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SymBio Pharmaceuticals

Earnings update

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SymBio will be undergoing a major transition in 2021 as it takes back the reigns to its Treakisym (bendamustine) franchise. The company will be making it first efforts to market the product line internally in Japan following the return of the rights from Eisai in December 2020. We expect these efforts to be bolstered by the recent launch of the ready-to-dilute (RTD) formulation of the product and the upcoming approval decision for diffuse large B-cell lymphoma (DLBCL) in May 2021.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/19	2,838	(4,250)	(184)	0	N/A	N/A
12/20	2,987	(4,514)	(137)	0	N/A	N/A
12/21e	9,228	1,508	27	0	38	N/A
12/22e	11,484	2,017	37	0	28	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

2021 goals: Relaunch Treakisym internally

In 2020 SymBio laid the groundwork for the transfer of Treakisym marketing rights through the establishment of its own sales team and other necessary infrastructure. The company has hired a salesforce of 53 representatives covering Japan. Other preparations include a new supply agreement that will hopefully alleviate the quality control issues experienced in 2020.

Convert existing patients to liquid formulations

The company's strategy for maximizing the value of Treakisym has been focused on the pipeline management of the product to give it a sales runway following the rights transfer and expiration of exclusivity in 2020. Key to this is converting existing patients onto the recently launched RTD formulation and the rapid infusion (RI) formulation expected to be approved in 2022, both of which carry exclusivity protections until 2031. This is a strategy that worked in the US where the majority of the market converted to the liquid formulations developed by the RTD formulation's licensor Eagle Pharmaceuticals.

Launch the DLBCL indication

Additionally, the company plans to expand the Treakisym market by seeking approval for the second-line treatment of DLBCL. We estimate the market for this condition in Japan at approximately 11,200 relapsed and refractory patients per year. This would be the first jurisdiction to our knowledge that would approve bendamustine for this indication, although it is well supported by the science. The company submitted a marketing application to the PMDA in May 2020 and we expect a response around the one year anniversary.

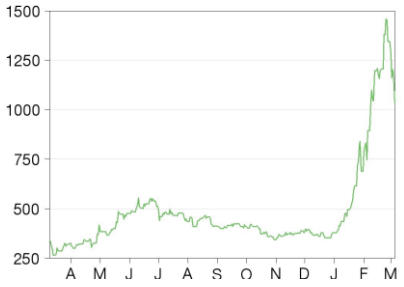
Valuation: Increased to ¥39.7bn

We have increased our valuation to ¥39.7bn from ¥37.8bn, although it is lower on a per share basis, (¥1,040 from ¥1,074) due to higher shares outstanding. This results from rolling forward our NPVs and is offset by lower net cash (¥3.85bn from ¥5.41bn).

8 March 2021

Price	**¥1,034**
Market cap	**¥39,499m**
	¥110/US$
Net cash (¥m) at 30 December 2020	3.85
Shares in issue	38.2m
Free float	91%
Code	4582
Primary exchange	TYO
Secondary exchange	OTC US

Share price performance



%	1m	3m	12m
Abs	15.5	163.1	148.0
Rel (local)	15.2	146.4	98.2
52-week high/low	¥1,460		¥264

Business description

SymBio Pharmaceuticals is a Japanese specialty pharma company with a focus on oncology and hematology. The Treakisym powder formulation was in-licensed from Astellas in 2005; liquid Treakisym was in-licensed from Eagle Pharmaceuticals in 2017; and brincidofovir was licensed from Chimerix in 2019.

Next events

Treakisym DLBCL approval decision	H121
Treakisym RI application	2021

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

The relaunch is only the beginning

A very large part of the company's operations over the preceding years has been in preparation for now, in 2021 when the company regains marketing rights to its lead asset Treakisym from Eisai. Eisai has been marketing the product in Japan since its launch in 2010, and returned the product rights to SymBio in December 2020. In 2020, SymBio established the necessary infrastructure and began building out its salesforce. It reported in February 2021 that it had hired a sales staff of 62, of whom 53 are medical representatives. Additionally the company has secured distributors and a new manufacturer for the product. There were significant supply disruptions in 2020 and earlier due to issues with the product from its earlier supplier Astellas, and we expect those problems to now be resolved.

