

SymBio Pharmaceuticals

Licence agreement for IONSYS terminated

The licence agreement between SymBio and The Medicines Company (MDCO) for the exclusive rights to develop the IONSYS (SyB P-1501) pain patch in Japan has terminated effective 30 November. SymBio is seeking damages of at least US\$82m (¥9bn) arising from MDCO's repudiation of the licence agreement. The termination is in line with our expectations after MDCO voluntarily withdrew IONSYS from sale in the US market in June; any compensation payments received from MDCO would represent upside to our forecasts and valuation. Our forecasts and valuation (¥19.7bn) are unchanged, as we have **already** removed all future costs and revenues for SyB P-1501 from our financial model.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/15	1,933	(2,630)	(81.33)	0.0	N/A	N/A
12/16	2,368	(2,317)	(59.00)	0.0	N/A	N/A
12/17e	3,599	(4,000)	(82.39)	0.0	N/A	N/A
12/18e	4,248	(1,999)	(39.54)	0.0	N/A	N/A

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

Suspended SyB P-1501 Phase III to be terminated

SymBio in-licensed IONSYS (SyB P-1501) for the treatment of post-operative pain from MDCO in October 2015, and initiated a Phase III trial of SyB P-1501 in Japan in June 2016. SymBio suspended enrolment in the trial in April. In conjunction with the termination of the licence agreement, SymBio will terminate the development of SyB P-1501, a process that it expects to complete by 31 March 2018.

Rigosertib Phase III interim analysis expected Q417

Partner Onconova reported in **November** that it expects the interim analysis of the INSPIRE Phase III trial of rigosertib to be performed in Q417 or early 2018. The study is investigating iv rigosertib as a second-line therapy in 225 patients with high-risk myelodysplastic syndrome. The trial is expected to fully enrol in H118 and report top-line data in 2018. SymBio holds Japan and Korea rights and has contributed 33 of ~170 trial sites that were active as at 31 October 2017.

Strong Treakisym sales growth continues

Growth of Treakisym sales continues to be strong, driven by the approval of two new indications in 2016. In-market sales grew by 53%y-o-y in the first nine months of 2017, and net sales to partner Eisai grew by 68%. SymBio reported net sales growth of 72% to ¥2,416m in Q317. Despite the sales growth, the net operating loss for Q317 has increased to ¥3.5bn from ¥1.9bn in Q316, due largely to higher spending on clinical trials and costs associated with in-licensing bendamustine HCl RTD and RI injection products. SymBio has maintained its 2017 financial guidance, which was revised upwards in September.

Valuation: rNPV of ¥19.7bn (\$174m) or ¥410/share

Our risk-adjusted valuation is unchanged at ¥19,672m (\$174m) or ¥410/share. We estimate that net cash of ¥4.6bn at 30 September should be sufficient to fund operations into H218, by which point the Phase III clinical trial for rigosertib iv should be complete. We model ¥620m of indicative debt in FY18.

Corporate update

Pharma & biotech

14 December 2017

Price **¥219**

Market cap **¥10,731m**

¥113/\$

Net cash (¥m) at end September 2017 4,591

Shares in issue 49.0m

Free float 76%

Code 4582

Primary exchange Japan

Secondary exchange OTC US

Share price performance



% 1m 3m 12m

Abs (2.7) (4.8) (14.8)

Rel (local) (4.1) (13.9) (27.5)

52-week high/low ¥311.0 ¥200.0

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

Rigosertib iv Phase III interim analysis Q417

In-licensing activities TBD

Treakisym sales update Q118

Analysts

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SymBio Pharmaceuticals is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

