



Biota Holdings Limited (BTA)

Speculative Buy

2nd Royalty Buyout a Prelude to Settlement? Tamiflu[®] Safety Concerns Continue

\$1.80

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Key Points

Biota has bought out the Victorian College of Pharmacy's (VCP) royalty right to Relenza[™] of approx 3.57% for an undisclosed cash payment.

A second undisclosed payment will be paid should future Relenza[™] sales meet an agreed target, similar to that agreed with CSIRO.

From FY08 onwards, Biota will have zero royalty obligations to any third party on Relenza[™] royalties it receives from GSK.

Roche/Chugai to conduct new toxicology, animal and human trials of Tamiflu[®] to ascertain effects on brain accumulation and function.

Follows on from Japanese Ministry of Health warning against prescribing Tamiflu[®] to teenagers.

Summary

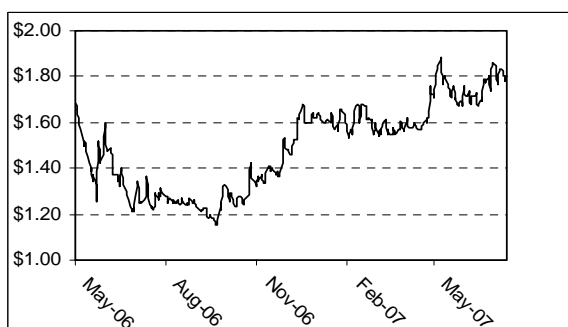
Market Capitalisation (M)	\$324.7
Share Price	\$1.80
Shares on Issue (M)	182.7
52 Week High	\$1.92
52 Week Low	\$1.13
Valuation Per Share (fully diluted)	\$2.61
12 Month Price Target	\$2.61
Cash (M) as at 31/12/06	\$41.9

Key Financials (A\$'000)

Year End	FY06 Actual	FY07 Est.	FY08 Est.
Relenza Royalties	5,189	42,690	57,670
Partnering Income*	2,243	5,234	6,923
Total Revenue	14,967	61,973	87,262
Litigation Expense	(4,397)	(7,750)	(7,750)
Total Op. Expenses	(17,314)	(32,680)	(46,176)
R&D Expenses	(7,685)	(10,579)	(13,872)
EBITD (ex Abs)	(10,134)	18,921	24,611
EBIT	(11,120)	17,736	22,628
Adj. NPAT	(8,864)	20,045	26,057
Reported Profit	(11,306)	23,542	26,513
Adj. EPS (c)	(5.4)	11.2	14.3
Reported EPS (c)	(6.9)	13.1	14.5
Adj. PE Ratio (x)	n/a	13.7	12.4

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

Share Price Graph (A\$)



Our View

- We consider the buyout of the Victorian College of Pharmacy (VCP) Relenza[™] royalty obligation as prudent capital management on Biota's part. The VCP deal comes hot on the heels of the 10.4% royalty buyout negotiated with CSIRO in May, both of which we view as value accretive. Moreover, Biota will now capture all future upside on Relenza[™] sales, which we view as significant particularly if further evidence emerges of GSK capacity expansion (current TC est. 35m courses). Implicitly, we view the buyout agreements as further evidence of the potential for a settlement with GSK in the ongoing litigation, which we believe will encompass an upfront payment, with potential for an increase in the 7% royalty rate (see sensitivity analysis pg 3). Submission of the amended financial claim against GSK is expected on July 19th, which we believe could well exceed \$600 million (up from \$308-\$430 million previously), given the significant underestimation of the pandemic stockpiling market.
- Though no causal link between Tamiflu[®] and serious psychiatric or neurological events has been established, significant concerns remain. Approximately 35 million treatments or 70% of world's consumption of Tamiflu[®] emanates from Japan. We hosted a call with Biota scientific management to explore the pre-clinical effects of Relenza[™] versus Tamiflu[®] (details pg 2) as a proxy to determine whether Relenza[™] is likely to also show psychiatric or neurological events through widespread use in humans, due to brain exposure. Our discussions indicate that Relenza[™] administration is very unlikely to result in any significant brain exposure, thereby limiting any potential for drug-induced psychiatric effects.
- No financial impact on our FY07 adjusted NPAT of \$20.0 million (reported NPAT \$23.5 million) from the VCP buyout is expected. Further, we have not made material changes to our adjusted FY08 NPAT expectations of \$26.1 million. However, on our forward modelling to 2014 (when Relenza[™] patents are exhausted), the PV cost saving of removing the buyout (excluding future one-off payments) is approximately \$11.5 million, or value accretive by \$0.06 per share (fully diluted). We continue with our Speculative Buy recommendation and as a result of the royalty buyout, and PV adjustments to other development programs have made a modest upgrade to our 12 month price target of 3.2% to \$2.61.

Pre-clinical CNS Effects of Relenza™ V Tamiflu®

We hosted a conference call with scientific personnel at Biota, to discuss the implications of Roche/Chugai relaunching both human clinical trials and further animal studies of Tamiflu® to examine:

1. the pharmacokinetic and metabolic properties in the brain;
2. whether the drug acts on any endogenous targets other than the virus in the brain;
3. additional toxicity studies using immature rats;
4. effect on human volunteers with respect to sleep; and
5. transport of the drug to the cerebral spinal fluid in human volunteers.

We examined whether brain effects from Relenza™ use possible.

While no such concerns have arisen with Relenza™, we believe it pertinent to examine the pre-clinical evidence compiled thus far on the drug to ascertain whether similar problems may arise through widespread use. At present, Tamiflu® has been used in over 50 million patients, and holds a ~97% share of the seasonal influenza market. Japan accounts for up to 70% of world consumption of Tamiflu® for seasonal use.

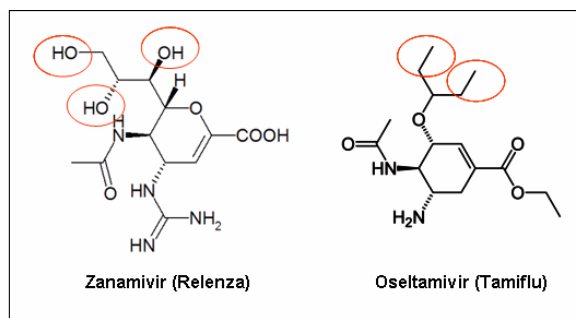
Issue is whether both drugs can cross the BBB

Much of the current concern with Tamiflu® is how the drug actively crosses the blood brain barrier, and how might it directly exert an effect within the brain, which may lead to a neurological consequence. The main function of the blood-brain barrier (BBB) is to protect the brain from changes in the levels in the blood of ions, amino acids, peptides, and other substances. The barrier prevents water-soluble substances in the blood from passing between the cells that make up the barrier. The only way for water-soluble substances to cross the BBB is by passing directly through the walls of the cerebral capillaries, and because their cell membranes are made up of a lipid/protein bilayer, they also act as a major part of the BBB. In contrast, fat-soluble molecules, can pass straight through the lipids in the capillary walls and so gain access to all parts of the brain.

Three scientific papers show evidence that Relenza™ would not cross BBB.

The highlighted regions of the Relenza™ molecule (so called “hydroxyl groups”) in the schematic diagram (across) are responsible for its solubility and therefore hydrophilic (“water loving”) properties. In contrast, oseltamivir is a more hydrophobic molecule (particular regions highlighted), and as such is more readily able to interact with, and enter, the BBB. We note three relevant scientific papers that all provide excellent evidence that Relenza™ is unlikely to (1) cross the BBB and therefore

(2) exert an effect on CNS function. In Dines *et al.*, 1998 the investigators noted that “zanamivir is a highly polar molecule and therefore its penetration into cell membranes is poor, with a volume of distribution representing that of extra cellular water”. Based on what we know about the BBB, such properties render zanamivir unable to passively cross the BBB. Furthermore, the authors noted that because of its highly polar nature, “any of the [Relenza™] drug that does enter systemic circulation is efficiently cleared through the kidneys in humans and animals, resulting in a short systemic half life”; a view shared by Freund *et al.*, 1999.



Source: Wikipedia

Low serum conc. of Relenza™, and short half-life.

This is supported by clinical evidence, where pharmacokinetic studies of orally inhaled zanamivir indicated that approximately 4% to 17% of the inhaled dose was systemically absorbed. The peak serum concentrations ranged from 17 to 142 ng/ml within 1 to 2 hours following a 10 mg dose. In contrast for oseltamivir 75% of an oral dose reaches the systemic circulation with peak serum concentrations of 551 ng/ml (fasting) and 441 ng/ml (fed) reached, up to four times greater than zanamivir. Finally, whole body localisation experiments in mice indicated no detectable zanamivir localisation in the brain both at 90 minutes and 24 hours post administration (Fenton *et al.*, 1999).