The product also lost marketing exclusivity in 2020, so SymBio has developed a strategy for protecting its market share in the product by converting existing patients to new formulations of the product. This is a strategy that worked in the US, where a majority of patients have been converted to liquid formulations (RTD and a rapid infusion, RI, formulation) of the drug developed by Eagle Pharmaceuticals and licensed by Teva. The RTD formulation was approved by the PMDA in 2020 and launched by SymBio in January 2021. The RI formulation has been in pivotal clinical studies (last patient enrolled in September 2020), and the company announced that it expects it to be launched in 2022. The company has guided that it hopes to convert the majority of patients onto the RTD formulation in 2021, and we hope the company will provide details on this progress.

In addition to the new formulations, the company is also awaiting the approval of the product for DLBCL, which we expect by May 2021. The product is not approved for this indication in other geographies that we are aware of, but has established efficacy in the indication, and the company demonstrated this in pivotal studies.

In other news, the company has initiated a collaboration with the University of Tokyo to explore potential applications for rigosertib in combination with bendamustine. Rigosertib is an RAS inhibitor developed by Onconova Therapeutics, to which Symbio has licensed the Japanese rights. The product failed to meet its primary endpoint in a Phase III clinical study in patients with high-risk myelodysplastic syndrome, but the intention is that the collaboration with the University of Tokyo can identify a useful application for the drug. The focus of the research will continue to be in hematopoietic indications. We do not currently assign any value to rigosertib, but believe at the very least it is worthy of further study. The product is also in a Phase I investigator-sponsored study of non-small cell lung cancer (NSCLC).

Financials and guidance

SymBio announced revenue of ¥2.98bn in 2020, which came in higher than our expectations (¥2.61bn). We expected a more severe impact on sales from COVID-19 and the supply disruption in the second half of the year. SG&A expenses also came in under our estimates (¥3.11bn vs ¥3.32bn), despite the company successfully building out its salesforce. We have revised our 2021 forecasts to take into account this more efficient cost base, but otherwise our forecasts remain largely unchanged. We expect a substantial increase in SG&A expenses with the new marketing costs for Treakisym: ¥5.65bn in 2021 from ¥3.11bn in 2020 (reported as non-R&D operating costs). The other changes to our model are limited to minor adjustments to future run rates based on the 2020 financials.

The company released guidance and forecasts for 2021 and onward, which are close to our own estimates. It expects to be profitable for the first time in 2021, with a revenue forecast of ¥9.15bn

(vs our estimate of ¥9.23bn) and ordinary profit of ¥1.36bn (our estimate ¥1.41bn). In addition, the company's mid-range plan also outlined a series of aggressive goals for 2021 that go beyond guidance, including a target revenue objective of ¥11.3bn. The company estimates that to reach this goal the company would need to have ¥8.7bn in sales in existing markets, which is close to our current assumptions, as well as ¥2.6bn in sales for DLBCL, which we believe would be a challenge. We currently forecast about ¥500m in DLBCL sales in 2021, because we expect some headwinds with a new marketing team targeting a new indication for the product.

The company ended 2021 with ¥3.85bn in cash. We do not expect the company to need additional capital to finance its operations, but it may raise capital to continue to expand its product development pipeline. In December, the company concluded its rights offering after raising ¥4.24bn during the year.

Valuation

We have increased our valuation to ¥39.7bn from ¥37.8bn, although it is lower on a per share basis, ¥1,040 per share from ¥1,074 per share, due to increased shares outstanding. The increase in valuation is driven by rolling forward our NPVs, and is offset by lower cash (¥3.85bn at year-end 2020 from ¥5.41bn in H120) and the small change to SG&A costs outlined above. Otherwise our estimates remain unchanged.

Exhibit 1: Valuation of SymBio

Program	Indication	Probability of success	Launch year	Peak revenue (¥m)	Valuation (¥m)
Treakisym	Low grade NHL/MCL (r/r and 1st line); CLL	100–95%	2010	8,600	20,990.54
Treakisym (DLCBL)	r/r DLBCL	90%	2021	9,600	13,664.69
Brincidofovir	AdV following HSCT	20%	2025	9,100	1,242.42
Total					35,897.65
Net cash and equivalents (December 2020)					3,848.63
Total firm value (¥m)					39,746.28
Total basic shares (m)					38.20
Value per basic share (¥)					1,040.40

