

SymBio Pharmaceuticals

Supply issues continue

SymBio reported sales of \$25.8m (¥2.838bn) for 2019 and an operating loss of \$39.1 (¥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 \$31.2m (¥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)	PTP* (\$m)	EPADR (\$)	DPADR (\$)	P/E (x)	Gross yield (%)
12/18	34.9	(25.0)	(1.50)	0.00	N/A	N/A
12/19	25.8	(39.8)	(1.72)	0.00	N/A	N/A
12/20e	31.2	(46.2)	(1.55)	0.00	N/A	N/A
12/21e	83.3	8.7	0.45	0.00	11.8	N/A

Source: SymBio reports. Note: Converted at ¥110/US\$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

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 \$28.1m (¥3.092bn) to the final total of \$25.8(¥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 \$338m or \$12.28 per share

We have increased our valuation to \$338m (¥37.2bn) from \$300m (¥32.7bn), although it is down slightly on a per share basis (\$12.28 from ¥11.87). This increase is driven by rolling forward our NPVs, offset at the share level by a higher share count and exchange rate effects. 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.

FY19 earnings update

Pharma & biotech

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Price* **\$5.33**

Market cap **\$147m**

*Underlying ¥ price converted at ¥110/US\$
ADR/Ord conversion ratio 1:1

Net cash (\$m) at Dec. 2019 + subsequent exercises 41.2

ADRs in issue 27.5

ADR code SYMQY

ADR exchange OTC

Underlying exchange Tokyo

Depository BNY

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

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 \$28.1m (¥3.092bn, all values converted at ¥110/\$) from \$40.6m (¥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 \$25.8 (¥2.838bn) for the year, down approximately \$9m (¥1bn) from 2018. Furthermore, operating losses also exceeded expectations at \$39.1 (¥4.301bn, compared to the revised guidance of \$32.6/¥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

The company has guided toward sales of \$30.9 (¥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 \$46.3 (¥5.090bn) for 2020 as it gears up operations for its own internal salesforce. We currently forecast costs of approximately \$9m (¥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

We have increased our valuation to \$338m (¥37.2bn) from \$300m (¥32.7bn), although it is down slightly on a per share basis (\$12.28 from ¥11.87). 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) and exchange rate effects. 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)	NPV/ADR (\$/ADR)
Treakisym	Low grade NHL/MCL (r/r and 1st line); CLL	2010	78	175.2	100-95%	167.7	6.09
Treakisym (DLCL)	r/r DLCL	2021	87	118.0	90%	105.5	3.83
Rigosertib (IV)	r/r HR-MDS	2023	35	25.6	50%	12.0	0.44
Rigosertib (oral)	LR-MDS (mono) or First-line HR-MDS (combo)	2025	68	37.9	15%	3.8	0.14
Brincidofovir	vHC	2025	38	29.8	30%	7.8	0.28
Net Cash (Dec. 2019 + subsequent exercises)				41.2	100%	41.2	1.50
Valuation				427.7		338.2	12.28

Source: Symbio Pharmaceuticals reports, Edison Investment Research

Financials

We have lowered our revenue forecasts for 2020 to \$31.2m (from \$37.1) to reflect the company's predicted rundown in sales to Eisai. However, our forecasts for operational losses are roughly similar to previous estimates (\$46.1m from \$47.7m), as we now forecast marginally lower SG&A costs associated with the commercial build out (\$32.0m from \$34.9m). The company ended 2019 with \$35.6m in cash, and subsequently raised \$5.7m through its ongoing rights offering. We currently include \$5.5m in financing in 2020 (recorded as illustrative debt) primarily to provide a cash buffer (of \$7m) going into the 2021 commercial launch.

