EDISON

SymBio Pharmaceuticals

Strategy update

Preparing to establish own sales organisation

Pharma & biotech

SymBio announced in October that it has begun preparations to establish its own sales organisation to market Treakisym and other anticancer drugs in Japan after the marketing agreement with Eisai expires in December 2020. The announcement validates our decision earlier this year to adopt self-commercialisation in Japan in our base-case valuation model. Self-commercialisation will improve operating margins and allow it to establish a team of in-house experts to communicate the benefits of Treakisym (and rigosertib if approved) to healthcare providers. Our valuation increases to ¥25.5bn as we roll forward the DCF model; our earnings forecasts and valuation assumptions are unchanged.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/16	2,368	(2,317)	(59.0)	0.0	N/A	N/A
12/17	3,444	(3,977)	(79.8)	0.0	N/A	N/A
12/18e	4,203	(3,030)	(46.0)	0.0	N/A	N/A
12/19e	4,325	(3,617)	(46.5)	0.0	N/A	N/A

Note: *PBT and EPS (diluted) are normalised, excluding exceptional items.

Liquid formulations and DLBCL justify own sales

The extension of Treakisym's lifecycle through the in-license of liquid formulations from Eagle Pharmaceuticals plus the potential for the r/r diffuse large B-cell lymphoma (DLBCL) Phase III to drive further sales growth from 2021 (if successful) support the rationale for SymBio to establish its own salesforce to market Treakisym and other drugs. Treakisym in-market sales grew by ~61% to ¥7.6bn in 2017 (on an NHI basis), supported by two new indications approved in 2016. We model Treakisym sales of ¥10.7bn in FY21, allowing SymBio to attain profitability in the first year of self-commercialisation.

New Treakisym indications, rigosertib to drive growth

Treakisym (bendamustine hydrochloride) plus rituximab is already established as standard-of-care for malignant lymphoma in a number of settings. SymBio initiated a Phase III study in r/r DLBCL in August 2017, with top-line data expected in 2019. We estimate the r/r DLBCL indication could double the peak sales potential for Treakisym, if approved. In July SymBio filed for approval of Treakisym as part of a pre-treatment regimen prior to CAR-T therapy with Kymriah. In addition, SymBio aims to recruit 40 Japanese patients, as part of partner Onconova's 360-patient global Phase III trial of intravenous (iv) rigosertib in r/r higher-risk myelodysplastic syndromes (MDS) and plans to file for approval in Japan in 2021.

Valuation: rNPV of ¥25.5bn ($225m) or ¥327/share

We roll forward our DCF model and increase our risk-adjusted valuation to ¥25,469m ($225m) (vs ¥23,823m). The extra 20m shares issued under the 45th stock acquisition rights (raising ¥2,590m) sees value per share decline to ¥327 (vs ¥412/share). Our valuation assumptions and earnings forecasts are unchanged, as we already adopted self-commercialisation in Japan as the base-case valuation scenario in our April report. SymBio has reaffirmed its guidance, which already allowed for expenses related to establishing its own salesforce.

7 December 2018

Price	**¥252**
Market cap	**¥19,631m**
	¥113/$
Net cash (¥m) at end June 2018	3,050
Shares in issue	77.9m
Free float	84%
Code	4582
Primary exchange	Japan
Secondary exchange	OTC US

Share price performance

%	1m	3m	12m
Abs	15.1	96.9	15.6
Rel (local)	18.6	106.9	26.7
52-week high/low		¥263	¥116

Business description

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

Next events

Treakisym sales update	Q119
DLBCL top-line data	2019
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Edison profile page

Establishing own salesforce for revitalised Treakisym

SymBio acquired the rights to develop and commercialise Treakisym from Astellas in Japan (2005) and subsequently in China/Hong Kong, Korea, Taiwan and Singapore (April 2007). Treakisym is approved in Japan for the treatment of the haematological cancers chronic lymphocytic leukaemia (CLL) and low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (lg NHL/MCL). Orphan exclusivity on the currently-marketed freeze dried powder (FD) Treakisym product expires in October 2020.