Source: SymBio reports, Edison Investment Research

Exhibit 2: Financial summary

¥m	2019	2020	2021e	2022e
JPN GAAP, year-end 31 December	JPN GAAP	JPN GAAP	JPN GAAP	JPN GAAP
INCOME STATEMENT				
Revenue	2,837.8	2,987.1	9,227.8	11,483.8
Cost of Sales	(1,973.0)	(2,120.2)	(1,618.7)	(2,261.2)
Gross Profit	864.8	866.9	7,609.1	9,222.6
R&D	(2,441.6)	(2,266.6)	(465.0)	(820.0)
SG&A	(2,724.8)	(3,106.5)	(5,647.7)	(6,398.5)
EBITDA	(4,263.5)	(4,441.4)	1,561.2	2,069.6
Depreciation & amortisation	(38.1)	(64.8)	(64.8)	(65.4)
Normalised operating profit	(4,174.5)	(4,403.8)	1,598.8	2,106.5
Reported operating profit	(4,301.6)	(4,506.2)	1,496.4	2,004.1
Net interest	(75.0)	(109.7)	(90.3)	(89.1)
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	4.2	529.5	0.0	0.0
Profit Before Tax (norm)	(4,249.5)	(4,513.5)	1,508.4	2,017.5
Profit Before Tax (reported)	(4,372.5)	(4,086.4)	1,406.1	1,915.1
Reported tax	(3.8)	(3.8)	(476.4)	(577.3)
Profit After Tax (norm)	(4,253.3)	(4,517.3)	1,032.1	1,440.1
Profit After Tax (reported)	(4,376.3)	(4,090.2)	929.7	1,337.7
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(4,253.3)	(4,517.3)	1,032.1	1,440.1
Net income (reported)	(4,376.3)	(4,090.2)	929.7	1,337.7
Basic average number of shares outstanding (m)	23.2	33.0	38.2	39.6
EPS - basic normalised (¥)	(183.72)	(137.10)	27.02	37.29
EPS - diluted normalised (¥)	(180.46)	(135.38)	26.72	36.89
EPS - basic reported (¥)	(189.03)	(124.13)	24.34	34.64
Dividend (¥)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	386.5	459.4	429.3	421.6
Intangible Assets	240.5	301.8	251.0	217.1
Tangible Assets	75.5	76.7	97.4	123.7
Investments & other	70.4	80.9	80.9	80.9
Current Assets	4,887.5	5,815.3	6,600.7	8,048.2
Stocks	0.0	944.4	181.8	254.0
Debtors	549.3	407.0	1,011.3	1,258.5
Cash & cash equivalents	3,910.8	3,848.6	4,792.4	5,920.4
Other	427.4	615.2	615.2	615.2
Current Liabilities	(872.2)	(1,615.3)	(1,440.8)	(1,543.0)
Creditors	(33.2)	(583.5)	(483.3)	(574.1)
Tax and social security	(87.8)	(81.9)	0.0	0.0
Short term borrowings	0.0	0.0	0.0	0.0
Other	(751.3)	(949.9)	(957.5)	(968.9)
Long Term Liabilities	(1.6)	(2.1)	(2.1)	(2.1)
Long term borrowings	0.0	0.0	0.0	0.0
Other long term liabilities	(1.6)	(2.1)	(2.1)	(2.1)
Net Assets	4,400.1	4,657.3	5,587.0	6,924.8
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	4,400.1	4,657.3	5,587.0	6,924.8
CASH FLOW				
Op Cash Flow before WC and tax	(4,334.4)	(4,021.6)	1,470.9	1,980.5
Working capital	(242.1)	(229.0)	(23.8)	(228.6)
Exceptional & other	229.5	130.0	102.4	102.4
Tax	(3.8)	(3.8)	(476.4)	(577.3)
Net operating cash flow	(4,350.7)	(4,124.4)	1,073.1	1,276.9
Capex	(216.5)	(160.3)	(129.4)	(148.8)
Acquisitions/disposals	0.0	0.0	0.0	0.0
Equity financing	3,740.0	4,222.1	0.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Net Cash Flow	(827.2)	(62.6)	943.7	1,128.1
Opening net debt/(cash)	(4,821.4)	(3,910.8)	(3,846.7)	(4,790.5)
FX	(83.4)	(1.5)	0.0	0.0
Other non-cash movements	0.0	1.9	0.0	0.0
Closing net debt/(cash)	(3,910.8)	(3,848.6)	(4,790.5)	(5,918.5)

Source: SymBio reports, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holbom
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia