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Biota Holdings Limited (BTA)

Outperform

1H10 NPAT of \$33.5m in-line; 2H Outlook Remains Solid

\$2.05

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Summary

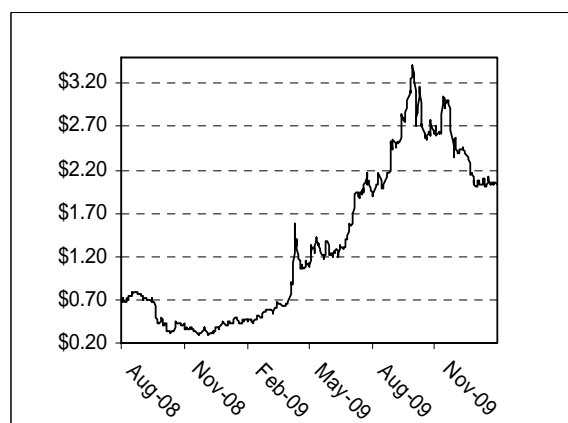
Market capitalisation (M)	\$360.8
Share price	\$2.05
Shares on issue (M)	179.0
52 week low	\$0.41
52 week high	\$3.34
Ave Monthly Vol (M)	26.3
Valuation Per Share (fully diluted)	\$2.79
Cash (M) as at 31/12/09	\$52.0

Key Financials (A\$'000)

Year End	1H10 Actual	FY10 Est.	FY11 Est.
Relenza Royalties	56,715	129,168	54,417
Partnering Income*	554	7,467	10,667
Total Revenue	61,663	145,105	73,461
Total Op. Expenses	(6,936)	(16,516)	(12,252)
R&D Expenses	(8,612)	(24,617)	(32,973)
EBITDA	44,664	101,547	22,003
Normalised NPAT	35,595	80,825	16,602
Adj. NPAT	35,595	80,825	16,602
Adj. EPS (c)	20.2	45.5	9.3
Adj. PE Ratio (x)	n/a	4.5	22.1

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

Share Price Graph (A\$)



1H Key Points

1H10 reported NPAT of \$33.5m, in-line with expectations.

Driven by recognised Relenza royalties of \$56.7m, as a result of pandemic influenza stockpiling and Japanese retail sales.

Expenses down 13.2% on pcp to \$20.3m reflecting cessation of litigation against GSK and reduction in Phase 2a cost for HRV program.

Cash of \$52m, with \$64m receivables, consisting of \$62.9m attributable to Relenza, which will be paid June 30 on a GSK April FY.

Our View

- **Solid 1H Result, As Anticipated** – Reported NPAT of \$33.5m was attributable to the largest ever half for Relenza, commensurate with significant government orders (>60 countries) for Relenza in response to the global pandemic influenza threat. Research and license income was down significantly (down 81% and 77.4%, respectively on pcp), reflecting the cessation of the AZ collaboration for RSV and the tail end of revenue recognitions associated with upfront license payments from AZ and Boehringer. The Company expects to move to \$50m in total project expenditure per annum over the next “few years”, as it drives the R&D pipeline into clinical studies, and potentially further partnering.
- **Back the Key Milestones** – We have not explicitly incorporated expectations associated with upfront payments attributable to a LANI ROW license deal in our FY10 estimates. As such, and depending on the level of 2H Relenza royalties, particularly in the 3Q, this could represent meaningful upside to our FY10 NPAT estimates. We have made no adjustments to our expectations on a ROW LANI license, and based on past mgt comments, we are tipping a deal within 2H10 of US\$200m in upfront/milestones ex royalties, shared 50/50 with Daiichi Sankyo. We also note the imminent approval of LANI in Japan, which based on an approval time line of a competing influenza treatment (peramivir) may transpire before the end of April.
- **Outlook** – We are cautious on the prospects for returns to shareholders despite the substantial net cash flow potential for FY10 (TC est. \$83.2m). We cite the unpredictable nature of Relenza sales and the substantial ramp in R&D spend over the next two years. Any returns are likely to be cosmetic in our view, and unlikely to manifest until at least LANI, and possibly HRV are licensed. The lynchpin to our FY10 Relenza estimates remains the 3Q10 result, due in April. Our 2H10 Relenza estimate remains unchanged at \$72.5m, driven by stockpile re-balances and fulfilment of government pandemic orders. To re-iterate, we believe FY10 represents the peak cycle of government stockpiling for Biota prior to patent expirations across most major jurisdictions commencing in 2014. We maintain our FY10 adjusted NPAT of \$80.8m, though we freely acknowledge 2H10 Relenza sales remain key to the scale of FY10 NPAT. On our estimates, Biota trades on a forward EV/EBITDA of 1.9x and a PER of 5.0x. We maintain our Outperform recommendation on the 3-5 month positive outlook, based on significant milestones and Relenza, and have upgraded our PT by 6.9% to \$2.79.

1H Result Summary

Reported 1H10 NPAT of \$33.5m.

Biota has recorded an impressive 1H10 NPAT of \$33.5m, on Relenza revenues of \$56.7m thanks to major capacity expansion by GSK in response to the swine influenza pandemic which commenced in early 2Q CY09. A snapshot of the result and our estimates is shown below.

Table 1: Financial Highlights 1H10

	1H09A	1H10A	Change (%)	TC est. 1H10	Difference (%)	Comment
Relenza Royalties	3.8	56.7	1385.1%	56.7	0.0%	Bang on, given 2Q of GSK results
Research/License Income	6.7	1.4	-79.7%	0.9	-33.5%	Reduction attributable to AZ license return, tail off in of upfront license recognitions
R&D Expenditure	(6.3)	(8.6)	35.9%	(9.2)	6.8%	Adjusted for acquisition amortisation, we were slightly ahead, expect increased R&D in 2H
EBITDA	9.6	44.7	365.2%	43.1	-3.5%	
PBT	10.1	43.5	328.8%	41.7	-4.0%	
Adjusted NPAT (ex acq. amort)	7.2	35.6	393.4%	35.7	0.3%	\$2.1m in amortisation charges from Prolysis acquisition in 4Q CY09
Reported NPAT	7.2	33.5	364.2%	33.0	-1.4%	In-line with expectations

Source: Biota report, TC

Operating expenses of \$20.3m down 13.2% on pcp.

Expenses in the business were well managed, with total operating expenses of \$20.3m for the half, down from \$23.4m in pcp. On an underlying basis (excluding our estimated \$2.1m in amortisation charges from the Prolysis acquisition), R&D increased 35.9% on pcp which relates to increased spend on the Prolysis pre-clinical programs. A summary of the expenses in the 1H is shown below.

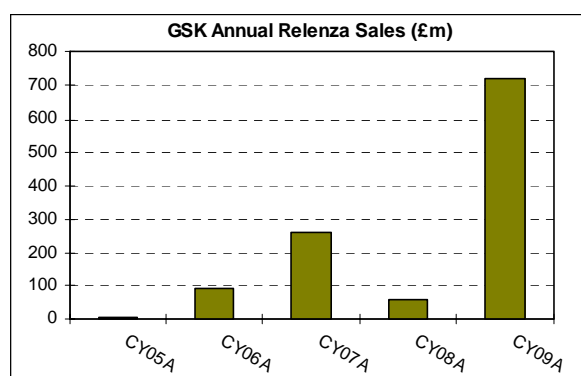
\$ million	1H09A	1H10A	Change	TC. est 1H10	Difference (%)
Admin Expense*	(1.2)	(1.6)	30.1%	(1.2)	-23.4%
Product Development	(6.0)	(4.8)	-20.8%	(5.9)	23.3%
Business Development	(0.4)	(0.6)	26.2%	(0.5)	-6.8%
R&D Expenses**	(6.3)	(8.6)	35.9%	(9.2)	6.4%
Litigation Expenses	(7.3)	0.0	-100.0%	0.0	n/a

* Excludes D&A; ** Excludes acquisition amortisation; Source: Biota report

2Q Relenza Result Drives 1H Earnings

As we reported earlier, GSK recorded the highest ever quarter for Relenza with sales of £256m (A\$462m) with US, European and ROW sales of £62m, £39m, and £155m, respectively all up >100% on pcp. Biota recorded A\$32.6m in indicative royalties for the quarter. GSK commented at the conference call that CY09 sales of £720m represented strong capacity expansion to meet government pandemic orders globally and a strong retail performance in Japan (£191m). A summary of GSK Relenza sales since CY05 is shown above.

