EDISON

SymBio Pharmaceuticals

Earnings update

The first whole quarter of internal SymBio sales

Pharma & biotech

SymBio reported Q121 sales of ¥1.42bn of its drug Treakisym (bendamustine) for hematologic malignancies. This is the first quarter in which the product is being sold by SymBio directly, and it marks a substantial increase over prior sales trends. Sales have more than doubled since Q420 (¥0.6bn). Part of what is driving this is the early 2021 launch of the company's ready-to-dilute (RTD) formulation. Moreover, SymBio recently expanded the indications approved for the drug to include diffuse large B-cell lymphoma (DLBCL), which may also drive future sales.

Year end	Revenue (¥bn)	PBT* (¥bn)	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	64.4	N/A
12/22e	11,484	2,018	37	0	47.0	N/A

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

SymBio markets Treakisym for the first time

SymBio is simultaneously executing on multiple parts of its strategy to control the lifecycle of Treakisym and expand its sales in Japan. In late 2020, the rights to market the drug in Japan were returned to the company from Eisai, so SymBio now directly markets the product in Japan. The strong growth in the product is in spite of residual Eisai inventory on the market, as well as the negative impacts of COVID-19. The return of rights to the product has also substantially improved SymBio's margins on the product: 71% gross margins from 23% in Q120. The company's other expenses have only increased slightly (¥1.22bn in other operational costs from ¥1.09bn in Q120).

DLBCL expanded to RTD formulation

SymBio is expanding the market for Treakisym both by launching new formulations of the drug such as RTD (approved in September 2020) and rapid infusion (RI, approval expected in 2022), and by seeking approval for new indications, in particular for DLBCL. As part of this the company will be submitting partial change applications to the PMDA (similar to sNDA applications to the FDA) to expand the target indications for the new formulations as well. For instance, in April 2021 SymBio received approval to market the RTD formulation for DLBCL.

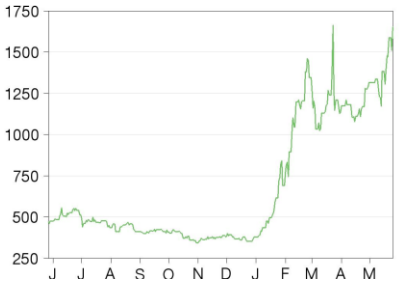
Valuation: ¥43.4bn or ¥1,133 per basic share

Our valuation of SymBio is approximately flat: ¥43.4bn or ¥1,133 per basic share, from ¥43.2bn or ¥1,131 per share previously. We have rolled forward our NPVs and this was offset by a lower new net cash (¥2.93bn from ¥3.85bn). We expect the company to reach profitability in 2021.

27 May 2021

Price	**¥1,740**
Market cap	**¥66,645m**
	¥110/US$
Net cash (¥bn) at 31 March 2021	2.93
Shares in issue	38.3m
Free float	91%
Code	4582
Primary exchange	TYO
Secondary exchange	OTC US

Share price performance



%	1m	3m	12m
Abs	41.0	13.9	249.6
Rel (local)	40.7	14.3	173.6
52-week high/low	¥1,740		¥337

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

RI approval decision	2021

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

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Commercial update

The most recent quarter reported by SymBio, Q121, is the first in which it has truly operated as an independent commercial entity. In early December 2020 the company formally commenced sales of Treakisym using its own internal salesforce and the current period marks the first with its sales wholly under SymBio's control. This is part of the company's longstanding strategy to manage the asset following the return of marketing rights to it from Eisai at the end of 2020. SymBio reported sales of ¥1.42bn, which we consider very encouraging. We currently forecast sales of ¥9.23bn for 2021, which is largely based on the company recapturing the prior Eisai market, and a smaller increase (~¥500m) as it enters the DLBCL market (more below). Part of the strategy to retain this market is through the offering of additional formulations of the drug. SymBio has already received approval for the RTD formulation, which it launched in January 2021, and this may have helped sales. The company submitted an application for the RI formulation in May 2021 and expects to be able to market the product in 2022. SymBio has stated that it intends to convert 91% of existing prescribers to the liquid formulation by the end of 2021.

Internally marketing the product has substantially improved the company's margins from previous reports: 71% gross margins from 23% in Q120. Other operational expenses were ¥1.22bn compared to ¥1.09bn in Q120, which we think is a very small increase associated with the launch of a drug for the first time. We expect the cost of selling to increase throughout 2021 as the company puts increasing effort into marketing the RTD formulation and markets the drug for DLBCL. We forecast ¥6.11bn in operational costs in 2021, which remains unchanged from our previous estimates. The operational loss for Q121 was ¥0.21bn. Based on this, we believe that SymBio may reach profitability in 2021, so we do not expect it to need additional capital for normal operations.

Development update

SymBio previously announced the approval of Treakisym for the treatment of DLBCL in March 2021. In April 2021, it announced that the RTD formulation of the drug was also approved for this indication. Although we are not surprised by this decision, we are encouraged that the company is executing on its two-pronged strategy to convert patients onto its proprietary formulations of the drug as well as to expand the market to include additional indications like DLBCL. The application for the RTD formulation was a 'partial change' application, which is similar to a supplemental new drug application (sNDA) used in the US with the FDA, and is much expedited compared to initial approvals. We expect SymBio to also seek approval of the RI formulation for DLBCL in the future. The company submitted an application for the RI formulation in May 2021.

DLBCL is an intermediate or high-risk form of Non-Hodgkin's lymphoma (NHL), but accounts for the largest fraction of NHL cases in Japan and elsewhere. Approximately 45% of NHL cases in Japan are DLBCL, corresponding to approximately 16,000 patients.[1] Assuming that 70% of DLBCL patients progress to receive second-line therapy, we forecast a target market of 11,200 second-line (r/r) DLBCL patients per year, which would approximately double the addressable market for the drug. This combination has been previously studied in a number of different trials across the globe, and is among the arsenal of treatment regimens available to doctors despite not being formally approved elsewhere.

[1] Chihara D, et al. (2013) Differences in incidence and trends of haematological malignancies in Japan and the United States. *Brit J Haem* 164, 536-545.

Valuation

We have increased our valuation to ¥43.4bn or ¥1,133 per basic share, from ¥43.2bn or ¥1,131 per share previously. This minor increase is driven by rolling forward our NPVs, and offset by lower net cash (¥2.93bn from ¥3.85bn). Otherwise our models 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	21,596.57
Treakisym (DLCBL)	r/r DLBCL	100–95%	2021	9,600	17,543.02
Brincidofovir	AdV following HSCT	20%	2025	9,100	1,278.62
Total					40,418.21
Net cash and equivalents (March 2021)					2,933.67
Total firm value (¥m)					43,351.87
Total basic shares (m)					38.26
Value per basic share (¥)					1,133.14

Source: SymBio Pharmaceuticals reports, Edison Investment Research

Exhibit 2: Financial summary

¥m	2019	2020	2021e	2022e
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	38.6
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)	(1,423.3)	(1,525.4)
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)	(940.0)	(951.3)
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	5,604.6	6,942.3
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	4,400.1	4,657.3	5,604.6	6,942.3
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)	(3,848.6)	(4,792.4)
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)	(4,792.4)	(5,920.4)

Source: SymBio Pharmaceuticals 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 Holborn
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