Exhibit 2: Financial summary

Accounts: JPN GAAP, year end: 31 December, \$'000s		2016	2017	2018	2019	2020e	2021e
Total revenues		21,528	31,311	34,868	25,798	31,213	83,266
Cost of sales		(13,308)	(21,936)	(24,206)	(17,936)	(21,849)	(16,716)
Gross profit		8,220	9,375	10,662	7,861	9,364	66,550
SG&A (expenses)		(12,401)	(17,823)	(18,147)	(24,771)	(32,044)	(50,927)
R&D costs		(15,155)	(27,435)	(16,661)	(22,196)	(23,664)	(6,955)
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		(19,337)	(35,882)	(24,146)	(39,106)	(46,343)	8,669
Finance income/ (expense)		50	28	6	2	178	73
Other income/(expense) included in adjusted		67	25	(0)	38	0	0
Other income/(expense) excluded from adjusted		(1,775)	(298)	(848)	(684)	0	0
Reported PBT		(20,995)	(36,128)	(24,988)	(39,750)	(46,165)	8,742
Income tax expense		(35)	(35)	(35)	(35)	3,602	3,672
Reported net income		(21,029)	(36,162)	(25,023)	(39,784)	(42,563)	12,414
Average number of ADRs - basic (m)		9.8	12.5	16.6	23.2	27.5	27.5
Basic Earnings per ADR	USD	(2.14)	(2.90)	(1.50)	(1.72)	(1.55)	0.45
Adjusted EBITDA		(19,104)	(35,614)	(23,831)	(3,876)	(4,546)	940
Adjusted EBIT		(19,337)	(35,882)	(24,146)	(3,911)	(4,634)	867
Adjusted PBT		(21,062)	(36,153)	(24,988)	(3,979)	(4,617)	874
Adjusted Earnings per ADR	USD	(2.15)	(2.90)	(1.50)	(1.72)	(1.55)	0.45
Adjusted diluted Earnings per ADR	USD	(2.15)	(2.90)	(1.50)	(1.72)	(1.55)	0.44
Balance sheet							
Property, plant and equipment		678	426	518	686	791	1,285
Goodwill		0	0	0	0	0	0
Intangible assets		382	626	649	2,187	1,537	1,102
Other non-current assets		699	910	660	640	640	640
Total non-current assets		1,758	1,961	1,827	3,513	2,968	3,027
Cash and equivalents		51,994	26,791	43,831	35,553	7,273	14,691
Inventories		2,479	3,296	4,853	0	2,454	1,878
Trade and other receivables		4,432	4,453	3,743	4,993	3,421	9,125
Other current assets		1,868	2,155	2,469	3,885	3,885	3,885
Total current assets		60,773	36,696	54,895	44,432	17,033	29,579
Non-current loans and borrowings		4,091	0	0	0	5,522	5,522
Trade and other payables		0	0	0	0	0	0
Other non-current liabilities		13	13	12	15	15	15
Total non-current liabilities		4,104	13	12	15	5,537	5,537
Trade and other payables		2,926	5,494	6,601	1,099	4,506	4,697
Current loans and borrowings		0	0	0	0	0	0
Other current liabilities		5,639	3,701	5,548	6,830	6,830	6,830
Total current liabilities		8,565	9,195	12,149	7,929	11,336	11,527
Equity attributable to company		49,862	29,449	44,562	40,001	3,128	15,542
Non-controlling interest		0	0	0	0	0	0
Cashflow statement							
Profit before tax		(20,995)	(36,128)	(24,988)	(39,750)	(46,165)	8,742
Depreciation and Amortisation		233	269	315	346	886	731
Share based payments		1,246	1,102	1,342	0	0	0
Other adjustments		1,791	381	552	2,081	(178)	(73)
Movements in working capital		(114)	(315)	1,677	(2,201)	2,525	(4,937)
Net cash from operating activities (pre-tax)		(17,839)	(34,692)	(21,102)	(39,523)	(42,933)	4,464
Interest paid / received		54	28	5	5	178	73
Income taxes paid		(35)	(35)	(35)	(35)	3,602	3,672
Cash from operations (CFO)		(17,819)	(34,698)	(21,132)	(39,552)	(39,153)	8,208
Capex		(254)	(518)	(362)	(1,968)	(341)	(790)
Acquisitions & disposals net		0	0	0	0	0	0
Other investing activities		(145)	(186)	124	0	0	0
Cash used in investing activities (CFIA)		(399)	(705)	(238)	(1,968)	(341)	(790)
Net proceeds from issue of shares		29,329	10,584	38,837	33,982	5,691	0
Movements in debt		4,091	0	0	0	5,522	0
Other financing activities		(163)	0	0	19	0	0
Cash from financing activities (CFF)		33,256	10,584	38,837	34,000	11,213	0
Currency translation differences and other		(1,785)	(384)	(428)	(758)	0	0
Increase/(decrease) in cash and equivalents		13,254	(25,202)	17,039	(8,278)	(28,280)	7,418
Cash and equivalents at end of period		51,994	26,791	43,831	35,553	7,273	14,691
Net (debt) cash		47,903	26,791	43,831	35,553	1,750	9,169
Movement in net (debt) cash over period		9,163	(21,112)	17,039	(8,278)	(33,803)	7,418

Source: SymBio Pharmaceuticals reports, Edison Investment Research

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