Global sales of Relenza reached £720m in CY09.



Source: GSK

We were particularly pleased by the retail sales in Japan, which have historically been very low relative to Tamiflu. We note over the 2008/9 influenza season to Mar 09, GSK shipped 5m courses for seasonal use in Japan prior to swine flu, which in essence represented our forward seasonal expectations from this market. The inference from

sales, were volumes closer to 15m during CY09.

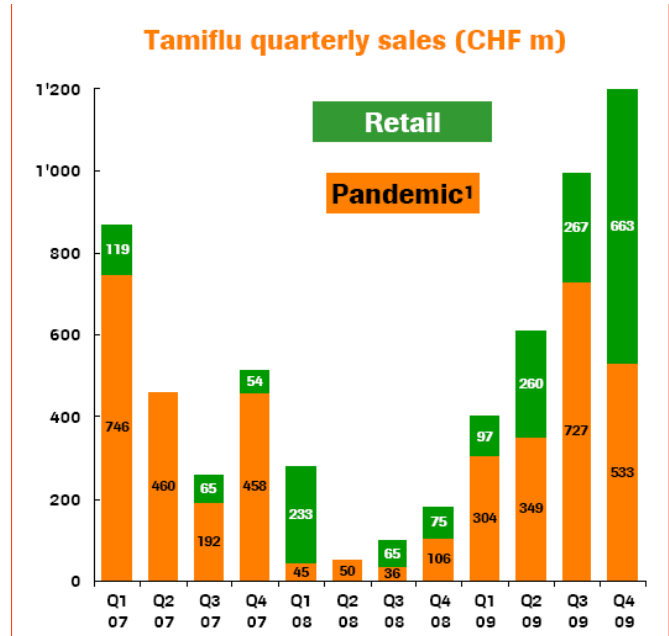
We believe this rapid change in Japanese sentiment towards inhaled influenza drugs serves to support the imminent launch of LANI by Daiichi Sankyo post approval given the similarity of administration (inhalation) but with greatly superior dosing characteristics for LANI (1x only for treatment v 2x per day over 5 days for Relenza) and a better inhaler. The market for seasonal use Tamiflu in Japan clearly continues to be impacted by the ongoing prescription ban for teenage use under a "normal" scenario, which because of swine flu CY09 was not a normal influenza season.

Change in Japanese flu market a positive for LANI.

Tamiflu sales for CY09 were also very strong, reaching A\$3.4b.

We note that Roche recorded global sales of Tamiflu of CHF3.2b (A\$3.4b) in 2009, an increase of 435%, or CHF2.6b, compared with 2008 (see across). 4Q CY09 of CHF1.2b (A\$1.3b) was CHF500m ahead of guidance provided at the 3Q of CHF700m or CHF2.7b for CY09, which was partially driven by a surprise surge in Tamiflu sales in Japan (CHF132m ahead of guidance). Roche commented the very high growth was driven by unprecedented demand from governments and in the retail pharmacy sector (particularly in the 4Q) following the pandemic (H1N1) 2009 ('swine flu') outbreak, which began in April and spread rapidly worldwide. From our perspective, the strong retail component underscores an element of personal stockpiling, which by inference should also be the case for Relenza - though this is difficult to quantitate. They have guided CHF1.2b in CY10 Tamiflu sales.

Retail sales of Tamiflu during 4Q CY09 highlight an element of personal stockpiling.



Source: Roche

3Q Relenza Result Will Determine Extent of FY10 NPAT

The lynchpin to our FY10 Relenza estimates remains the 3Q10 result, due in April. Our 2H10 Relenza estimate remains unchanged at \$72.5m, driven by stockpile re-balances and fulfilment of government pandemic orders. To re-iterate, we believe FY10 represents the peak cycle of government stockpiling for Biota prior to patent expirations across most major jurisdictions commencing in 2014.

A lot rides on the 3Q Relenza result in our view.

We note comments in early 3Q CY09 by the Department of Health and Human Services (HHS), who wished, *inter alia*, to increase the proportion of zanamivir (Relenza) in the national stockpile relative to oseltamivir (Tamiflu), in light of a few recent instances of H1N1 resistance to the latter. The split at the time of the release was 80% oseltamivir and 20% zanamivir and the agency would like to move to 50/50, but quote "that will take time".

Evidence suggests orders continue to accumulate, magnitude unknown.

In Jan 2010, the Department of Homeland Security (DHS), Office of Procurement Operations (OPO), intends to issue a sole source contract to GlaxoSmithKline (GSK) after March 12, 2010. The cost of the contract was kept confidential. In our view, such information does indicate a continued desire by the US government to press ahead with stockpile re-adjustments, despite the lull in pandemic influenza globally. We have previously forecast a re-balance of the federal/state stockpile to 50/50 could be worth as much as \$62-\$85m in royalties to Biota.

Outlook

We note that two further (and significant) milestones are anticipated, outside of the GSK quarterly reporting of Relenza, being (1) the approval of LANI in Japan, which based on peramivir's approval timeline of 2.3 months, may get the nod before the end of April and (2) a LANI rest of world (ex-Japan) license deal, which we also expect during the current half.

We have presented a summary of other anticipated milestones throughout CY10, below.

Solid 12 month milestone outlook for Biota, most interest in 1H CY10.

Biota CY10 Milestone Chart	Timing
Completion of LANI Phase 1 (UK) studies	Complete
Regulatory approval of LANI in Japan	1H CY10
GSK 1Q10 Royalties	Apr-10
Licence Deal for LANI (CS-8958) Ex-Japan	1H CY10
Licence Deal for HRV (BTA798)	2H CY10
GSK 2Q10 Royalties	Jul-10
LANI Phase 3 prophylaxis trial results (Japan)	3Q CY10
GSK 3Q10 Royalties	Oct-10

Source: Taylor Collison estimates

We have updated our forecasts for FY10-FY12 as a result of the 1H result, as shown below.

Changes to Forecasts

	FY10E			FY11E			FY12E		
	Previous	Revised	Change	Previous	Revised	Change	Previous	Revised	Change
Relenza Volumes (m)	73.8	73.8	0.0%	31.1	31.1	0.0%	31.6	31.6	0.1%
Relenza Royalties (A\$m)	129.2	129.2	0.0%	54.4	54.4	0.0%	55.3	55.3	0.1%
EBITDA	101.6	101.5	-0.1%	22.0	22.0	0.0%	25.2	25.1	-0.3%
Reported NPAT	72.5	72.4	-0.1%	10.6	12.5	17.5%	23.1	21.8	-5.5%
Reported EPS (c)	40.8	40.8	0.0%	5.9	7.0	17.9%	12.9	12.2	-5.5%
Adj. NPAT	80.7	80.8	0.2%	14.7	16.6	12.9%	23.1	21.8	-5.5%
Adj. EPS (c)	45.5	45.5	0.1%	8.2	9.3	13.1%	12.9	12.2	-5.5%

Source: Taylor Collison estimates

Cash flows are also expected to benefit from the current taxation position of the Company, with approximately \$40m of tax losses in FY10 expected to be utilised on profits in excess of that amount. Actual tax payments are expected to commence in 1H11. On this basis, there is an additional benefit to cash flows during FY10.