Treakisym is marketed by Eisai in Japan, Singapore and South Korea under a business partnership agreement that expires in December 2020.

In September 2017, SymBio in-licensed two liquid formulations of bendamustine HCl (Treakisym) from Eagle Pharmaceuticals (Eagle). The new formulations are protected by patents that extend to 2031, which will add around 10 years to the Treakisym product lifecycle compared to the company's marketed FD powder Treakisym product. The new formulations are more convenient for healthcare workers and for patients, which will be important advantages as SymBio seeks to switch users away from the FD formulation.

The extended period of patent protection for the liquid formulations has made investment in a Phase III study of Treakisym in the DLBCL indication an attractive proposition for SymBio. DLBCL comprises around 45% of NHL cases in Japan, and we estimate that approval in this indication could double the sales potential of Treakisym.

Taken together, the patented liquid formulations and the DLCBL Phase III justify SymBio investing in establishing its own sales organisation to market Treakisym and other drugs such as rigosertib (if approved), in our view. We estimate that SymBio could earn an operating profit margin of 50% of net sales of Treakisym under a self-commercialisation model, compared to an estimated margin of 10–12% of in-market top-line sales under the arrangement with Eisai.

Own sales organisation provides leverage for new products

SymBio has noted that having its own sales organisation in place will enable it to better understand and respond to market needs, positioning it to deliver the benefits of Treakisym to healthcare providers and patients. Treakisym is used in the haematology departments of approximately 900 institutions across Japan, with the top 400 institutions accounting for ~90% of sales. If rigosertib is approved for treating MDS, the top 400 institutions would similarly be expected to account for the majority of use. Therefore, SymBio would be in a position to market rigosertib (if approved) through its own sales organisation for minimal additional cost. The same operation leverage would apply were SymBio to in-licence or develop other haematological drugs. Establishing its own sales organisation will be an important step towards achieving SymBio's vision of establishing itself as a leading speciality pharma company.

Pipeline progress

Exhibit 1 summarises the status of SymBio's product pipeline. The main areas of focus are:

- Obtaining approval for the two liquid formulations of Treakisym to extend the product lifecycle out to 2031.
- Completion of the Phase III study of Treakisym in DLBCL, which could potentially double the sales potential of Treakisym.

- Participating in the global Phase III study of iv rigosertib in MDS, which could become SymBio's second product for haematological cancers.
- Completion of ongoing Phase I studies of oral formulations of Treakisym and rigosertib, which could lead to development of additional indications for both drugs.

Exhibit 1: Status of the SymBio pipeline

Drug	Indication	Phase 1	Phase 2	Phase 3	NDA	MA
SyB L-0501 TREAKISYM®	r/r Low-grade NHL/MCL	Approved October 2010				
	CLL	Approved August 2016				
	1st line Low-grade NHL/MCL	Approved December 2016				
	r/r DLBCL	P3 initiated August 2017				
	RTD (Ready-to-Dilute) Injection (liquid formulation)	NDA under preparation				
	RI (Rapid Infusion) Injection (liquid formulation)	Clinical trial initiated				
SyB C-0501 TREAKISYM® ORAL	Advanced solid tumors	P1 initiated January 2018				
SyB C-0501 TREAKISYM® ORAL	SLE	Pre-clinical study ongoing				
SyB L-1101 RIGOSERTIB IV	Post-HMA Higher Risk MDS	Global P3 (INSPIRE study)				
SyB C-1101 RIGOSERTIB ORAL	1. 1st line Higher Risk MDS* 2. Transfusion dependent Lower Risk MDS *monotherapy to be followed by combination therapy with azacitidine	P1 initiated June 2017				

Source: SymBio

Key news anticipated for SymBio in 2019 includes:

- Top-line data from the DLBCL and rigosertib Phase III studies.
- Filing for approval of the ready-to-dilute (RTD) liquid Treakisym formulation.
- Update on the clinical study of the rapid infusion Treakisym formulation.

