



Biota Holdings Limited (BTA)

Speculative Buy

Major EV De-Rating Highlights Frustration; LANI moves to Phase 3

\$0.40

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Key Points

LANI (CS-8958) has commenced a pivotal Phase 3 adult influenza trial and a Phase 2/3 paediatric trial, undertaken by Daiichi Sankyo.

Biota has seen its Enterprise Value (EV) decline to approximately \$10.4m from \$198m 12 months previous.

Recent AGM highlighted frustration at the current board over GSK settlement in light of major settlement offer, circa \$80m, in CY06 (inc. future royalties).

Unaudited 1Q09 PBT of \$10.7m, driven by net gain on GSK settlement of \$12.5m, in line with previous guidance.

Current cash backing of \$0.34 per share.

Guidance of one further licence deal (HRV or LANI) during FY09.

Summary

Market Capitalisation (M)	\$69.8
Share Price	\$0.40
Shares on Issue (M)	174.6
52 Week High	\$1.40
52 Week Low	\$0.295
Valuation Per Share (fully diluted)	\$1.74
Cash (M) as at 31/10/08	\$59.3

Key Financials (A\$'000)

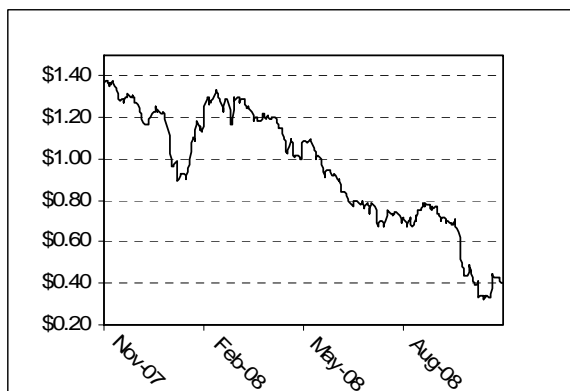
Year End	FY08 Actual	FY09 Est.	FY10 Est.
Relenza Royalties	20,544	22,885	10,198
Partnering Income*	5,871	4,496	22,933
Total Revenue	44,989	40,316	40,253
Total Op. Expenses	(41,397)	(18,283)	(15,900)
R&D Expenses	(10,287)	(15,060)	(11,333)
EBITDA	(9,897)	16,315	9,740
Normalised NPAT	10,735	2,736	10,727
Adj. NPAT	(6,489)	16,409	10,727
Adj. EPS (c)	(3.5)	9.3	6.1
Reported EPS (c)	(3.5)	9.3	6.1
Adj. PE Ratio (x)	n/a	4.3	6.6

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

Our View

- The CS-8958 trial design is broadly in-line with the recent Phase 2 study, which relied on a non-inferiority response of influenza symptoms versus Tamiflu®. In the Phase 2 study, CS-8958 was equivalent in effect at 1x dose per week versus 75mg twice daily for five days of Tamiflu®. Completion of these 2x Phase 2/3 trials is largely dependent on the severity or otherwise of the Northern Hemisphere influenza season. Moreover, Daiichi Sankyo will be directly competing for patients with Shionogi's peramivir i.v Phase 3 trial. The dosing and cohort of patients for the Phase 3 studies remains undisclosed by Daiichi Sankyo.
- Biota has been given a very strong signal by shareholders at the recent AGM that the current board needs restructuring, principally in response to new information presented at the AGM address. Three offers of settlement by GSK were rejected up until 4Q CY06, after which time legal costs accelerated significantly, resulting in further legal costs of \$41.3m including costs upon settlement. Prior to that date, the Company had incurred legal costs of approximately \$7.7m. We consider this to be one of the key reasons for the precipitous sell down in the stock, coupled with the completion of the share buy-back and general market conditions.
- While the stock has rebounded off its lows of \$0.295, representing a 13.2% discount to cash backing, we do not see confidence returning to the stock until board refreshment occurs. The lack of transparency with respect to GSK's strategy for Relenza™ may also be of concern; however, we still remain confident of a major order (Japan or the UK, or both) during FY09. Our model for Relenza™ reflects this observation, suggesting at-risk Relenza™ royalties of \$14.7m exist, which could result in our FY09E NPAT revision to just \$2.7m (versus \$16.4m). However, given the aggressive decline in market value and significant discount to our risk-adjusted valuation of \$1.72 (previous \$1.80), we maintain our Speculative Buy recommendation.

Share Price Graph (A\$)



LANI (CS-8958) Multiple Phase 3 Trials Commence

Daiichi investing into 2x Phase 2/3 trials for CS-8958.

Daiichi Sankyo's Phase 3 program for CS-8958 is broader than we had anticipated, with the Company aiming for two simultaneous clinical trials, in adults and children under 9 years of age (Phase 3 and Phase 2/3, respectively). Daiichi has not disclosed the dosing regime for CS-8958 in both clinical trials, though we note the dosing regime for the paediatric study is likely to be significantly lower, in line with that of Tamiflu®. In our view, such studies are seeking to simultaneously broaden the envisaged label claim for CS-8958 in the Japanese market.

We still expect filing for approval at the end of CY09.

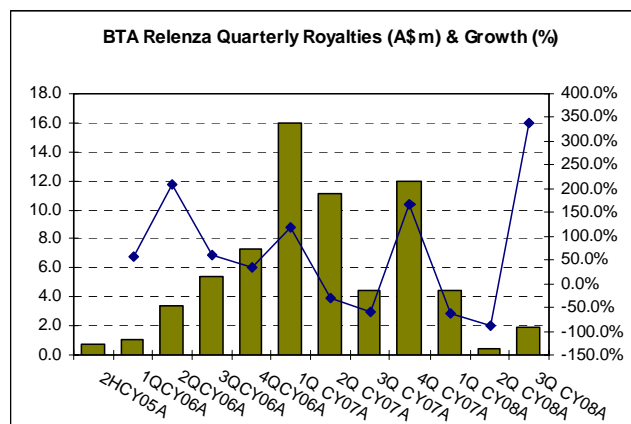
CS-8958 has been designated as a priority item by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) - providing priority review on matters including clinical trial planning. We note that Daiichi provided no guidance on likely filing dates for CS-8958 in Japan. However, previous guidance indicated an intention to file at the end of CY09. Provided one or both of the current Daiichi trials is fully recruited this influenza season, we see no reason why this historic guidance cannot be met.

We note the National Institutes of Health (NIH) has funded Biota's western clinical trials, and future slated trials with US\$5.6m. Daiichi Sankyo's first Japanese Phase 2 trial (on several hundred patients) for CS-8958 (LANI) showed that a 1x per week dose of CS-8958 (LANI) was statistically indistinguishable from a cohort consisting of 75mg of Tamiflu® administered 2x daily for 5 days. Therefore, CS-8958 was equivalent in effectiveness to Tamiflu® in treating influenza symptoms; a major efficacy result given dosing.

Relenza™ – 1Q09 Royalties of \$1.9m

1Q09 Relenza™ royalties of \$1.9m.

Biota has booked \$1.9m in royalties on 1Q09 Relenza™ sales of £12m (A\$27.1m). 1Q09 US, European and International sales of £5m, £0m and £7m, respectively were recorded (see across). In the first nine months of CY08, GSK has recorded Relenza™ sales of US\$86m. The result was largely unsurprising given we had seen no tangible orders from the UK and Japan particularly. Our FY09E Relenza™ royalties of \$22.9m are predicated on at least one major stockpiling order. We have previously estimated that Japan and the UK are the most logical jurisdictions.



Source: Biota

Japanese update – 59.8 billion Yen towards pandemic influenza commencing April 2009.

The Japanese Health Ministry has allocated 59.8 billion Yen for the fiscal 2009 budget to fight pandemic influenza, commencing April 1st. We note the intention of the Japanese is to double existing stockpiles (28m Tamiflu®, 1.4m Relenza™), where we expect a 25% overall Relenza™ component, implying potential royalties of A\$25m to Biota. Similarly, if the UK government goes the same way with its intention to double its 14.6m Tamiflu® stockpile, Biota could expect royalties of \$12.8m. We note the UK government is still at the tender stage for the stockpile and no guidance has been forthcoming as to when likely orders will eventuate.

New Phase 2 Data on Peramivir

I.v. peramivir effective in Japanese study of seasonal influenza.

Shionogi recently reported Phase 2 data from a seasonal influenza study of peramivir, a neuraminidase inhibitor licensed from Biocryst Pharmaceuticals (NASDAQ:BCRX). The Shionogi study found that a single intravenous (i.v) dose of peramivir was effective and well tolerated in patients with acute seasonal influenza versus placebo. Shionogi are preparing for a Phase 3 study for the upcoming influenza season in Japan, placing it in direct competition with the Phase 3 study of LANI (CS-8958).

Non-inferiority Phase 2 study, equivalent to Tamiflu®.

Biocryst also completed a similar exploratory Phase 2 study of i.v. peramivir versus Tamiflu®, rather than strict placebo. There was no statistical difference between the three treatment arms in the study (which is similar to the CS-8958 Phase 2 study reported in 3Q CY08). The peramivir study enrolled patients hospitalised for acute serious or potentially life-threatening influenza. Peramivir was administered i.v. per day for 5 days in this study. While the data highlights the potential utility of the drug, we remained concerned about resistance to this drug, similar to that of Tamiflu®.

Resistance remains a big concern, likely to limit interest in the drug.

The mutation that has been observed in H1N1 viruses more recently in the field (denoted H274Y) has conferred resistance to Tamiflu®, but not Relenza™. While the wild type strains to our knowledge have yet to be tested, we note that a 2007 scientific study using *in vitro* cultivation techniques had identified H1N1 viruses with the H274Y mutation were resistant to both peramivir and Tamiflu®.

We continue to believe the utility of peramivir is limited to pandemic stockpiling versus seasonal use, simply because the route of administration (i.v. intramuscular) is undesirable in otherwise healthy patients. In more severely ill influenza patients, who are unable to swallow a tablet (Tamiflu®) or inhale (Relenza™), peramivir may also gain traction. However, given the drug suffers from the same resistance issue as Tamiflu®, we believe it unlikely the drug will ever occupy more than several percentage points in strategic stockpiles.

Shelf Life Extensions to Tamiflu® - A Strategic Tactic?

Shelf life of Tamiflu® extended to 7 years.

We note from Roche comments that no significant additional pandemic orders were received in the first nine months with the US, Canadian, South Korean and Hong Kong authorities having extended the shelf life of government stockpiles of Tamiflu® to 7 years (up from 5 years) with data filed to support similar extensions in other countries.

Forward Relenza™ model does not account for Tamiflu® cannibalisation.

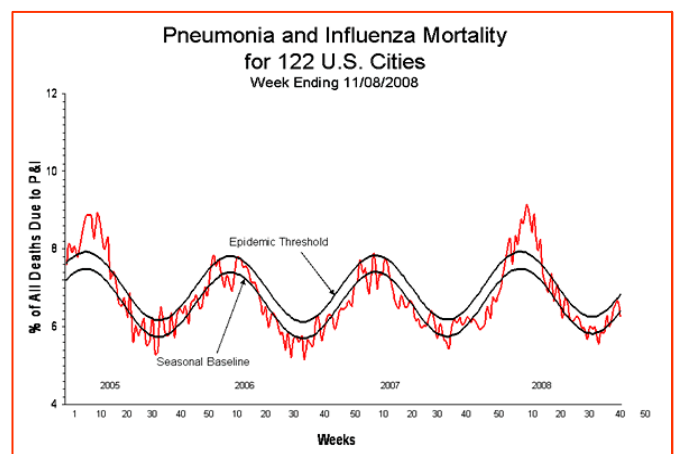
We believe this is a deliberate strategy by Roche to delay active replenishment orders now starting to appear, which may be biased to Relenza™, given current uncertainty with respect to the effectiveness of treatment with Tamiflu®. As an example, we understand from an industry source that the current Dutch stockpile of antiviral has now expired (est. to contain 1.25m Relenza™ treatments and 5m Tamiflu® treatments). We have not factored into our forward model any replenishment cannibalisation by Relenza™ of Tamiflu® stockpiles; only the replenishment of existing Relenza™ stockpiles, though we do view this scenario as a significant swing factor to forward Relenza™ royalties. We note from management that it is unlikely the Relenza™ label will also be extended beyond five years.

Update on Current Influenza Season

Low level influenza detection at present in the US.

During the current week (week 44) in the US, a low level of influenza activity was observed (see across), which is below the typical epidemic threshold. Thirteen states reported sporadic influenza activity, with 36 states reporting no influenza activity. This is typical of YOY influenza seasons, with significant influenza cases reported from approximately week 45 onwards. At this juncture, no further information from the Centers for Disease Control and Prevention (CDC) has been given with regards to anti-viral resistance; though we note a low level of typed viruses were in fact H1. We believe a significant recurrence of the resistance observed last influenza season could help drive the Relenza™ stockpiling proposition.