We anticipate FCF of \$103.2m or \$83.2m adjusted for the capital return/unfranked dividend paid in the 1H. Such collections, coupled with the potential for tax losses to be completely recovered and therefore future tax paid generating franking credits, will increase the pressure on management to return cash to shareholders in FY11, most likely via franked dividends +/- share buy-backs.

As a cautionary note, given the unpredictability of future Relenza royalty collections and the R&D spend increasing substantially over the next two years via the Prolysis acquisition and pending MaxThera acquisition we expect any return to shareholders will be small, unless GSK guide positively on Relenza, which we doubt.

Maintain Outperform and \$2.79 PT.

We maintain our FY10 adjusted NPAT of \$80.8m, though we freely acknowledge 2H10 Relenza sales remain key to the scale of FY10 NPAT. On our estimates, Biota trades on a forward EV/EBITDA of 1.9x and a PER of 5.0x. We maintain our Outperform recommendation on the 3-5 month positive outlook and have upgraded our PT by 6.9% to \$2.79.

Biota Holdings Limited - Summary of Forecasts

BTA \$2.05

PROFIT & LOSS SUMMARY (A\$'000)						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
Relenza Royalties	3,819	45,000	56,715	129,168	54,417	55,333
Partnering (Licence) Income	2,447	4,426	554	7,467	10,667	12,000
Research income (inc Grants)	5,315	10,966	2,941	6,020	1,420	700
Total Revenue	13,561	63,334	61,663	145,105	73,461	83,055
<i>Growth (pcp)</i>	-55.3%	40.8%	354.7%	129.1%	-49.4%	13.1%
Net Gain on GSK Settlement	12,736	12,756	0	0	0	0
Net Operating Revenue	17,885	60,280	54,727	128,590	61,209	70,479
R&D Expenses	(6,339)	(13,348)	(8,612)	(24,617)	(32,973)	(38,364)
EBITDA	9,601	43,997	44,664	101,547	22,003	25,123
Depreciation	(570)	(1,184)	(629)	(1,316)	(1,322)	(1,357)
Amortisation	(840)	(3,931)	(2,026)	(4,750)	(3,531)	0
EBIT	8,191	38,882	42,009	95,482	17,150	23,766
Net Interest	1,945	2,935	1,451	2,426	6,233	6,993
Pre-Tax Profit	10,136	41,817	43,460	97,908	23,383	30,759
Tax Expense	(2,922)	(3,636)	(7,865)	(17,083)	(6,781)	(8,920)
Minorities	0	0	0	0	0	0
NPAT Normalised *	(5,522)	20,343	35,595	80,825	16,602	21,839
NPAT Adj.	7,214	38,181	35,595	80,825	16,602	21,839
<i>Growth (pcp)</i>	30.6%	n/a	393.4%	111.7%	-79.5%	31.5%
Net Adjustments**	0	0	(2,110)	(8,410)	(4,150)	0
Reported Profit	7,214	38,181	33,485	72,415	12,452	21,839

PER SHARE DATA						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
Adjusted EPS (c)	4.1	21.7	20.2	45.5	9.3	12.2
<i>Growth (pcp)</i>	34.5%	n/a	398.6%	110.1%	-79.6%	31.5%
Reported EPS (c)	4.1	21.7	19.0	40.8	7.0	12.2
<i>Growth (pcp)</i>	34.5%	n/a	369.0%	88.3%	-83.0%	75.4%
Dividend (c)	0.0	0.0	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%	0%	0%
Gross CF per Share (c)	0.4	18.4	(8.2)	58.7	7.5	15.6
NTA per share (c)	30.7	50.3	60.8	92.3	102.7	114.9

VALUATION MULTIPLES						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
Adjusted PE Ratio (x)	n/a	9.5	n/a	4.5	22.1	16.8
PE Ratio (x)	n/a	9.5	n/a	5.0	29.5	16.8
Dividend Yield (%)	n/a	0.0%	0.0%	0.0%	0.0%	0.0%
EV/EBITDA (x)	n/a	6.2	n/a	1.9	8.1	6.1
EV/EBIT (x)	n/a	7.0	n/a	2.0	10.4	6.4

