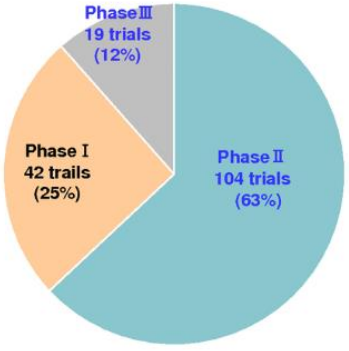
There is now a lot of work going on to develop new combined drug therapies in which Treakisym is the basic component. On July 2, 2018 approval was given for a new anti-CD20 antibody called obinutuzumab (commercial name Gazyva, developed by Roche, and in Japan jointly by Chugai Pharmaceutical and Nippon Shinyaku) to be used in combination with Treakisym for the treatment of follicular lymphoma. According to Symbio, in Europe and the US in the field of malignant lymphoma there are now more than 160 therapies being developed combining B-R and novel pharmaceutical preparations. Also, it is understood that development is proceeding on combination therapies involving immunity checkpoint inhibitors. Treakisym is likely to be used as the key component even if new therapies appear, and this position is unlikely to be challenged in the near term.

Status of novel treatment developments targeting B-R combinations

By indication



By development stage

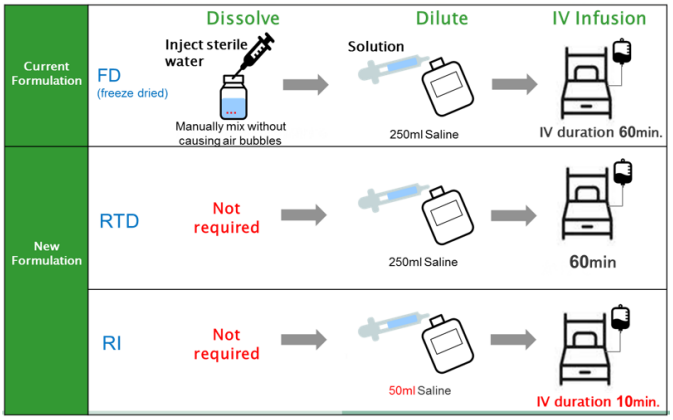


Note: NHL=non-Hodgkin's lymphoma; FL=follicular lymphoma; DLBCL= diffuse large B-cell lymphoma; CLL=chronic lymphocytic leukemia; MCL=mantle cell lymphoma; HL=Hodgkin's lymphoma
Source: Prepared by SymBio using data from Syteline

Steady progress in procedures to change to more easily administered new preparations. By means of these changes the company aims to extend patent protection and product life cycle to 2031

The company is gradually moving ahead in the process to change drug preparations, as one plank in its product life cycle management strategy for Treakisym products. For the RTD preparation, the preparation of documents related to an application for approval began in June and approval is expected in 2021. For the RI preparation the company received guidance from the Pharmaceuticals and Medical Devices Agency (PMDA) and began preparing planning documentation for clinical trials in May. It will commence trials on 36 cases in 2019 with the aim of winning approval in 2022

Reference: Comparison of different types of administration



Source: SymBio IR meeting materials

Decision approaching on building a sales structure

For sales post-2021, the company is still debating whether to establish its own marketing structure or set up a business partnership with another company. It has received tie-up approaches from a considerable number of companies and plans to come to a conclusion by the end of September.

In passing, arbitration on the company's dispute with The Medicines Company in the US concerning the self-pain management product IONSYS is still ongoing (SymBio has requested the International Chamber of Commerce to rule on its claim for compensation in the amount of JPY9 billion against The Medicines Company).

Product pipeline progress

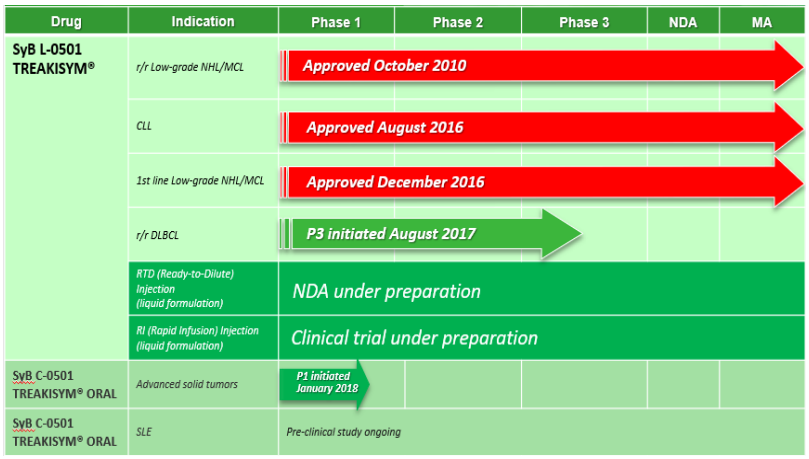
SymBio's development strategy focuses on expanded applications and different formulations for Treakisym, and the development of rigosertib. In terms of a new licensing-in this product is at an early stage of development and the costs of licensing-in are regarded as small.

