EDISON

SymBio Pharmaceuticals

Regulatory update

Treakisym RTD approved

Pharma & biotech

SymBio announced on 23 September 2020 that it has received approval from the PMDA for the ready-to-dilute (RTD) formulation of Treakisym (bendamustine) in Japan. This formulation, licensed from Eagle Pharmaceuticals, is part of SymBio's pipeline management strategy and the company has exclusivity on the formulation until 2031. The company intends to begin marketing the product in January 2021.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/18	3,836	(2,626)	(158)	0	N/A	N/A
12/19	2,838	(4,250)	(184)	0	N/A	N/A
12/20e	2,608	(4,729)	(145)	0	N/A	N/A
12/21e	9,228	1,531	30	0	14	N/A

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

Part of the strategy to extend the product lifecycle

The RTD formulation is one of two formulations of bendamustine licensed by SymBio from Eagle. This and the rapid infusion (RI) formulation are both intended to simplify the preparation and administration of the drug, which is highly insoluble in its native form. In the US, the RTD and RI formulations (marketed by Eagle and Teva respectively) have substantially replaced the market for the powdered formulation.

RI formulation on deck

SymBio also reported in September 2020 that the last patient has had his or her last evaluation for the company's ongoing pivotal clinical study of the RI formulation of Treakisym. The study is of a Phase I/II design intended to demonstrate the safety of the formulation and of the 10-minute infusion protocol. The company is targeting a submission of a marketing application for the product in H222, for launch in 2023.

New guidance

The company issued new guidance for 2020, which includes downward revisions in revenue (¥3.04bn from ¥3.40bn), but also lower operating losses (¥4.59bn from ¥5.09bn). Additionally, the company has added the $4.95m arbitration award it is receiving from The Medicines Company in its estimates, which further improves the firm's expected net loss (¥3.80bn from ¥4.80bn). We remain more conservative in our estimates with ¥2.61bn in revenue on account of ongoing supply issues.

Valuation: Increased to ¥37.8bn or ¥1,074 per share

We have increased our valuation to ¥37.8bn or ¥1,074 per share from ¥37.6bn or ¥1,068 per share. Otherwise our valuation models remain unchanged. We forecast company profitability in 2021 with the relaunch of Treakisym with SymBio's internal salesforce and the associated improved margins.

30 September 2020

Price	**¥420**
Market cap	**¥14,784m**
	¥110/US$
Net cash (¥m) at 30 June 2020	5,410
Shares in issue	35.2m
Free float	94%
Code	4582
Primary exchange	TYO
Secondary exchange	OTC US

Share price performance

%	1m	3m	12m
Abs	5.0	(18.0)	(35.9)
Rel (local)	1.6	(23.4)	(38.0)
52-week high/low		¥791	¥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 RTD launch	January 2021
Treakisym DLBCL approval decision	H121

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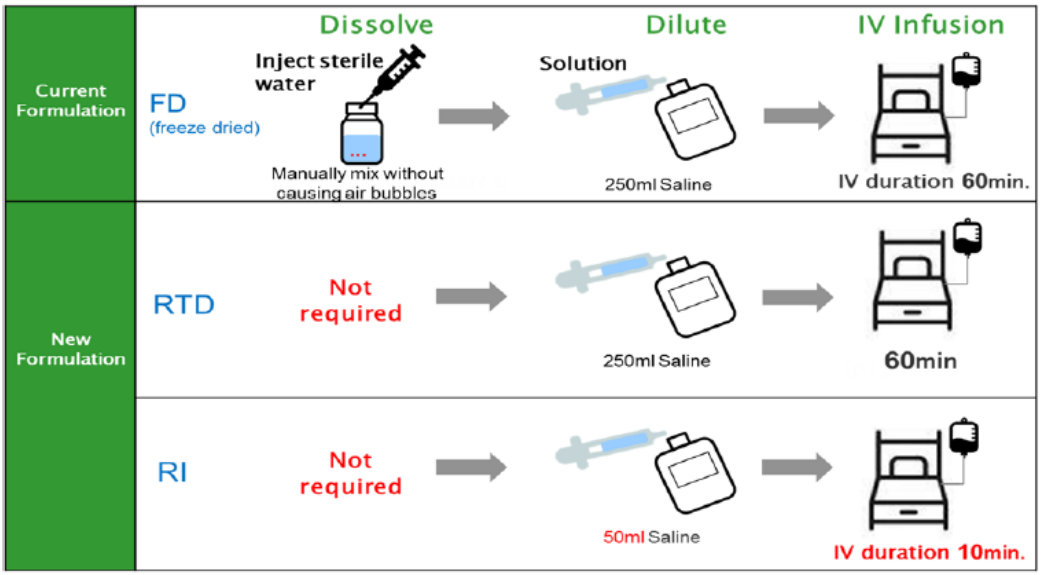
Edison profile page

