



31 March 2009

Biota Holdings Limited (BTA)

Speculative Buy

Daiichi Sankyo Lines up CS-8958 (LANI) in Japan

\$0.60

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Key Points

Daiichi Sankyo has exercised its co-ownership right to commercialise CS-8958 (LANI) in Japan.

Enrolment of the pivotal Phase 3 clinical trial in Japan and elsewhere in Asia has also been completed.

Contract to manufacture and market CS-8958 signed, pending Phase 3 trial results and marketing approval.

Biota entitled to an undisclosed royalty on sales and fixed sum payments on sales milestones.

Summary

Market Capitalisation (M)	\$104.8
Share Price	\$0.60
Shares on Issue (M)	174.6
52 Week High	\$1.25
52 Week Low	\$0.29
Valuation Per Share (fully diluted)	\$1.55
Cash (M) as at 31/12/08	\$55.4

Our View

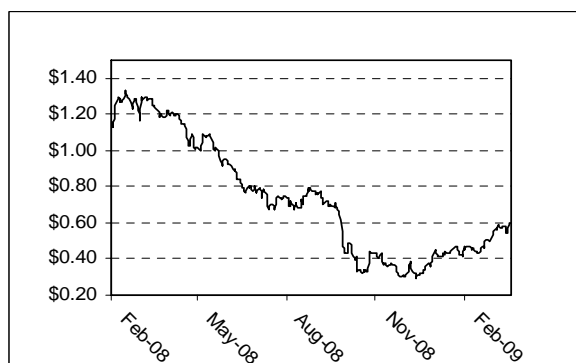
- The exercise of rights in Japan by Daiichi was ahead of our expectations, which we believed would be tied to the Phase 3 study results mid-year. However, in our view, the exercise is a positive sign on the likely success of the Daiichi trial. Based on the success of the Daiichi Phase 2b study, and likely study benefits to LANI from circulating Tamiflu[®] resistant virus (H1N1) we remain confident of Phase 3 success. While the present Phase 3 study represents a head to head treatment study versus Tamiflu[®], we note the intention of Daiichi to seek a prophylaxis (preventative) Phase 3 study during the next influenza season in late CY09. Daiichi guidance at a recent briefing indicated a regulatory filing on treatment use of LANI will be made prior to end March 2010. This bodes well for Biota, with a stake in potentially two out of three neuraminidase inhibitor drugs on the market in Japan and in light of Japanese/Korean data and US CDC data indicating seasonal H1N1 influenza resistance at 99.1% with Tamiflu[®] and 0.0% for Relenza[™]. The active form of LANI is chemically very similar to Relenza[™].
- Based on a dosing advantage (1x per week, versus 2x per day for marketed influenza drugs), and an overall lack of resistance to date, we see LANI as an ideal seasonal drug in Japan, traditionally the world's largest consumer of anti-influenza drugs. On this basis, we value the Japanese seasonal market, net to Biota, on a risk-adjusted basis, at \$16.9m or ~\$0.10 per share. We anticipate regulatory approval beginning FY11 will provide Biota with estimated unadjusted first year royalties of A\$1.4m at an estimated net royalty rate of 2.5%. Japanese approval in our view is likely to drive ROW licensing initiatives, where we have factored in a substantially higher royalty component (17.5%) with upfront/milestone payments we believe could be conservatively valued at US\$100m, given the attractiveness of LANI for pandemic stockpiling and the current problems with Tamiflu[®]. However, given ROW licensees may require an additional two influenza seasons to undertake clinical trials sufficient for western regulatory approvals, we have pushed back market approval expectations into FY13, which has affected our stock valuation by negative 10 cps.
- We consider the next 2Q to be significant for Biota, principally because of major clinical milestones (LANI Phase 3, HRV Phase 2a due mid-year) and GSK Relenza[™] quarterly sales data (April, July). We have made no material changes to our FY09 and FY10 estimates, though we note material upside to our FY09 Relenza[™] royalty estimates (\$17.5m) is possible, dependent on revenue recognition from the recent UK govt order. We maintain our Speculative Buy recommendation and revised valuation of \$1.55.

Key Financials (A\$'000)

Year End	FY08 Actual	FY09 Est.	FY10 Est.
Relenza Royalties	20,544	17,563	27,801
Partnering Income*	5,871	4,069	23,410
Total Revenue	44,989	34,878	54,889
Total Op. Expenses	(41,397)	(22,368)	(12,919)
R&D Expenses	(10,287)	(13,171)	(11,274)
EBITDA	(9,897)	10,120	28,727
Normalised NPAT	10,735	(2,464)	27,551
Adj. NPAT	(6,489)	9,215	27,551
Adj. EPS (c)	(3.5)	5.3	15.8
Adj. PE Ratio (x)	n/a	11.4	3.8

* Upfront/Milestones only (ex-R&D income)

Share Price Graph (A\$)