(1) Treakisym (general name: bendamustine)

(SyB L0501 (Freeze-dried agent)/SyB L1701 (RTD preparation)
/SyB L-1702 (RI preparation)/SyB C-0501 (oral preparation))

Treakisym

Treakisym pipeline



Source: SymBio IR meeting materials

Patient enrolment for Phase 3 trials directed at r/r DLBCL proceeding smoothly, aiming for approval in 2021

Currently in Phase 3 clinical trials for second-line treatment of relapsed/refractory middle and high-grade non-Hodgkin's lymphoma (r/r DLBCL). The company is targeting 60 cases and by the end of July 2018 had completed enrolment of 20 patients, with 48 targeted by year-end 2018. The general schedule is for application for approval to be submitted in the first half of 2020 for approval in 2021.

The CAR-T therapy is a third-line therapy and therefore is not in direct competition with Treakisym

In April 2018, Novartis submitted for approval its CAR-T therapy for the treatment of r/r DLBCL. However, this is intended as a third-line therapy and therefore not a direct competitor to Treakisym, which is mainly for second-line indications.

Four subjects now enrolled for oral formulation Phase 1(targeting solid cancers). Seeking amenable carcinomas

Patient enrolment for Phase 1 trials for the Treakisym oral preparation started in May 2018 and 4 cases had been completed by July. Targeted indications are advanced breast cancer, progressive small cell lung cancer, glioblastoma, metastatic brain tumour, non-small cell lung cancer and mesothelioma. In addition to confirming safety considerations the plan is to search for carcinomas against which oral agents are effective. In addition, in collaboration with the Keio University School of Medicine the company has initiated a pre-clinical study to confirm the therapeutic effect on systemic lupus erythematosus (SLE), which is one type of autoimmune disease. The pre-clinical study should be completed within the year, with Phase 1 beginning in the first half of next year.

As noted earlier, the process involved in changing drug formulations is going well. As a result of these changes the Treakisym group could see its life-cycle extended to 2031.

Rigosertib

(2) Rigosertib (injection preparation:SyB L-1101/Oral preparation SyB C-1101

Rigosertib pipeline

[Rigosertib]

Pipeline	Indication(s)	Clinical Trial			NDA※1	MA※2
		Phase 1	Phase 2	Phase 3		
SyB L-1101 Anti-cancer agent (IV)	Post-HMA Higher Risk MDS	Global P 3 (INSPIRE study)				
SyB C-1101 Anti-cancer agent (oral)	1.1st line Higher Risk MDS 2.With azacitidine (under preparation)	P 1 (monotherapy)				

MDS: Myelodysplastic syndromes

Source: SymBio IR meeting materials

Rigosertib injection formulation (SyB L-1101)

The plan is to complete patient enrolment for injection formulation Phase 3 trials by October. Good progress is being made toward an application date in 2021

In January 2018, as a result of the interim analysis of Phase 3 international collaborative trials (INSPIRE trials) it was decided to continue the trials, increasing the number of cases from 225 to 360. SymBio is also continuing in Japan, raising its number of cases to 40. As of the end of July 2018, 36 patient enrolments have been completed and it is expected that 40 cases will be reached by October. Phase 3 will be more or less completed in the next business year and, in 2021, the plan is to apply for approval to target those high-risk myelodysplastic (MDS) patients for whom the standard therapy was ineffective or for whom there was a relapse.

Rigosertib oral formulation (SyB C-110)

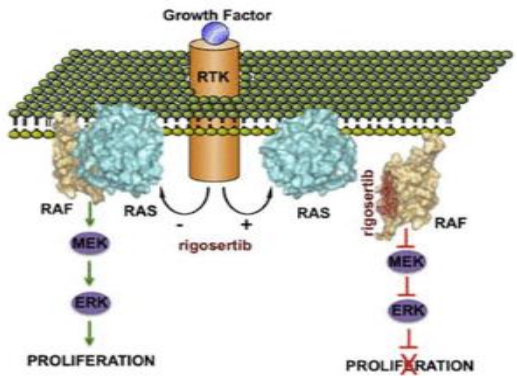
Enrolment of subjects for the Phase 1 oral formulation is now underway. Following that, the company plans to participate in the Phase 3 international collaborative trials being organised by Onconova.

Enrolment now underway of subjects for Phase 1 first-line oral formulation treatment of relapsed/refractory high-risk MDS. In Europe and the US, the original licensor, Onconova, is conducting Phase 1/2 trials in combination with azacitidine and expects to issue the final results in December 2018. After completing Phase 1 in Japan Symbio plans to participate in the international collaborative Phase 3 trials planned by Onconova, and then submit an application.

