

# SymBio Pharmaceuticals

## Supply issues continue

FY19 earnings update

Pharma &amp; biotech

21 February 2020

**Price** **¥586**
**Market cap** **¥16,115m**

¥110/US\$

Net cash (¥m) at December 2019 + subsequent exercises 4,537

Shares in issue 27.5m

Free float 92.2

Code 4582

Primary exchange TYO

Secondary exchange OTC US

SymBio reported sales of ¥2.838bn for 2019 and an operating loss of ¥4.301bn. Sales were down from 2018 due to the previously announced quality control issue for the supply of Treakisym from Astellas. We forecast sales of ¥3.433bn in 2020 as the company winds down its sales to Eisai in anticipation of the launch of its own internal salesforce and marketing effort for the drug in 2021.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/18	3,836	(2,749)	(166)	0	N/A	N/A
12/19	2,838	(4,377)	(189)	0	N/A	N/A
12/20e	3,433	(5,078)	(170)	0	N/A	N/A
12/21e	9,159	962	50	0	11.7	N/A

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

## Quality and supply issues continue

The quantity control issues that were announced in August 2019 were expected to have a negative impact on sales for the year. Further, the company announced in the annual report that although Astellas replaced the initial bad shipments, there were additional quality control issues and missed delivery dates. This further exacerbated the revenue loss to the company from its August 2019 guidance of ¥3.092bn to the final total of ¥2.838bn. Astellas is reportedly addressing the issue, but SymBio is unable to confirm at this time.

## Preparing for internal marketing of Treakisym

Treakisym is currently marketed through the company's partner Eisai, but the rights to the drug will revert to SymBio at the beginning of 2021. In anticipation, the company will be building out its own internal salesforce and marketing program for the drug over the coming year. SymBio is also advancing two expansions of the program: the ready to dilute formulation (NDA submitted in September 2019) and a label expansion to diffuse large B-cell lymphoma (DLBCL, NDA submission expected Q220).

## Valuation: Increased to ¥37.2bn or ¥1,351 per share

We have increased our valuation to ¥37.2bn (\$338m) from ¥32.7bn (\$300m), although it is up less on a per share basis (¥1,351 from ¥1,342). This increase is driven by rolling forward our NPVs, offset at the share level by a higher share count. We expect to update our valuation with the announcement of results for the Phase III myelodysplastic syndrome (MDS) clinical study of rigosertib from the drug's sponsor, Onconova, planned for H120.

## Share price performance



%	1m	3m	12m
Abs	(6.4)	(10.9)	(32.8)
Rel (local)	(2.5)	(10.1)	(35.3)

52-week high/low	¥1,088	¥542
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## 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. Rigosertib was in-licensed from Onconova. And brincidofovir was licensed from Chimerix in 2019.

## Next events

DLBCL NDA filing	Q220
Rigosertib Phase III results	H120

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## Supply issues with Astellas persist and continue to negatively affect sales and earnings

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SymBio previously [reported](#) in August 2019 that shipments of Treakisym (bendamustine) from its supplier Astellas had suffered from a series of quality control issues. At the time management revised its 2019 revenue guidance down to ¥3.092bn from ¥4.465bn. However, the company reported in its 2019 financial report that quality control and supply issues have persisted, causing delays that continue to have a negative impact on sales. SymBio had net sales of ¥2.838bn for the year, down approximately ¥1bn from 2018. Furthermore, operating losses also exceeded expectations at ¥4.301bn (compared to the revised guidance of ¥3.587bn in August 2019).

Astellas eventually replaced all of the defective batches of drug, but these shipments were affected by unreliable delivery dates and further quality control issues. SymBio stated in its report that Astellas has implemented a corrective and preventative action program to address these issues, but it is too early to evaluate the effectiveness of these measures. As Astellas is the sole licensor of bendamustine rights worldwide, SymBio has relatively little recourse over the supply issues it has faced.

## Shift towards internal sales

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The company has guided toward sales of ¥3.404bn in 2020, although this reduction is driven by a planned rundown of deliveries to the company's marketing partner Eisai rather than inventory issues. SymBio will gain full rights to market Treakisym in Japan at the beginning of 2021 and it intends to relaunch the drug with its own internal sales force at that time. In anticipation of this, deliveries to Eisai will be reduced to allow for a reduction in its inventory. Because of the planned reduction in volume, we expect the effects of continued supply issues (if they occur) to be limited.

SymBio forecasts an operating loss of ¥5.090bn for 2020 as it gears up operations for its own internal salesforce. We currently forecast costs of approximately ¥1bn associated with building this organization and establishing its supply chain.

The company is targeting profitability in 2021 with the re-launch of Treakisym. In addition to bringing sales of the product in house, the company has also made multiple efforts to expand its market. The company submitted an NDA in September 2019 with the Japanese regulatory authorities for the ready-to-dilute (RTD) formulation of the drug. It is also planning an NDA submission for the label expansion to treat DLBCL in Q220; the drug previously showed positive results in Phase III for DLBCL in November 2019. The company expects approval for this NDA in Q221.