Liquid formulations extend Treakisym lifecycle

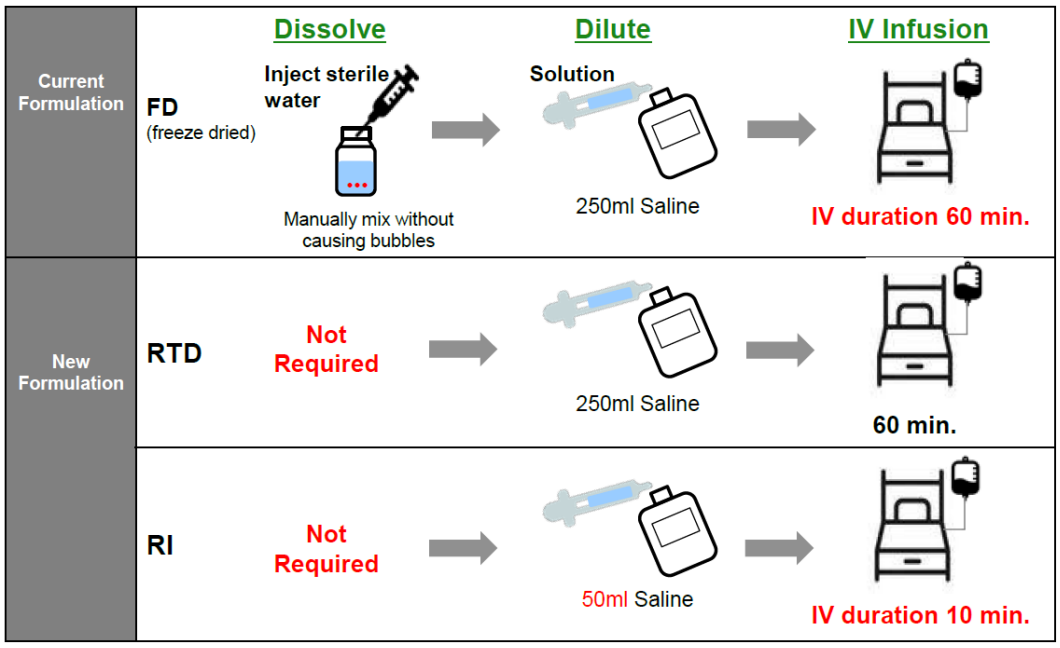
The new liquid formulations of Treakisym that SymBio in-licensed from Eagle are more convenient for healthcare workers and for patients.

The first in-licensed product is an RTD liquid formulation that will significantly reduce dose preparation time, making it easier and safer for health professionals. This compares to the FD Treakisym, which has to be reconstituted before administration, a time-consuming process that carries the risk of exposing healthcare workers to cytotoxic powders and vapours.

The second in-licensed product is a rapid-infusion (RI) formulation that will cut drug infusion time to 10 minutes from 60 minutes for the current Treakisym product (and the RTD formulation).

Exhibit 2 illustrates the differences in use between the current FD Treakisym and the new liquid RTD and RI formulations.

Exhibit 2: Comparison of the current FD powder and new liquid formulations



Source: SymBio

Liquid formulations aim to maintain SymBio's market share

We expect the approval pathway for the RTD Treakisym formulation to be relatively straightforward, as the same dose of drug is administered to patients in the same way, with the only difference being the way the dose is prepared. SymBio is aiming to launch the RTD product in H121, which would allow it to be well established in the marketplace before the expected entry of the first FD generics in 2022.

The RI product represents a greater change to the current treatment protocols, so approval of this product is expected to take longer – we model a 95% chance of a launch by the start of 2023. Given the greater convenience for patients of the rapid 10-minute infusion with the RI formulation, we expect over 95% of patients to be switched to this product.