Rigosertib has the potential to become a cancer therapy targeting Ras. Its success could be a dramatic event

In addition, it has been established that rigosertib acts as a mimicking molecule of RAS (a cancer-related gene) and competes to inhibit a signalling molecule binding to an activated RAS. In other words, it is possible that rigosertib has the effect of inhibiting carcinogenesis by activated RAS, or inhibits the proliferation of cells which have already become cancerous due to an activated RAS. Apparently, some 30% of cancer patients have RAS mutations, but there has to date been no example of a successful cancer therapy targeting RAS. At present a lot of attention is focused on clinical studies of rasopathies under the leadership of the NCI.

Reference: How rigosertib acts on RAS



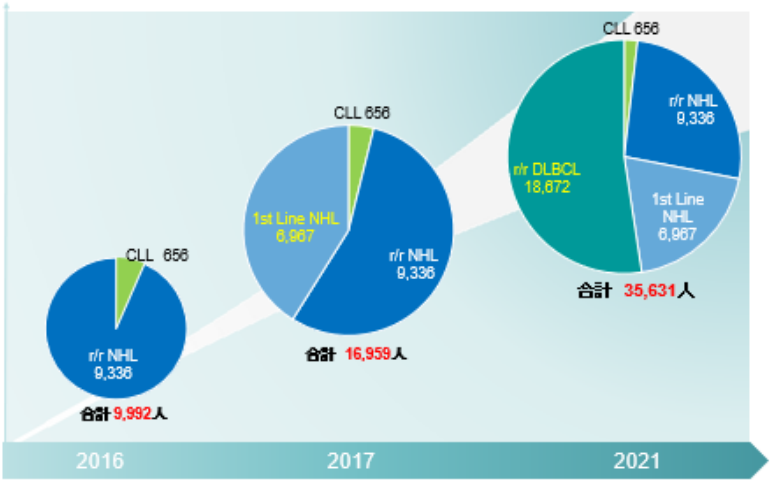
Source: SymBio IR meeting materials

Conclusion

With Treakisym's acceptance as a standard therapy it is now approved for three indications. And with its current Phase 3 status with respect to r/r DLBCL our trial calculation of a JPY20 billion market size is looking more feasible

In our previous report (dated 19th February 2018) we gave details on the market size of Treakisym and rigosertib. That estimate is given added credence as a result of Treakisym's recognition in the first half as a standard therapy. We therefore adhere to our modelling of JPY10.6 billion market size for Treakisym's three approved indications: 1 recurrent/refractory low-grade NHL/MCL; 2 chronic lymphocytic leukemia (CLL); and 3 untreated low-grade NHL /MCL. We also reiterate our market-size estimate of JPY9.8 billon for r/r DLBCL, now at Phase 3.

The Treakisym market



Source: SymBio IR meeting materials

Rigosertib has a potential market of JPY16.2 billion

We posit the potential market size for the rigorsertib injection formulation at JPY4.6 billion, and for the oral formulation at JPY11.6 billion (for details see our previous report).

While pipeline development is proceeding well there has been no progress to Phase 3. Hence, we maintain our estimate of pipeline value unchanged

We have maintained our estimate of pipeline value unchanged because since our last report there has been no progress to Phase 3 (for all assumptions underlying our estimate see our previous report).

For Treakisym, assuming that the company takes on its own merchandising from 2021 we posit a value of JPY31.9 billion (before tax, discount rate 10%). For Rigosertib, we posit a value of around JPY9 billion (before tax, discount rate 10%) assuming a probability of success of 50% for the injection preparation and 30% for the oral preparation. As for SymBio's total value (before tax),we must take into account not only the two drugs but also the present value of the total company's costs, such as basic research costs and cash in hand, which produces an estimated total of JPY30.4 billion. Assuming a discount rate of 8% the figure we posit is JPY36.7 billion.

Taking into account the company's normal drug search activities, all-company administration costs and cash, we arrive at an estimated corporate value of JPY30.4 billion before tax and around JPY21.0 billion after tax (tax rate 31%)

Estimates of corporate value and pipeline value

(JPY100 mil)

	Discount rate 10%	8%
Total (before tax)	**303.6**	**367.0**
Treakisym	319.2	369.1
Rigosertib	89.6	113.9
All-company costs	-135.7	-146.5
Cash	30.5	30.5

(Ref) Assuming eff. Tax rate 30%	Disc. rate 10%	Disc. rate 8%
Total (pre-tax)	209.5	253.2
13/08/2018 Market value	72.3	

Source: Calculated by Fair Research

Even after allowing for the dilution attendant on exercise of multi-year stock options it seems that the stock market is undervaluing SymBio shares

The company's market value as of August 17 stands at JPY7.48 billion (shares outstanding as of end of June). Adding to the company's market value the maximum proceeds, around JPY8.5 billon, from the exercise of stock option rights unexercised as off the end of June 2018, yields a sum of JPY16 billion. There is thus a disparity with the company's value, JPY30.4 billion (before tax) or JPY 21.0 billion (after tax). Hence, even taking into account the dilution generated by the financing it seems likely that the stock market has undervalued SymBio.

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