## Valuation

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We have increased our valuation to ¥37.2bn (\$338m) from ¥32.7bn (\$300m), although it is up less on a per share basis (¥1,351 from ¥1,342). The increase is largely due to rolling forward our NPVs to 2020, offset by the increase in shares following recent large exercises of share acquisition rights (1.1m shares issued in January 2020, for a total of ¥626m). The effect of the Astellas supply issues on the valuation is primarily due to unrealized sales in 2019 leading to lower than expected cash (or alternately more dilution to compensate), although we have adjusted our 2020 revenue estimates to align with company guidance. However, these negative effects have less of an impact than rolling forward our NPVs given the expected ramp in earnings in 2021 and beyond.

A major upcoming value inflection point for the company is the announcement of results for the ongoing Phase III MDS clinical study of rigosertib from the drug's sponsor, Onconova, planned for H120.

**Exhibit 1: Valuation of Symbio**

Product	Indication	Launch	Peak sales (¥m)	NPV (¥m)	Probability	rNPV (¥m)	rNPV/share (¥)
Treakisym	Low grade NHL/MCL (r/r and first line); CLL	2010	8,600	19,270	100-95%	18,451	670.0
Treakisym (DLCL)	r/r DLCL	2021	9,600	12,975	90%	11,610	421.6
Rigosertib (IV)	r/r HR-MDS	2023	3,800	2,820	50%	1,324	48.1
Rigosertib (oral)	LR-MDS (mono) or first-line HR-MDS (combo)	2025	7,500	4,171	15%	423	15.4
Brincidofovir	vHC	2025	4,200	3,280	30%	855	31.1
Net cash (December 2019 + subsequent exercises)				4,537	100%	4,537	164.7
Valuation				47,052		37,199	1,350.9

Source: Symbio Pharmaceuticals reports, Edison Investment Research

## Financials

We have lowered our revenue forecasts for 2020 to ¥3.4bn (from ¥4.0bn) to reflect the company's predicted rundown in sales to Eisai. However, our forecasts for operational losses are roughly similar to previous estimates (¥5.1bn from ¥5.2bn), as we now forecast marginally lower SG&A costs associated with the commercial build out (¥3.5bn from ¥3.8bn). The company ended 2019 with ¥3.91bn in cash, and subsequently raised ¥626m through its ongoing rights offering. We currently include ¥607m in financing in 2020 (recorded as illustrative debt) primarily to provide a cash buffer (of ¥800m) going into the 2021 commercial launch.