DLBCL indication could substantially increase Treakisym sales

SymBio is seeking to add another indication for the treatment of r/r DLBCL, an intermediate or high-risk form of NHL, with Treakisym. It commenced a Phase III trial to confirm the safety and efficacy of Treakisym plus rituximab in r/r DLBCL in August 2017. SymBio's mid-range plan aims to file an NDA in H120. We model Phase III costs of ¥2bn and a potential launch in H221.

DLBCL is a rapidly growing, intermediate or high-risk form of NHL, in contrast to the slower-growing indolent or low-risk lymphomas that are included in the current approvals for Treakisym. There is currently no standard chemotherapy for the treatment of DLBCL.

DLBCL is the most common form of NHL and is estimated to represent 45% of NHL cases in Japan[1]. Based on epidemiology studies[1] and Globocan data, we estimate there will be 35,500 new cases of NHL and 16,000 new cases of DLBCL in Japan in 2020. 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 in Japan by 2020.

1 Chihara et al; British Journal of Haematology, 2014, 164, 536–545; doi: 10.1111/bjh.12659

The patient market of 11,200 r/r DLBCL patients in Japan is almost as large as the combined market of ~12,500 patients for the currently approved indications for Treakisym in CLL and first-line and r/r low-grade NHL and MCL patients. Given the high unmet need for this patient group, we model a 50% market penetration and peak sales (net sales after discounts) of ¥9.6bn for DLBCL vs ¥9.5bn for the currently approved indications.

IV rigosertib - a potential second product for SymBio

SymBio in-licensed rigosertib (*iv* and oral formulations, Japan and Korean rights) from Onconova in 2011 for MDS, a rare blood cancer. SymBio is contributing patients from Japan to the global Phase III INSPIRE trial of *iv* rigosertib for the treatment of second-line higher-risk MDS (HR-MDS); as of the end of July 2018 it had already enrolled 36 patients in the study.

Onconova announced in January 2018 that it is moving forward with the study as it had been cleared to continue following an interim analysis by the independent data monitoring committee (DMC). Following a pre-planned sample size re-estimation conducted by the DMC as part of the interim analysis, the target enrolment was expanded from 225 to 360 patients, with the aim of increasing the power of the trial. SymBio will continue to collaborate with Onconova on the study and plans to increase the total enrolment in Japan to 40 patients. Onconova is guiding for top-line results of the overall survival analysis after 288 events to be available in 2019. SymBio aims to file for approval in 2021.

Onconova raised US$28.8m in May and had a cash balance of US$22.4m at 30 September 2018. With operating expenses currently averaging ~US$6m per quarter, it should have sufficient funds to report top-line data from the INSPIRE trial.

Valuation

We have rolled our valuation model forward in time, which increased our valuation of SymBio to ¥25,469m ($225m), based on a risk-adjusted NPV analysis. We use a 10% discount rate for approved products and 12.5% elsewhere. The additional 20m shares in issue following the exercise of the 45th stock acquisition rights (raising ¥2,580m) sees value per share decline to ¥327/share (vs ¥412/share). Our valuation includes Treakisym approved indications and the r/r DLBCL indication, plus rigosertib. Our valuation assumptions and financial forecasts are unchanged. Our main assumptions are summarised in Exhibit 3 below.

Exhibit 3: SymBio rNPV valuation

Product	Indication	Launch	Peak sales (¥m)**	NPV (¥m)	Probability (%)	rNPV (¥m)	NPV/share (¥/share***)
Treakisym	lg NHL/MCL (r/r and first line); CLL	2010*	9,500	17,378	95–100%	16,670	214.0
Treakisym (DLBCL)	r/r DLBCL	2021	9,600	9,501	60%	4,858	62.4
Rigosertib (IV)	r/r HR-MDS	2023	3,800	2,009	50%	702	9.0
Rigosertib (oral)	First-line HR-MDS (combo)	2025	7,500	3,318	15%	292	3.7
Net cash at 30 December 2017				2,947	100%	2,947	37.8
Valuation				35,153		25,469	327.0

Source: Edison Investment Research. Note: *Treakisym was launched in 2010 in r/r low-grade NHL/MCL; it received approvals in Japan in CLL in August 2016 and in first-line, low-grade NHL/MCL in December 2016; **we present Treakisym peak sales estimates net of discounts, to align with sales reporting by Eisai; 77.9m shares on issue.