Accounts: JPN GAAP; year end: 31 December; ¥m	2013	2014	2015	2016	2017e	2018e
PROFIT & LOSS						
Total revenues	1,532	1,955	1,933	2,368	3,599	4,248
Cost of sales	(1,214)	(1,428)	(1,350)	(1,464)	(2,534)	(2,991)
Gross profit	318	527	583	904	1,065	1,257
SG&A (expenses)	(946)	(1,056)	(1,100)	(1,364)	(1,850)	(1,924)
R&D costs	(1,053)	(774)	(2,035)	(1,667)	(3,145)	(1,350)
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	(1,681)	(1,303)	(2,552)	(2,127)	(3,930)	(2,017)
Finance income/ (expense)	10	25	16	5	(70)	17
Other income/(expense) included in adjusted	0	(2)	2	7	0	0
Other income/(expense) excluded from adjusted	69	168	(95)	(195)	0	0
Reported PBT	(1,601)	(1,112)	(2,628)	(2,309)	(4,000)	(1,999)
Income tax expense	(4)	(4)	(4)	(4)	(4)	(4)
Reported net income	(1,605)	(1,116)	(2,632)	(2,313)	(4,003)	(2,003)
Average number of shares - basic (m)	23.2	30.8	32.4	39.3	48.6	50.7
Basic EPS (¥)	(69.29)	(36.26)	(81.26)	(58.82)	(82.39)	(39.54)
Adjusted EBITDA	(1,672)	(1,291)	(2,527)	(2,101)	(3,903)	(1,987)
Adjusted EBIT	(1,681)	(1,303)	(2,552)	(2,127)	(3,930)	(2,017)
Adjusted PBT	(1,601)	(1,110)	(2,630)	(2,317)	(4,000)	(1,999)
Adjusted EPS (¥)	(69.29)	(36.20)	(81.33)	(59.00)	(82.39)	(39.54)
Adjusted diluted EPS (¥)	(69.29)	(36.20)	(81.33)	(59.00)	(82.39)	(39.54)
BALANCE SHEET						
Property, plant and equipment	9	49	53	75	95	117
Goodwill	0	0	0	0	0	0
Intangible assets	8	66	52	42	35	29
Other non-current assets	37	49	53	77	77	77
Total non-current assets	53	164	158	193	206	223
Cash and equivalents	5,294	5,092	4,261	5,719	1,725	400
Inventories	125	245	133	273	347	328
Trade and other receivables	0	273	301	487	641	582
Other current assets	2,215	1,681	132	205	205	205
Total current assets	7,634	7,290	4,827	6,685	2,919	1,515
Non-current loans and borrowings	0	0	0	450	0	471
Trade and other payables	0	0	0	0	0	0
Other non-current liabilities	3	2	2	1	1	1
Total non-current liabilities	3	2	2	451	1	472
Trade and other payables	0	306	320	322	408	267
Current loans and borrowings	0	0	0	0	0	150
Other current liabilities	251	182	231	620	620	620
Total current liabilities	251	488	551	942	1,029	1,037
Equity attributable to company	7,433	6,964	4,432	5,485	2,095	229
Non-controlling interest	0	0	0	0	0	0
CASH FLOW STATEMENT						
Profit before tax	(1,601)	(1,112)	(2,628)	(2,309)	(4,000)	(1,999)
Depreciation and Amortisation	8	13	24	26	27	30
Share based payments	67	95	103	137	137	137
Other adjustments	(27)	(207)	26	197	70	(17)
Movements in working capital	(127)	(78)	190	(13)	(141)	(63)
Interest paid / received	7	27	18	6	(70)	17
Income taxes paid	(4)	(4)	(4)	(4)	(4)	(4)
Cash from operations (CFO)	(1,677)	(1,266)	(2,272)	(1,960)	(3,981)	(1,899)
Capex	0	(109)	(24)	(28)	(40)	(47)
Acquisitions & disposals net	0	0	0	0	0	0
Other investing activities	(1,332)	423	1,513	(16)	0	0
Cash used in investing activities (CFIA)	(1,332)	314	1,489	(44)	(40)	(47)
Net proceeds from issue of shares	4,057	544	(2)	3,226	477	0
Movements in debt	0	0	0	450	(450)	621
Other financing activities	(1)	(1)	(1)	(18)	0	0
Cash from financing activities (CFF)	4,057	544	(3)	3,658	27	621
Currency translation differences and other	7	206	(45)	(196)	0	0
Increase/(decrease) in cash and equivalents	1,054	(202)	(831)	1,458	(3,994)	(1,325)
Cash and equivalents at end of period	5,294	5,092	4,261	5,719	1,725	400
Net (debt) cash	5,294	5,092	4,261	5,269	1,725	(221)
Movement in net (debt) cash over period	1,054	(202)	(831)	1,008	(3,544)	(1,946)

Source: Edison Investment Research, SymBio Pharmaceuticals accounts

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