**Exhibit 2: Financial summary**

Accounts: JPN GAAP, Yr end: 31 December; ¥m	2016	2017	2018	2019	2020e	2021e	2022e	2023e	2024e	2025e
Total revenues	2,368	3,444	3,836	2,838	3,433	9,159	11,418	12,705	13,988	15,336
Cost of sales	(1,464)	(2,413)	(2,663)	(1,973)	(2,403)	(1,839)	(2,254)	(1,897)	(2,090)	(2,292)
Gross profit	904	1,031	1,173	865	1,030	7,321	9,164	10,808	11,898	13,044
SG&A (expenses)	(1,364)	(1,961)	(1,996)	(2,725)	(3,525)	(5,602)	(6,460)	(7,610)	(7,517)	(8,087)
R&D costs	(1,667)	(3,018)	(1,833)	(2,442)	(2,603)	(765)	(1,040)	(1,815)	(1,547)	(866)
Other income/(expense) included in adjusted	0	0	0	0	0	0	0	0	0	0
Other income/(expense) excluded from adjusted	0	0	0	0	0	0	0	0	0	0
Reported EBIT	(2,127)	(3,947)	(2,656)	(4,302)	(5,098)	954	1,665	1,383	2,834	4,092
Finance income/ (expense)	5	3	1	0	20	8	24	64	103	172
Other income/(expense) included in adjusted	7	3	(0)	4	0	0	0	0	0	0
Other income/(expense) excluded from adjusted	(195)	(33)	(93)	(75)	0	0	0	0	0	0
Reported PBT	(2,309)	(3,974)	(2,749)	(4,372)	(5,078)	962	1,689	1,447	2,937	4,264
Income tax expense	(4)	(4)	(4)	(4)	396	404	83	(554)	(1,120)	(1,624)
Reported net income	(2,313)	(3,978)	(2,753)	(4,376)	(4,682)	1,365	1,772	893	1,817	2,640
Average number of shares - basic (m)	9.8	12.5	16.6	23.2	27.5	27.5	27.5	27.5	27.5	27.5
Basic EPS	(235.27)	(319.14)	(165.54)	(189.03)	(170.02)	49.59	64.35	32.44	65.98	95.86
Adjusted EBITDA	(2,101)	(3,917)	(2,621)	(4,264)	(5,000)	1,034	1,740	1,461	2,918	4,187
Adjusted EBIT	(2,127)	(3,947)	(2,656)	(4,302)	(5,098)	954	1,665	1,383	2,834	4,092
Adjusted PBT	(2,317)	(3,977)	(2,749)	(4,377)	(5,078)	962	1,689	1,447	2,937	4,264
Adjusted EPS	(236.02)	(319.35)	(165.54)	(189.22)	(170.02)	49.59	64.35	32.44	65.98	95.86
Adjusted diluted EPS	(236.02)	(319.35)	(165.54)	(189.22)	(170.02)	48.84	63.38	31.96	65.00	94.42
<b>Balance sheet</b>										
Property, plant and equipment	75	47	57	75	87	141	204	266	325	380
Goodwill	0	0	0	0	0	0	0	0	0	0
Intangible assets	42	69	71	241	169	121	89	68	53	43
Other non-current assets	77	100	73	70	70	70	70	70	70	70
Total non-current assets	193	216	201	386	327	333	364	404	449	494
Cash and equivalents	5,719	2,947	4,821	3,911	800	1,616	3,156	4,067	5,647	8,061
Inventories	273	363	534	0	270	207	253	213	235	257
Trade and other receivables	487	490	412	549	376	1,004	1,251	1,392	1,533	1,681
Other current assets	205	237	272	427	427	427	427	427	427	427
Total current assets	6,685	4,037	6,038	4,887	1,874	3,254	5,088	6,100	7,842	10,426
Non-current loans and borrowings	450	0	0	0	607	607	607	607	607	607
Trade and other payables	0	0	0	0	0	0	0	0	0	0
Other non-current liabilities	1	1	1	2	2	2	2	2	2	2
Total non-current liabilities	451	1	1	2	609	609	609	609	609	609
Trade and other payables	322	604	726	121	496	517	610	768	738	728
Current loans and borrowings	0	0	0	0	0	0	0	0	0	0
Other current liabilities	620	407	610	751	751	751	751	751	751	751
Total current liabilities	942	1,011	1,336	872	1,247	1,268	1,362	1,520	1,489	1,479
Equity attributable to company	5,485	3,239	4,902	4,400	344	1,710	3,482	4,375	6,192	8,832
Non-controlling interest	0	0	0	0	0	0	0	0	0	0
<b>Cashflow statement</b>										
Profit before tax	(2,309)	(3,974)	(2,749)	(4,372)	(5,078)	962	1,689	1,447	2,937	4,264
Depreciation and Amortisation	26	30	35	38	97	80	75	77	84	95
Share based payments	137	121	148	0	0	0	0	0	0	0
Other adjustments	197	42	61	229	(20)	(8)	(24)	(64)	(103)	(172)
Movements in working capital	(13)	(35)	184	(242)	278	(543)	(201)	57	(192)	(181)
Interest paid / received	6	3	1	1	20	8	24	64	103	172
Income taxes paid	(4)	(4)	(4)	(4)	396	404	83	(554)	(1,120)	(1,624)
Cash from operations (CFO)	(1,960)	(3,817)	(2,325)	(4,351)	(4,307)	903	1,647	1,028	1,709	2,554
Capex	(28)	(57)	(40)	(217)	(37)	(87)	(106)	(118)	(129)	(140)
Acquisitions & disposals net	0	0	0	0	0	0	0	0	0	0
Other investing activities	(16)	(20)	14	0	0	0	0	0	0	0
Cash used in investing activities (CFIA)	(44)	(78)	(26)	(216)	(37)	(87)	(106)	(118)	(129)	(140)
Net proceeds from issue of shares	3,226	1,164	4,272	3,738	626	0	0	0	0	0
Movements in debt	450	0	0	0	607	0	0	0	0	0
Other financing activities	(18)	0	0	2	0	0	0	0	0	0
Cash from financing activities (CFF)	3,658	1,164	4,272	3,740	1,233	0	0	0	0	0
Currency translation differences and other	(196)	(42)	(47)	(83)	0	0	0	0	0	0
Increase/(decrease) in cash and equivalents	1,458	(2,772)	1,874	(911)	(3,111)	816	1,540	910	1,580	2,414
Opening Net (debt) cash	4,261	5,719	2,947	4,821	3,911	193	1,009	2,549	3,459	5,039
Cash and equivalents at end of period	5,719	2,947	4,821	3,911	800	1,616	3,156	4,067	5,647	8,061
Net (debt) cash	5,269	2,947	4,821	3,911	193	1,009	2,549	3,459	5,039	7,453
Movement in net (debt) cash over period	1,008	(2,322)	1,874	(911)	(3,718)	816	1,540	910	1,580	2,414

Source: Symbio Pharmaceuticals reports, Edison Investment Research

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