We model a 95% likelihood that the RI Treakisym formulation will be launched by the start of 2023, thereby minimising the penetration of generic copies of the FD Treakisym formulation. We model branded Treakisym market share gradually declining from 96% in 2022 to 75% in 2031, followed by a more rapid decline from 2032 after the liquid formulation patents expire.

Our Treakisym valuation assumes that SymBio earns an average net margin of 10–12% on top-line reported Treakisym sales until 2020. We assume that after 2020 the net operating margin gradually increases to reach 50% in 2024 and subsequent years as SymBio switches to self-commercialisation of Treakisym via its own salesforce and the liquid formulations in-licensed from Eagle gain market share vs powder formulations.

We model ¥1.5bn of development costs to achieve approval for the RTD and RI liquid formulations of Treakisym. We estimate that a salesforce of 60 would be needed to market Treakisym in Japan. At a fully-loaded cost of $250,000 per person, this would cost US$15m or approximately ¥1.7bn per year.

Scenario analysis

In a scenario where the Treakisym market share declines to 50% by 2031 (vs 75% for the base case), our valuation would fall by around ¥2.0bn (¥38/share) to around ¥23.4bn (¥301/share).

We currently assume stable Treakisym pricing apart from a 5% price cut in 2022 when FD powder generics are expected to enter the market. However, should Treakisym be subject to an additional price cut in the future, this could represent downside to our forecasts; a 10% price cut in 2019 would remove around ¥2.4bn from our Treakisym rNPV, or ¥31/share.

Exhibit 4: SymBio's 2018 outlook and 2019 targets versus our estimates

	2018 guidance	2018 estimates	2019 targets	2019 estimates
Revenue	¥ 4,201m	¥ 4,203m	¥ 4,238m	¥ 4,325m
R&D	¥ 2,311m	¥ 2,250m	N/A	¥ 2,200m
SG&A (including R&D)	¥ 4,350m	¥ 4,289m	N/A	¥ 4,920m
Operating loss	¥ 2,981m	¥ 3,045m	¥ 3,786m	¥ 3,640m
Ordinary loss	¥ 3,044m	¥ 3,030m	¥ 3,849m	¥ 3,617m
Net loss	¥ 3,056m	¥ 3,034m	¥ 3,853m	¥ 3,621m