No data on anti-viral resistance.



Source: CDC

Outlook

Major EV de-rating highlights frustration over GSK settlement.

Biota is currently trading marginally above cash backing (EV of \$10.4m), which is a significant de-rating from an EV of \$198m only 12 months ago. We do not consider this rationale pricing for a Company with demonstrable expertise in drug development, partnering and commercialisation. However, the initiation, promulgation and execution of the GSK litigation by the Biota board in our view has resulted in a sharp deterioration in confidence.

The pipeline outlook, in our view, remains robust. As indicated, the Phase 3 LANI study has commenced, suggesting the next event we expect relates to the completion of the HRV Phase 2 study, self-initiated and funded by Biota (see below).

Milestone chart robust, with license deal expected n FY09 for HRV or LANI.

Biota 12 Month Milestone Chart	Timing
Completion of RSV Phase 1 Studies	1H CY09
Commencement of RSV Phase 2 Studies	4Q CY09
Completion of multiple LANI Phase 1 (UK) studies	1H CY09
Completion of HRV Phase 2a Study	4Q CY08 / 1Q CY09
Commencement of Daiichi Japanese Phase 3 LANI Study	4Q CY08
Completion of Daiichi Japanese Phase 3 LANI Study	2Q/3Q CY09

Source: Taylor Collison estimates

Maintain Speculative Buy recommendation.

While the lack of transparency with respect to GSK's strategy for Relenza™ may be of concern; we remain confident of a major order (Japan or the UK, or both) during FY09, representing a significant milestone. Our model for Relenza™ reflects this observation, suggesting at-risk Relenza™ royalties of \$14.7m exist, which could result in our FY09E NPAT revision to just \$2.7m (versus \$16.4m). However, given the aggressive decline in market value and significant discount to our risk-adjusted valuation of \$1.72 (previous \$1.80), we maintain our Speculative Buy recommendation.

Biota Holdings Limited - Summary of Forecasts

BTA \$0.40

PROFIT & LOSS SUMMARY (A\$'000)

	FY06A	FY07A	FY08A	FY09E	FY10E
Relenza Royalties	5,189	39,789	20,544	22,885	10,198
Partnering (License) Income	2,243	5,726	5,871	4,496	22,933
Research income (inc Grants)	4,021	8,740	15,042	9,560	3,633
Total Revenue	14,967	57,300	44,989	40,316	40,253
<i>Growth (pcp)</i>	196.4%	282.8%	-21.5%	-10.4%	-0.2%
Net Gain on GSK Settlement	0	0	0	12,500	0
Net Operating Revenue	(2,635)	27,576	3,592	34,533	24,353
R&D Expenses	(7,685)	(8,198)	(10,287)	(15,060)	(11,333)
EBITDA	(12,576)	16,871	(9,897)	16,315	9,740
Depreciation	(986)	(1,228)	(933)	(1,509)	(1,599)
Amortisation	0	(317)	(1,681)	(1,556)	(693)
EBIT	(13,562)	15,326	(12,511)	13,250	7,447
Net Interest	2,256	2,507	3,202	3,159	3,280
Pre-Tax Profit	(11,306)	17,833	(9,309)	16,409	10,727
Tax Expense	0	2,347	2,820	0	0
Minorities	0	0	0	0	0
NPAT Normalised *	(4,836)	21,424	10,735	2,736	10,727
NPAT Adj.	(11,306)	20,180	(6,489)	16,409	10,727
<i>Growth (pcp)</i>	n/a	n/a	-132.2%	-352.9%	-34.6%
Net Adjustments	0	0	0	0	0
Reported Profit	(11,306)	20,180	(6,489)	16,409	10,727

PER SHARE DATA

Period	FY06A	FY07A	FY08A	FY09E	FY10E
Adjusted EPS (c)	(6.9)	11.2	(3.5)	9.3	6.1
<i>Growth (pcp)</i>	n/a	n/a	-131.7%	-362.0%	-34.6%
Reported EPS (c)	(6.9)	11.2	(3.5)	9.3	6.1
<i>Growth (pcp)</i>	n/a	n/a	-131.7%	-362.0%	-34.6%
Dividend (c)	0.0	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%	0%
Gross CF per Share (c)	(5.4)	6.9	2.4	10.7	41.8
NTA per share (c)	28.5	32.2	28.0	54.2	97.9

VALUATION MULTIPLES

Period	FY06A	FY07A	FY08A	FY09E	FY10E
Adjusted PE Ratio (x)*	n/a	3.6	-11.3	4.3	6.6
PE Ratio (x)	n/a	3.6	n/a	4.3	6.6
Dividend Yield (%)	0.0%	0.0%	0.0%	0.0%	300.0%
EV/EBITDA (x)	(2.4)	0.9	(1.7)	0.9	0.6
EV/EBIT (x)	(2.2)	0.9	(1.3)	1.1	0.8

CAPITAL RAISING ASSUMPTIONS

Period	FY06A	FY07A	FY08A	FY09E	FY10E
Shares Issued (m)	41.0	0.0	0.0	0.0	0.0
Issue Price (A\$)	0.76	0.0	0.0	0.0	0.0
Cash Raised (A\$m)	31.0	0.0	0.0	0.0	0.0

KEY RATIOS

Period	FY06A	FY07A	FY08A	FY09E	FY10E
EBITD/Sales Margin %	-84.0%	29.4%	-22.0%	40.5%	24.2%
EBIT/Sales Margin %	-90.6%	26.7%	-27.8%	32.9%	18.5%
Current ratio (x)	4.9	5.3	3.4	7.9	15.0
Net Debt : Equity (%)	-98.5%	-86.9%	-94.8%	-81.2%	-80.5%
ROE (%)	-24.1%	34.1%	-9.6%	23.4%	13.0%
Dividend Payout Ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%

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

BALANCE SHEET SUMMARY (A\$'000)

Period	FY06A	FY07A	FY08A	FY09E	FY10E
Cash	46,183	62,156	60,164	62,467	71,150
Receivables	5,864	9,350	4,270	6,047	6,038
Inventories	0	0	0	0	0
Other	0	0	0	0	0
Total Current Assets	52,047	71,506	64,434	68,515	77,188
Investments	0	0	0	0	0
Inventories	0	0	0	0	0
Property Plant & Equip	5,512	5,152	7,543	7,995	7,896
Intangibles	0	13,447	12,113	10,557	9,863
Deferred Tax Assets	0	2,349	5,168	5,168	5,168
Other	0	0	0	0	0
Total Non-Current Assets	5,512	20,948	24,824	23,720	22,928
TOTAL ASSETS	57,559	92,454	89,258	92,235	100,115
Accounts Payable	4,034	6,004	12,023	4,032	4,025
Borrowings	0	0	0	0	0
Provisions	516	1,097	1,122	1,122	1,122
Other (Inc Def Rev)	6,011	6,457	6,059	3,533	0
Total Current Liab	10,561	13,558	19,204	8,687	5,147
Borrowings	0	0	0	0	0
Provisions	100	6,339	6,622	6,622	6,622
Other (Inc Def Rev)	0	1,022	0	0	0
Total Non-Current Liab	100	7,361	6,754	6,754	6,754
TOTAL LIABILITIES	10,661	20,919	25,958	15,441	11,901
TOTAL EQUITY	46,898	71,535	63,300	76,794	88,214

CASH FLOW SUMMARY (A\$'000)

Period	FY06A	FY07A	FY08A	FY09E	FY10E
EBIT (excl Abs/Extr)	(13,562)	15,326	(12,511)	13,250	7,447
Add: Depreciation	986	1,228	933	1,509	1,599
Amortisation	0	317	1,681	1,556	693
Change in Pay.	863	1,970	6,019	(7,991)	(6)
Less: Tax paid	0	2,347	2,820	0	0
Net Interest	2,256	2,507	3,202	3,159	3,280
Change in Rec.	(5,374)	(3,486)	5,080	(1,777)	9
Change in Prov.	(20)	(6,820)	(308)	0	0
Change in Def Tax Assets	0	(2,349)	(2,819)	0	0
Change in Inv.	0	0	0	0	0
Change in Def. Rev.	6,011	1,468	(1,420)	(2,526)	(3,533)
Gross Cashflows	(8,840)	12,508	4,358	8,735	10,183
Capex	(1,985)	(893)	(3,785)	(1,500)	(1,500)
Free Cashflows	(10,825)	11,615	573	7,235	8,683
Re-Purchase of Shares**	0	0	(3,020)	(4,932)	0
Net Cash Flow	(10,825)	11,615	(2,447)	2,303	8,683

** 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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