CAPITAL RAISING ASSUMPTIONS						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
Shares Issued (m)	0.0	0.0	0.0	0.0	0.0	0.0
Issue Price (A\$)	0.0	0.0	0.0	0.0	0.0	0.0
Cash Raised (A\$m)	0.0	0.0	0.0	0.0	0.0	0.0

KEY RATIOS						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
EBITDA/Sales Margin %	70.8%	69.5%	72.4%	70.0%	30.0%	30.2%
EBIT/Sales Margin %	60.4%	61.4%	68.1%	65.8%	23.3%	28.6%
Current ratio (x)	6.1	7.6	6.9	6.6	10.0	9.7
Net Debt : Equity (%)	-84.0%	-89.4%	-42.7%	-99.1%	-98.9%	-101.2%
ROE (%)	10.0%	47.6%	37.9%	60.2%	9.3%	11.2%
Dividend Payout Ratio (%)	n/a	0.0%	0.0%	0.0%	0.0%	0.0%

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

** Amortisation charges for MaxThera and Prolysis acquisitions in 4Q CY09

BALANCE SHEET SUMMARY (A\$'000)						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
Cash	55,386	86,704	51,986	189,878	181,848	208,224
Receivables	6,925	8,067	63,966	14,511	13,958	12,458
Inventories	0	0	0	0	0	0
Other	0	0	0	0	0	0
Total Current Assets	62,311	94,771	115,952	184,389	195,806	220,682
Inventories	0	0	0	0	0	0
Property Plant & Equip	7,229	6,924	6,864	6,608	6,787	6,929
Intangibles	11,408	8,402	14,704	7,680	0	0
Other	2,246	1,532	992	992	992	992
Total Non-Current Assets	20,883	16,858	22,560	15,281	7,778	7,921
TOTAL ASSETS	83,194	111,629	138,512	199,670	203,584	228,604
Accounts Payable	1,885	5,631	2,549	5,804	7,346	8,306
Borrowings	0	0	0	0	0	0
Provisions	1,055	1,561	3,451	1,122	1,344	1,427
Other	7,313	5,262	10,775	21,185	10,883	13,022
Total Current Liab	10,253	12,454	16,775	28,111	19,573	22,754
Borrowings	0	0	0	0	0	0
Provisions	6,991	2,143	86	86	86	86
Other	0	0	0	0	0	0
Total Non-Current Liab	6,991	2,143	86	86	86	86
TOTAL LIABILITIES	17,244	14,597	16,861	28,197	19,659	22,840
TOTAL EQUITY	65,950	97,032	121,651	171,473	183,925	205,764

CASH FLOW SUMMARY (A\$'000)						
Period	1H09A	FY09A	1H10A	FY10E	FY11E	FY12E
EBIT (excl Abs/Extr)	8,191	38,882	42,009	95,482	17,150	23,766
Add: Depreciation	570	1,184	629	1,316	1,322	1,357
Amortisation	840	3,931	2,026	13,160	7,681	0
Change in Pay.	(10,138)	(6,392)	(3,082)	173	1,542	959
Less: Tax paid	0	0	0	0	(17,083)	(6,781)
Net Interest	1,945	2,935	1,451	2,426	6,233	6,993
Change in Rec.	(2,655)	(3,797)	(55,899)	(6,444)	553	1,499
Other	(11,340)	(8,191)	(3,632)	(6,638)	(7,459)	83
Gross Cashflows	629	32,483	(14,472)	104,224	13,470	27,876
Capex	(462)	(798)	(196)	(1,000)	(1,500)	(1,500)
Free Cashflows	167	31,685	(14,668)	103,224	11,970	26,376
Buy-Back/Cap. Return**	(4,945)	(5,145)	(20,007)	(20,007)	0	0
Net Cash Flow	(4,778)	26,540	(34,675)	83,217	11,970	26,376

** 5% buy back, ending 7th Oct 2008, \$20m capital return in Nov 09

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