Source: Edison Investment Research

Exhibit 5: Financial summary

Accounts: JPN GAAP, Yr end: 31 December; ¥m	2014	2015	2016	2017	2018e	2019e
Total revenues	1,955	1,933	2,368	3,444	4,203	4,325
Cost of sales	(1,428)	(1,350)	(1,464)	(2,413)	(2,959)	(3,045)
Gross profit	527	583	904	1,031	1,244	1,280
SG&A (expenses)	(1,056)	(1,100)	(1,364)	(1,961)	(2,039)	(2,720)
R&D costs	(774)	(2,035)	(1,667)	(3,018)	(2,250)	(2,200)
Other income/(expense) included in adjusted	0	0	0	0	0	0
Other income/(expense) excluded from adjusted	0	0	0	0	0	0
Reported EBIT	(1,303)	(2,552)	(2,127)	(3,947)	(3,045)	(3,640)
Finance income/ (expense)	25	16	5	3	15	23
Other income/(expense) included in adjusted	(2)	2	7	3	0	0
Other income/(expense) excluded from adjusted	168	(95)	(195)	(33)	0	0
Reported PBT	(1,112)	(2,628)	(2,309)	(3,974)	(3,030)	(3,617)
Income tax expense	(4)	(4)	(4)	(4)	(4)	(4)
Reported net income	(1,116)	(2,632)	(2,313)	(3,978)	(3,034)	(3,621)
Average number of shares - basic (m)	30.8	32.4	39.3	49.9	66.0	77.9
Basic EPS	(36.26)	(81.26)	(58.82)	(79.78)	(45.99)	(46.48)
Adjusted EBITDA	(1,291)	(2,527)	(2,101)	(3,917)	(3,004)	(3,591)
Adjusted EBIT	(1,303)	(2,552)	(2,127)	(3,947)	(3,045)	(3,640)
Adjusted PBT	(1,110)	(2,630)	(2,317)	(3,977)	(3,030)	(3,617)
Adjusted EPS	(36.20)	(81.33)	(59.00)	(79.84)	(45.99)	(46.48)
Adjusted diluted EPS	(36.20)	(81.33)	(59.00)	(79.84)	(45.99)	(46.48)
Balance sheet						
Property, plant and equipment	49	53	75	47	48	49
Goodwill	0	0	0	0	0	0
Intangible assets	66	52	42	69	86	96
Other non-current assets	49	53	77	100	100	100
Total non-current assets	164	158	193	216	235	245
Cash and equivalents	5,092	4,261	5,719	2,947	2,315	500
Inventories	245	133	273	363	324	250
Trade and other receivables	273	301	487	490	576	498
Other current assets	1,681	132	205	237	237	237
Total current assets	7,290	4,827	6,685	4,037	3,452	1,485
Non-current loans and borrowings	0	0	450	0	0	1,491
Trade and other payables	0	0	0	0	0	0
Other non-current liabilities	2	2	1	1	1	1
Total non-current liabilities	2	2	451	1	1	1,493
Trade and other payables	306	320	322	604	349	400
Current loans and borrowings	0	0	0	0	0	0
Other current liabilities	182	231	620	407	407	407
Total current liabilities	488	551	942	1,011	756	807
Equity attributable to company	6,964	4,432	5,485	3,239	2,929	(570)
Non-controlling interest	0	0	0	0	0	0
Cash flow statement						
Profit before tax	(1,112)	(2,628)	(2,309)	(3,974)	(3,030)	(3,617)
Depreciation and Amortisation	13	24	26	30	40	49
Share based payments	95	103	137	121	121	121
Other adjustments	(207)	26	197	42	(15)	(23)
Movements in working capital	(78)	190	(13)	(35)	(303)	203
Interest paid / received	27	18	6	3	15	23
Income taxes paid	(4)	(4)	(4)	(4)	(4)	(4)
Cash from operations (CFO)	(1,266)	(2,272)	(1,960)	(3,817)	(3,175)	(3,247)
Capex	(109)	(24)	(28)	(57)	(59)	(60)
Acquisitions & disposals net	0	0	0	0	0	
Other investing activities	423	1,513	(16)	(20)	0	0
Cash used in investing activities (CFIA)	314	1,489	(44)	(78)	(59)	(60)
Net proceeds from issue of shares	544	(2)	3,226	1,164	2,603	0
Movements in debt	0	0	450	0	0	1,491
Other financing activities	(1)	(1)	(18)	0	0	0
Cash from financing activities (CFF)	544	(3)	3,658	1,164	2,603	1,491
Currency translation differences and other	206	(45)	(196)	(42)	0	0
Increase/(decrease) in cash and equivalents	(202)	(831)	1,458	(2,772)	(632)	(1,815)
Cash and equivalents at end of period	5,092	4,261	5,719	2,947	2,315	500
Net (debt) cash	5,092	4,261	5,269	2,947	2,315	(991)
Movement in net (debt) cash over period	(202)	(831)	1,008	(2,322)	(632)	(3,307)

Source: Edison Investment Research and SymBio accounts

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