Relenza™ unlikely to cause abnormal behaviour.

For human use, Relenza™ is currently contraindicated in patients with a hypersensitivity to formulation components (specifically lactose) and is not recommended for treatment or prophylaxis of patients with an underlying airway disease (asthma, COPD). No label warnings currently exist pertaining to abnormal behaviour, which based on our analysis of scientific studies and speaking with Biota scientific personnel, are unlikely to ever eventuate.

Prospects for Settlement – Impact on Price Target

Much has been made of the likelihood of Biota settling out of court with GSK. As indicated, a court date is scheduled for April 08. Based on our understanding of the Statement of Claim, Biota's case appears strong and ironically given the sizeable Relenza™ royalties, Biota now has the balance sheet strength to see the case through the courts, if required.

In our view, the buyout of both CSIRO's and VCP's royalty payment obligation could point to Biota manoeuvring towards a settlement with GSK, as any upfront payment it could receive as part of a negotiated settlement would have previously triggered a 14% royalty obligation to the CSIRO and the VCP. Recent management comments indicated an out of court settlement with GSK is possible before the case goes to trial.

Recent comments from Biota management also indicated that the potential financial claim against GSK will be increased from the indicative claim of A\$308-\$430 million, given the pandemic stockpiling market was under-estimated by approximately 50%. This suggests significant upside to the indicative damages claim of A\$308-A\$430 million. The revised statement of claim financial amendment is expected to be filed around July 19th, which we believe could top A\$600 million.

Amended financial claim filed July 19th.

We continue to value the potential per share value uplift from a settlement with GSK with a high degree of conservatism. In our current model (upgraded price target, \$2.61) we are assuming a fully taxed payment of \$43.0 million (FY08) and no royalty adjustment (see Table below, purple shade). Given recent management comments, we have undertaken a sensitivity analysis of the per share value/ target price impact in the event of settlement, which involves a one-off payment and future royalty uplift on our forward Relenza™ royalty estimates (max 20% royalty, A\$800 million settlement payment).

Conservative approach to valuing potential settlement.

Sensitivity Analysis - Price Target Impact: Litigation Settlement and Royalty Rate Adjustment

Settlement (A\$m)* / Royalty Mix**	43.0	50.0	60.0	70.0	80.0	90.0	100.0	150.0	200.0	250.0	300.0	400.0	500.0	600.0	700.0	800.0
7.0%	\$2.61	\$2.65	\$2.71	\$2.76	\$2.82	\$2.87	\$2.93	\$3.20	\$3.47	\$3.74	\$4.02	\$4.56	\$5.11	\$5.66	\$6.20	\$6.75
8.0%	\$2.73	\$2.77	\$2.82	\$2.88	\$2.93	\$2.99	\$3.04	\$3.31	\$3.59	\$3.86	\$4.13	\$4.68	\$5.23	\$5.77	\$6.32	\$6.87
9.0%	\$2.84	\$2.88	\$2.94	\$2.99	\$3.05	\$3.10	\$3.16	\$3.43	\$3.70	\$3.97	\$4.25	\$4.79	\$5.34	\$5.89	\$6.43	\$6.98
10.0%	\$2.96	\$3.00	\$3.05	\$3.11	\$3.16	\$3.22	\$3.27	\$3.54	\$3.82	\$4.09	\$4.36	\$4.91	\$5.46	\$6.00	\$6.55	\$7.10
11.0%	\$3.07	\$3.11	\$3.17	\$3.22	\$3.28	\$3.33	\$3.38	\$3.66	\$3.93	\$4.20	\$4.48	\$5.02	\$5.57	\$6.12	\$6.66	\$7.21
12.0%	\$3.19	\$3.23	\$3.28	\$3.34	\$3.39	\$3.45	\$3.50	\$3.77	\$4.05	\$4.32	\$4.59	\$5.14	\$5.69	\$6.23	\$6.78	\$7.32
13.0%	\$3.30	\$3.34	\$3.40	\$3.45	\$3.51	\$3.56	\$3.61	\$3.89	\$4.16	\$4.43	\$4.71	\$5.25	\$5.80	\$6.35	\$6.89	\$7.44
14.0%	\$3.42	\$3.46	\$3.51	\$3.57	\$3.62	\$3.67	\$3.73	\$4.00	\$4.28	\$4.55	\$4.82	\$5.37	\$5.92	\$6.46	\$7.01	\$7.55
15.0%	\$3.53	\$3.57	\$3.63	\$3.68	\$3.74	\$3.79	\$3.84	\$4.12	\$4.39	\$4.66	\$4.94	\$5.48	\$6.03	\$6.58	\$7.12	\$7.67
16.0%	\$3.65	\$3.69	\$3.74	\$3.80	\$3.85	\$3.90	\$3.96	\$4.23	\$4.51	\$4.78	\$5.05	\$5.60	\$6.15	\$6.69	\$7.24	\$7.78
17.0%	\$3.76	\$3.80	\$3.86	\$3.91	\$3.97	\$4.02	\$4.07	\$4.35	\$4.62	\$4.89	\$5.17	\$5.71	\$6.26	\$6.81	\$7.35	\$7.90
18.0%	\$3.88	\$3.92	\$3.97	\$4.03	\$4.08	\$4.13	\$4.19	\$4.46	\$4.74	\$5.01	\$5.28	\$5.83	\$6.38	\$6.92	\$7.47	\$8.01
19.0%	\$3.99	\$4.03	\$4.09	\$4.14	\$4.19	\$4.25	\$4.30	\$4.58	\$4.85	\$5.12	\$5.40	\$5.94	\$6.49	\$7.04	\$7.58	\$8.13
20.0%	\$4.11	\$4.15	\$4.20	\$4.26	\$4.31	\$4.36	\$4.42	\$4.69	\$4.97	\$5.24	\$5.51	\$6.06	\$6.60	\$7.15	\$7.70	\$8.24

*Assumes Net of Tax and during FY08; ** On TC estimates of GSK Relenza volumes/sales to FY14; Source: Taylor Collison

While we consider it very unlikely that a settlement will be reached on the total financial claim, our view is the sweet spot for settlement for both GSK and Biota lies around \$90-\$150 million as an upfront settlement payment (net of tax, success fee to lawyers or other costs), with an adjusted future royalty rate of 10-14% on Relenza™ sales. The impact of such a settlement and royalty range would be an upgraded price target of \$3.22-\$4.00 (representing an upgrade of 47.2% - 53.1%).

Maintain Speculative Buy.

Biota remains a high quality, profitable Australian biotechnology play, and is currently trading on 12.4x our forecast adjusted FY08 EPS. We see further upside in FY08 to our \$2.61 target should a settlement with GSK be achieved, though upfront and royalty payment dependent. We therefore maintain our Speculative Buy recommendation.

Biota Holdings Limited - Summary of Forecasts

BTA

\$1.80

PROFIT & LOSS SUMMARY (A\$'000)				
Period	FY05A	FY06A	FY07E	FY08E
Relenza Royalties	530	5,189	42,690	57,670
Partnering (License) Income	0	2,243	5,234	6,923
Research income (inc Grants)	1,554	4,021	10,815	18,539
Total Revenue	5,049	14,967	61,973	87,262
<i>Growth (pcp)</i>	-37.3%	196.4%	314.1%	40.8%
Net Operating Revenue	(6,859)	(2,347)	29,293	41,087
R&D Expenses	(7,337)	(7,685)	(10,579)	(13,872)
EBITD*	(11,785)	(10,134)	18,921	24,611
Depreciation	(867)	(986)	(1,102)	(1,984)
EBIT*	(12,652)	(11,120)	17,819	22,628
Net Interest	1,289	2,256	2,309	3,430
Pre-Tax Profit*	(11,363)	(8,864)	20,045	26,057
Tax Expense	0	0	6,013	1,283
Minorities	0	0	0	0
NPAT Adj.*	(11,363)	(8,864)	20,045	26,057
<i>Growth (pcp)</i>	n/a	n/a	n/a	30.0%
Net Adjustments	(3,700)	(2,442)	3,497	456
Reported Profit	(15,063)	(11,306)	23,542	26,513

PER SHARE DATA				
Period	FY05A	FY06A	FY07E	FY08E
Adjusted EPS (c) *	(9.2)	(5.4)	11.2	14.3
<i>Growth (pcp)</i>	n/a	n/a	n/a	27.6%
Reported EPS (c)	(12.2)	(6.9)	13.1	14.5
<i>Growth (pcp)</i>	n/a	n/a	n/a	11.0%
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%
Gross CF per Share (c)	(9.3)	(3.5)	12.8	11.2
NTA per share (c)	21.1	28.5	40.5	55.1

VALUATION MULTIPLES				
Period	FY05A	FY06A	FY07E	FY08E
Adjusted PE Ratio (x)*	n/a	n/a	16.1	12.6
PE Ratio (x)	n/a	n/a	13.7	12.4
Dividend Yield (%)	0.0%	0.0%	0.0%	0.0%
EV/EBITD (x)	(27.1)	(29.9)	12.6	8.8
EV/EBIT (x)	(23.4)	(24.6)	14.2	10.4

CAPITAL RAISING ASSUMPTIONS				
Period	FY05A	FY06A	FY07E	FY08E
Shares Issued (m)	n/a	41.0	0.0	0.0
Issue Price (A\$)	n/a	0.76	0.0	0.0
Cash Raised (A\$m)	n/a	31.0	0.0	0.0

KEY RATIOS				
Period	FY05A	FY06A	FY07E	FY08E
EBITD/Sales Margin %	-233.4%	-67.7%	30.5%	28.2%
EBIT/Sales Margin %	-250.6%	-74.3%	28.6%	25.9%
Current ratio (x)	6.3	4.9	4.8	5.8
Net Debt : Equity (%)	-92.7%	-98.5%	-93.9%	-85.0%
ROE (%)	-43.6%	-18.9%	33.4%	30.0%
Dividend Payout Ratio (%)	0.0%	0.0%	0.0%	0.0%

* Excluding litigation expense, HCV/RSV license upfront/milestone payments, FITB

BALANCE SHEET SUMMARY (A\$'000)				
Period	FY05A	FY06A	FY07E	FY08E
Cash	24,753	46,183	68,599	85,480
Receivables	972	5,573	13,634	19,198
Inventories	0	0	0	0
Other	0	291	0	0
Total Current Assets	25,725	52,047	82,233	104,678
Investments	0	0	0	0
Inventories	0	0	0	0
Property Plant & Equip	4,702	5,512	5,668	7,816
Intangibles	0	0	0	0
Deferred Tax Assets	0	0	6,013	7,296
Other	0	0	0	0
Total Non-Current Assets	4,702	5,512	11,681	15,113
TOTAL ASSETS	30,427	57,559	93,914	119,791
Accounts Payable	3,171	4,034	9,296	13,089
Borrowings	366	0	0	0
Provisions	556	516	620	838
Other (Inc Def Rev)	0	6,011	7,220	4,181
Total Current Liab	4,093	10,561	17,136	18,108
Borrowings	366	0	0	0
Provisions	40	100	0	0
Other (Inc Def Rev)	0	0	3,728	1,096
Total Non-Current Liab	298	100	3,728	1,096
TOTAL LIABILITIES	4,391	10,661	20,865	19,205
TOTAL EQUITY	26,036	46,898	73,049	100,586

CASH FLOW SUMMARY (A\$'000)				
Period	FY05A	FY06A	FY07E	FY08E
EBIT (excl Abs/Extr)	(12,652)	(11,120)	17,736	22,628
Add: Depreciation	867	986	1,102	1,984
Amortisation	0	0	83	0
Change in Pay.	(78)	863	5,262	3,793
Less: Tax paid	0	0	6,013	1,283
Net Interest	1,289	2,256	2,309	3,430
Change in Rec.	(361)	(4,778)	(8,366)	(5,564)
Change in Prov.	(568)	(20)	(4)	(218)
Change in FITB	0	0	(6,013)	(1,283)
Change in Inv.	0	0	0	0
Change in Def. Rev.	0	6,011	4,938	(5,671)
Gross Cashflows	(11,503)	(5,802)	23,059	20,382
Capex	(4,323)	(1,985)	(1,500)	(3,500)
Free Cashflows	(15,826)	(7,787)	21,559	16,882
Dividends Paid	0	0	0	0
Net Cash Flow	(15,826)	(7,787)	21,559	16,882

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