Treakisym formulations and pipeline management

SymBio licensed the rights to both the RTD and RI formulations of bendamustine from Eagle Pharmaceuticals in September 2017. The two products were developed by Eagle as an improvement over freeze-dried bendamustine powder, which requires both a tedious solubilization and an extended infusion period. These products have substantially replaced the freeze-dried product on the US market. The RTD and RI formulations of bendamustine are marketed as Belrapzo and Bendeka respectively in the US. Belrapzo is marketed by directly by Eagle, which reported sales of $29.7m for the product in 2019. The more popular product is the RI formulation Bendeka, which is licensed to Teva Pharmaceuticals. Teva reported 2019 sales of its bendamustine products (which includes Bendeka and freeze-dried generics, but Teva notes that Bendeka is dominant) of $496m, down from $642m in 2018.

Exhibit 1: Treakisym formulations



Source: SymBio

SymBio licensed these products as part of a strategy to extend its period of exclusivity. Its exclusivity over the freeze-dried product expires in 2020, but the liquid formulations would extend this to 2031. The goal is to transition patients and providers over to the new formulations before new freeze-dried generics enter the market. Given the success of these products in the US, we believe that the increased convenience for healthcare providers supports such a strategy. The company guided that it expects to launch the RTD formulation in January 2021. The company reported earlier in September 2020 that the last patient had completed his or her last evaluation in the ongoing pivotal safety study for the RI formulation. The company has guided that approval is planned for H222 (which assumes a marketing application submission in H221).

New guidance

The company published a revision to its midrange plan in September 2020, which included updated guidance for the 2020 fiscal year (ending in December 2020). The company revised its sales outlook downward to ¥3.04bn from ¥3.40bn. The company cited COVID-19 and other factors as potential uncertainties in the projected sales. We remain more conservative and project H220 sales in the same range as H120 (¥1.36bn) and ¥2.61bn for 2020 as a whole. We are more conservative

because we are accounting for continued disruption in the supply of the product, which has routinely seen supply issues that have affected the ability of the company to deliver product over the past year, although we hope this issue is resolved. This is the major difference between the company's projections and our own. The supply issue is due to repeated delivery of batches from the company's supplier Astellas that have not met quality control standards and delays in the replacement of these batches. The company will be transitioning out of its supply agreements at the end of 2020, so we expect this effect to be limited to this year.

Despite lower revenue than its prior forecast, the company is now guiding to lower operating losses, ¥4.59bn from ¥5.09bn, due to cost-cutting measures put in place in anticipation of the impact of COVID-19. This brings the company's implied estimates for operational costs (¥7.64bn) more in line with ours (¥7.48bn). Finally, the company has added the value of the arbitration settlement it received against the Medicines Company in early September 2020 into its revised estimates for net loss (¥3.80bn from ¥4.80bn, previously). With the settlement included in our forecasts, we project a reported net loss of ¥4.34bn for 2020.

Valuation

We have increased our valuation to ¥37.8bn or ¥1,074 per share, from ¥37.6bn or ¥1,068 per share. This increase is solely due to the removal of our risk adjustment (95% probability of success previously) for the RTD formulation, which has increased the value of Treakisym for its approved indications to ¥19.15bn from ¥18.97bn. Otherwise, our models and sales forecasts remain unchanged.

Exhibit 2: 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	19,149.54
Treakisym (DLCBL)	r/r DLBCL	90%	2021	9,600	12,166.04
Brincidofovir	AdV following HSCT	20%	2025	9,100	1,062.05
Total					32,377.63
Net cash and equivalents (June 2020)					5,409.70
Total firm value (¥m)					37,787.33
Total basic shares (m)					35.18
Value per basic share (¥)					1,074.07