Biota Holdings Limited - Summary of Forecasts

BTA \$0.60

PROFIT & LOSS SUMMARY (A\$'000)				
	FY07A	FY08A	FY09E	FY10E
Relenza Royalties	39,789	20,544	17,563	27,801
Partnering (Licence) Income	5,726	5,871	4,069	23,410
Research income (inc Grants)	8,740	15,042	11,171	1,624
Total Revenue	57,300	44,989	34,878	54,889
<i>Growth (pcp)</i>	282.8%	-21.5%	-22.5%	57.4%
Net Gain on GSK Settlement	0	0	12,736	0
Net Operating Revenue	27,576	3,592	25,246	41,970
R&D Expenses	(8,198)	(10,287)	(13,171)	(11,274)
EBITDA	16,871	(9,897)	10,120	28,727
Depreciation	(1,228)	(933)	(1,207)	(1,254)
Amortisation	(317)	(1,681)	(1,653)	(1,890)
EBIT	15,326	(12,511)	7,260	25,583
Net Interest	2,507	3,202	1,955	1,969
Pre-Tax Profit	17,833	(9,309)	9,215	27,551
Tax Expense	2,347	2,820	0	0
Minorities	0	0	0	0
NPAT Normalised *	21,424	10,735	(2,464)	27,551
NPAT Adj.	20,180	(6,489)	9,215	27,551
<i>Growth (pcp)</i>	n/a	n/a	n/a	199.0%
Net Adjustments	0	0	0	0
Reported Profit	20,180	(6,489)	9,215	27,551

PER SHARE DATA				
Period	FY07A	FY08A	FY09E	FY10E
Adjusted EPS (c)	11.2	(3.5)	5.3	15.8
<i>Growth (pcp)</i>	n/a	n/a	n/a	199.0%
Reported EPS (c)	11.2	(3.5)	5.3	15.8
<i>Growth (pcp)</i>	n/a	n/a	n/a	199.0%
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%
Gross CF per Share (c)	6.9	2.4	10.0	40.7
NTA per share (c)	32.2	28.0	67.9	110.4

VALUATION MULTIPLES				
Period	FY07A	FY08A	FY09E	FY10E
Adjusted PE Ratio (x)	5.4	n/a	11.4	3.8
PE Ratio (x)	5.4	n/a	11.4	3.8
Dividend Yield (%)	n/a	n/a	0.0%	0.0%
EV/EBITDA (x)	1.2	(2.2)	2.1	(0.2)
EV/EBIT (x)	1.3	(1.8)	3.0	(0.3)

CAPITAL RAISING ASSUMPTIONS				
Period	FY07A	FY08A	FY09E	FY10E
Shares Issued (m)	0.0	0.0	0.0	0.0
Issue Price (A\$)	0.0	0.0	0.0	0.0
Cash Raised (A\$m)	0.0	0.0	0.0	0.0

KEY RATIOS				
Period	FY07A	FY08A	FY09E	FY10E
EBITD/Sales Margin %	29.4%	-22.0%	29.0%	52.3%
EBIT/Sales Margin %	26.7%	-27.8%	20.8%	46.6%
Current ratio (x)	5.3	3.4	4.8	14.6
Net Debt : Equity (%)	-86.9%	-94.8%	-88.3%	-79.1%
ROE (%)	34.1%	-9.6%	14.0%	30.5%
Dividend Payout Ratio (%)	n/a	n/a	0.0%	0.0%

*Excluding litigation expense and settlement, tax effected at 30%

BALANCE SHEET SUMMARY (A\$'000)				
Period	FY07A	FY08A	FY09E	FY10E
Cash	62,156	60,164	60,577	88,599
Receivables	9,350	4,270	5,232	8,233
Inventories	0	0	0	0
Other	0	0	0	0
Total Current Assets	71,506	64,434	65,809	96,832
Investments	0	0	0	0
Inventories	0	0	0	0
Property Plant & Equip	5,152	7,543	7,836	8,082
Intangibles	13,447	12,113	10,460	8,570
Deferred Tax Assets	2,349	5,168	5,168	5,168
Other	0	0	0	0
Total Non-Current Assets	20,948	24,824	23,464	21,820
TOTAL ASSETS	92,454	89,258	89,273	118,652
Accounts Payable	6,004	12,023	9,417	5,489
Borrowings	0	0	0	0
Provisions	1,097	1,122	1,122	1,122
Other (Inc Def Rev)	6,457	6,059	3,125	0
Total Current Liab	13,558	19,204	13,664	6,611
Borrowings	0	132	0	0
Provisions	6,339	6,622	6,991	0
Other (Inc Def Rev)	1,022	0	0	0
Total Non-Current Liab	7,361	6,754	6,991	0
TOTAL LIABILITIES	20,919	25,958	20,655	6,611
TOTAL EQUITY	71,535	63,300	68,617	112,041

CASH FLOW SUMMARY (A\$'000)				
Period	FY07A	FY08A	FY09E	FY10E
EBIT (excl Abs/Extr)	15,326	(12,511)	7,260	25,583
Add: Depreciation	1,228	933	1,207	1,254
Amortisation	317	1,681	1,653	1,890
Change in Pay.	1,970	6,019	(2,606)	(3,928)
Less: Tax paid	2,347	2,820	0	0
Net Interest	2,507	3,202	1,955	1,969
Change in Rec.	(3,486)	5,080	(962)	(3,002)
Change in Prov.	(6,820)	(308)	(369)	6,991
Change in Def Tax Assets	(2,349)	(2,819)	0	0
Change in Inv.	0	0	0	0
Change in Def. Rev.	1,468	(1,420)	(2,934)	(3,125)
Gross Cashflows	12,508	4,358	6,858	29,522
Capex	(893)	(3,785)	(1,500)	(1,500)
Free Cashflows	11,615	573	5,358	28,022
Re-Purchase of Shares**	0	(3,020)	(4,945)	0
Net Cash Flow	11,615	(2,447)	413	28,022

** Biota announced an on market buy-back of up to 5% (9.17m shares) of its issued capital commencing 10 mar 08

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Date Prepared: March 2009

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