

ADR research

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 \$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 (\$174m) are unchanged, as we have already removed all future costs and revenues for SyB P-1501 from our financial model.

Year end	Revenue (\$m)	PTP (\$m)	EPADR (\$)	DPADR (\$)	P/E (x)	Gross yield (%)
12/15	17.1	(23.3)	(0.72)	0.0	N/A	N/A
12/16	21.0	(20.5)	(0.52)	0.0	N/A	N/A
12/17e	31.9	(35.4)	(0.73)	0.0	N/A	N/A
12/18e	37.6	(17.7)	(0.35)	0.0	N/A	N/A

Note: Converted at ¥113/US\$.

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 <u>November</u> 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 enroll 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 \$21.4m in Q317. Despite the sales growth, the net operating loss for Q317 has increased to \$31.0m from \$16.8m 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 \$174m or \$3.6/ADR

Our risk-adjusted valuation is unchanged at \$174m or \$3.6/ADR. We estimate that net cash of \$40.7m 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 \$5.5m of indicative debt in FY18.

Corporate update

Pharma & biotech

15 December 2017

Price* US\$1.94 Market cap US\$95m

*Underlying ¥ price converted at ¥113/US\$ ADR/Ord conversion ratio 1:1

Net cash (\$m) at end September 2017 41

ADRs in issue 49.0m

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.

Next events

Rigosertib iv Phase III interim analysis Q417
In-licensing activities TBD
Treakisym sales update Q118

Analysts

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Edison profile page

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Accounts: JPN GAAP, year-end: December, \$'000s	2013	2014	2015	2016	2017e	2018
PROFIT & LOSS						
Total revenues	13,558	17,301	17,108	20,957	31,850	37,59
Cost of sales	(10,744)	(12,641)	(11,949)	(12,955)	(22,423)	(26,465
Gross profit SG&A (expenses)	2,814 (8,369)	4,661 (9,343)	5,159 (9,734)	8,002 (12,072)	9,428 (16,372)	11,12 (17,027
R&D costs	(9,317)	(6,850)	(18,006)	(12,072)	(27,832)	(11,027
Other income/(expense) included in adjusted	(9,517)	(0,030)	(10,000)	(14,733)	0	(11,347
Other income/(expense) excluded from adjusted	0	0	0	0	0	
Reported EBIT	(14,872)	(11,533)	(22,581)	(18,823)	(34,776)	(17,846
Finance income/ (expense)	89	219	144	48	(619)	15
Other income/(expense) included in adjusted	0	(16)	19	65	0	
Other income/(expense) excluded from adjusted	612	1,488	(841)	(1,728)	0	
Reported PBT	(14,172)	(9,841)	(23,259)	(20,437)	(35,395)	(17,69
ncome tax expense	(34)	(34)	(34)	(34)	(34)	(3-
Reported net income	(14,206)	(9,875)	(23,293)	(20,471)	(35,429)	(17,72
Average number of ADRs - basic (m)	23.2	30.8	32.4	39.3	48.6	50
Basic Earnings per ADR (US\$)	(0.61)	(0.32)	(0.72)	(0.52)	(0.73)	(0.3
Adjusted EBITDA	(14,800)	(11,421)	(22,367)	(18,596)	(34,537)	(17,58
Adjusted EBIT	(14,872)	(11,533)	(22,581)	(18,823)	(34,776)	(17,84
Adjusted PBT	(14,172)	(9,826)	(23,278)	(20,503)	(35,395)	(17,69
Adjusted Earnings per ADR (US\$)	(0.61)	(0.32)	(0.72)	(0.52)	(0.73)	(0.3
Adjusted diluted Earnings per ADR (US\$)	(0.61)	(0.32)	(0.72)	(0.52)	(0.73)	(0.3
BALANCE SHEET	70	40.4	400	000	000	4.00
Property, plant and equipment Goodwill		434	469 0	660	839 0	1,03
Intangible assets	69	585	460	372	307	26
Other non-current assets	324	430	465	680	680	68
Total non-current assets	469	1,449	1,394	1,711	1,826	1,97
Cash and equivalents	46,851	45,063	37,712	50,613	15,269	3,54
Inventories	1,107	2,164	1,177	2,413	3,072	2,90
Trade and other receivables	0	2,413	2,661	4,314	5,672	5,15
Other current assets	19,600	14,874	1,164	1,818	1,818	1,81
Total current assets	67,557	64,514	42,715	59,159	25,831	13,40
Non-current loans and borrowings	0	0	0	3,982	0	4,16
Trade and other payables	0	0	0	0	0	
Other non-current liabilities	27	20	14	12 3,995	12	4.4-
Total non-current liabilities Trade and other payables	27 0	20 2,708	2,831	2,848	12 3,614	4,17 2,36
Current loans and borrowings	0	2,700	2,031	2,040	3,014	1,32
Other current liabilities	2,221	1,610	2,045	5,489	5,489	5,48
Total current liabilities	2,221	4,318	4,876	8,337	9,103	9,17
Equity attributable to company	65,779	61,625	39,220	48,539	18,543	2,02
Non-controlling interest	0	0	0	0	0	
CASH FLOW STATEMENT						
Profit before tax	(14,172)	(9,841)	(23,259)	(20,437)	(35,395)	(17,69
Depreciation and Amortization	72	112	215	227	239	26
Share based payments	589	838	911	1,212	1,212	1,2
Other adjustments	(236)	(1,830)	231	1,744	619	(15
Movements in working capital	(1,123)	(688)	1,678	(111)	(1,251)	(56
Net cash from operating activities (pre-tax)	(14,869)	(11,409)	(20,226)	(17,365)	(34,575)	(16,92
nterest paid / received	59	238	156	53	(619)	15
Income taxes paid Cash from operations (CFO)	(34)	(34)	(34)	(34)	(34)	(3
. ,	,	(11,205)	(20,103)	(17,346)	(35,228)	(16,80
Capex Acquisitions & disposals net	0	(961)	(210)	(247) 0	(354)	(41
Other investing activities	(11,790)	3,743	13,389	(141)	0	
Cash used in investing activities (CFIA)	(11,790)	2,782	13,178	(388)	(354)	(41
Net proceeds from issue of shares	35,907	4,818	(16)	28,550	4,220	[31
Movements in debt	0	0	0	3,982	(3,982)	5,4
Other financing activities	(7)	(7)	(7)	(159)	0	
Cash from financing activities (CFF)	35,900	4,812	(23)	32,373	238	5,4
Currency translation differences and other	62	1,823	(402)	(1,738)	0	
ncrease/(decrease) in cash and equivalents	9,328	(1,788)	(7,351)	12,902	(35,345)	(11,72
Cash and equivalents at end of period	46,851	45,063	37,712	50,613	15,269	3,5
Net (debt) cash	46,851	45,063	37,712	46,631	15,269	(1,95
Movement in net (debt) cash over period	9,328	(1,788)	(7,351)	8,919	(31,362)	(17,22

Source: Edison Investment Research and SymBio Pharmaceuticals accounts. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of ¥113 to \$1. SymBio reports statutory accounts in Japanese yen. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.



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