Source: SymBio reports, Edison Investment Research

Exhibit 3: Financial summary

¥m	2018	2019	2020e	2021e	2022e
JPN GAAP, year-end 31 December					
INCOME STATEMENT					
Revenue	3,835.5	2,837.8	2,608.1	9,227.8	11,483.8
Cost of Sales	(2,662.7)	(1,973.0)	(1,956.0)	(1,618.7)	(2,261.2)
Gross Profit	1,172.9	864.8	652.0	7,609.1	9,222.6
R&D	(1,832.7)	(2,441.6)	(2,203.0)	(465.0)	(820.0)
SG&A	(1,996.2)	(2,724.8)	(3,324.8)	(5,772.5)	(6,396.9)
EBITDA	(2,621.4)	(4,263.5)	(4,754.8)	1,465.0	2,103.4
Depreciation & amortization	(34.7)	(38.1)	(121.0)	(93.4)	(97.7)
Normalised operating profit	(2,533.1)	(4,174.5)	(4,748.7)	1,498.7	2,132.9
Reported operating profit	(2,656.1)	(4,301.6)	(4,875.8)	1,371.6	2,005.7
Net interest	(92.7)	(75.0)	19.6	32.5	54.8
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0	0.0
Exceptionals	(0.0)	4.2	519.8	0.0	0.0
Profit Before Tax (norm)	(2,625.8)	(4,249.5)	(4,729.1)	1,531.3	2,187.7
Profit Before Tax (reported)	(2,748.7)	(4,372.5)	(4,336.4)	1,404.1	2,060.6
Reported tax	(3.8)	(3.8)	(3.8)	(468.6)	(592.6)
Profit After Tax (norm)	(2,625.8)	(4,249.5)	(4,729.1)	1,531.3	2,187.7
Profit After Tax (reported)	(2,752.5)	(4,376.3)	(4,340.2)	935.5	1,468.0
Minority interests	0.0	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0	0.0
Net income (normalised)	(2,629.6)	(4,253.3)	(4,732.9)	1,062.7	1,595.1
Net income (reported)	(2,752.5)	(4,376.3)	(4,340.2)	935.5	1,468.0
Basic average number of shares outstanding (m)	17	23	33	35	36
EPS - basic normalised (¥)	(158.14)	(183.72)	(144.83)	30.22	44.82
EPS - diluted normalised (¥)	(104.91)	(180.46)	(143.00)	29.86	44.30
EPS - basic reported (¥)	(165.54)	(189.03)	(132.81)	26.60	41.25
Dividend (¥)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	200.9	386.5	395.1	394.5	409.7
Intangible Assets	71.4	240.5	228.8	202.3	184.6
Tangible Assets	57.0	75.5	95.9	121.8	154.6
Investments & other	72.6	70.4	70.4	70.4	70.4
Current Assets	6,038.5	4,887.5	4,177.5	5,267.1	6,890.9
Stocks	533.8	0.0	219.7	181.8	254.0
Debtors	411.7	549.3	285.8	1,011.3	1,258.5
Cash & cash equivalents	4,821.4	3,910.8	3,244.6	3,646.6	4,951.0
Other	271.6	427.4	427.4	427.4	427.4
Current Liabilities	(1,336.3)	(872.2)	(1,236.6)	(1,390.0)	(1,561.0)
Creditors	(654.9)	(33.2)	(424.0)	(486.9)	(566.7)
Tax and social security	(71.2)	(87.8)	0.0	0.0	0.0
Short term borrowings	0.0	0.0	0.0	0.0	0.0
Other	(610.2)	(751.3)	(812.6)	(903.1)	(994.3)
Long Term Liabilities	(1.3)	(1.6)	(1.6)	(1.6)	(1.6)
Long term borrowings	0.0	0.0	0.0	0.0	0.0
Other long term liabilities	(1.3)	(1.6)	(1.6)	(1.6)	(1.6)
Net Assets	4,901.8	4,400.1	3,334.4	4,270.0	5,738.0
Minority interests	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	4,901.8	4,400.1	3,334.4	4,270.0	5,738.0
CASH FLOW					
Op Cash Flow before WC and tax	(2,714.0)	(4,334.4)	(4,215.5)	1,497.5	2,158.2
Working capital	184.5	(242.1)	346.8	(624.7)	(239.6)
Exceptional & other	208.8	229.5	127.1	127.1	127.1
Tax	(3.8)	(3.8)	(3.8)	(468.6)	(592.6)
Net operating cash flow	(2,324.5)	(4,350.7)	(3,745.3)	531.4	1,453.2
Capex	(26.2)	(216.5)	(102.3)	(129.4)	(148.8)
Acquisitions/disposals	0.0	0.0	0.0	0.0	0.0
Equity financing	4,272.1	3,740.0	3,201.7	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Net Cash Flow	1,921.3	(827.2)	(645.9)	402.0	1,304.4
Opening net debt/(cash)	(2,947.1)	(4,821.4)	(3,910.8)	(3,244.6)	(3,646.6)
FX	(47.0)	(83.4)	(20.3)	0.0	0.0
Other non-cash movements	0.0	0.0	0.0	0.0	0.0
Closing net debt/(cash)	(4,821.4)	(3,910.8)	(3,244.6)	(3,646.6)	(4,951.0)

Source: SymBio reports, Edison Investment Research

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