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Biota Holdings Limited (BTA)

Market Perform

Moves to a Fully Fledged Anti-Infective Drug Developer

\$2.72

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Key Points

Biota recently announced two anti-bacterial asset acquisitions from Prolysis Limited (Oxford, UK) and MaxThera, Inc. (Boston, MA).

For Prolysis, terms were A\$10.8m in BTA stock and a deferred payment of 15% from all milestones and royalties derived from licensing.

For MaxThera, terms were US\$1.2m in cash and US\$0.3m in BTA stock, with a deferred payment of 12% on all upfront and milestones derived from licensing.

Summary

Market capitalisation (M)	\$477.2
Share price	\$2.72
Shares on issue (M)	179.0
52 week low	\$0.28
52 week high	\$3.34
Ave Monthly Vol (M)	21.4
Valuation Per Share (fully diluted)	\$2.66
Cash (M) as at 30/9/09	\$77.1

Our View

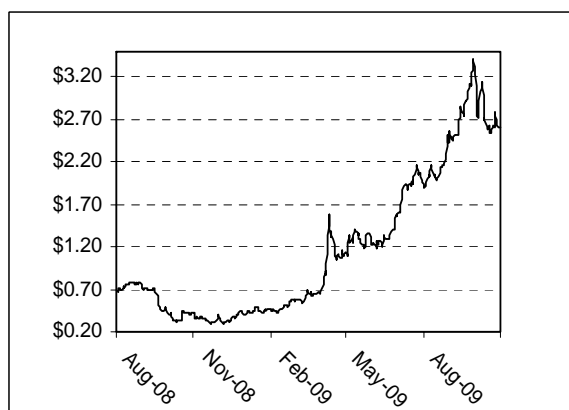
- Do the Acquisitions Make Strategic Sense?** – Until Biota articulated a strategy in FY09 to diversify its R&D pipeline, it was generally considered to be an anti-viral drug development company. The new acquisitions in bacterial antibiotic drug development diversify the business to a bona fide anti-infective company. It is important to note that while Biota has historically little internal skill sets relating to identification, isolation and characterisation of bacterial drug targets; it has a very strong small molecule drug development team. This is highly transferable to both MaxThera and Prolysis, in our view. Consistent with its operating model, Biota has acquired early stage technology, where it will spend collectively \$41m over the next 3-5 years (success dependent) to develop new drugs, possibly to Phase 1 clinical studies, and will likely seek partners to undertake efficacy studies (Phase 2). Both acquisitions represent a high risk/reward proposition, and as such we have notionally valued the technology at cost. We have analysed the science, overleaf.
- P&L Impact of the Acquisitions** – Biota has flagged it will write off the majority of the upfront consideration for both acquisitions, resulting in a one-off majority non-cash expense of \$12.4m in FY10 on our estimates. Excluding upfront charges, we estimate the EPS effects of the acquisition and additional R&D spend (excluding the prospects for licensing) as -6.5% in FY10, -39.4% in FY11 and -39.5% FY12. The key thematic for the next three FY, without additional partnering and offsetting research income will be a materially higher R&D cost base. We anticipate total operating expenses, including R&D, to move to \$53m in FY12. We note our current P&L estimates do not include (1) LANI partnering – 2H10e and (2) HRV partnering - 1H11e, both of which may add an additional 6.6c in EPS for FY10 and 9.9c in EPS for FY11.
- Outlook** – Biota remains on track to deliver a significant operating result for FY10, with 1Q10 PBT of \$18.1m recorded. We believe 2Q Relenza royalties will also be materially higher than the \$24m recorded in the 1Q (TC est. \$38m). As a result of the acquisitions and some upside adjustments to our FLUNET valuation owing to a more rapid pre-clinical development pathway than expected, we have reduced our valuation/PT by 8cps to \$2.66. We are forecasting a revised FY10 adjusted NPAT of \$84.5m, down 5.1% on previous estimates. On this basis, Biota currently trades on an EV/EBITDA of 3.1x and a PER of 5.7x. We maintain our Market Perform recommendation.

Key Financials (A\$'000)

Year End	FY09 Actual	FY10 Est.	FY11 Est.
Relenza Royalties	45,000	134,522	54,417
Partnering Income*	4,426	7,467	10,667
Total Revenue	63,334	150,678	72,178
Total Op. Expenses	(15,810)	(16,492)	(12,217)
R&D Expenses	(13,348)	(24,617)	(32,973)
EBITDA	43,997	106,925	22,038
Normalised NPAT	20,343	84,482	17,807
Adj. NPAT	38,181	84,482	17,807
Adj. EPS (c)	21.7	47.6	9.9
Adj. PE Ratio (x)	12.6	5.7	27.4

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

Share Price Graph (A\$)



A Science Synopsis Behind the Acquisitions

Prolysis Limited – Scientific Validation, Commercial Interest

Prolysis was established in 1998 and is a spin-out from the University of Oxford. It is dedicated to the discovery and development of effective anti-bacterial compounds. The Company has two active pre-clinical programs, targeting a bacterial enzyme known as DNA gyrase and a second program targeting cell division.

Prolysis consideration of A\$10.8m in BTA scrip + deferred payments.

As noted, Biota has acquired the assets of Prolysis for A\$10.8m in Biota scrip of which 60% is escrowed for 12 months and a deferred payment relating to a 15% share of all milestones and royalties (excluding upfront payments) from any licensing Biota undertakes. Biota has committed to spend A\$25m over the next 3 years developing key programs.

No issued patents from Prolysis.

We have undertaken some preliminary patent application searches (and issued patents) using both the US patent office and the World Intellectual Property Organization (WIPO) and found nine PCT applications in process from Prolysis. There is currently no issued US patents. From an IP perspective, there still remains a risk that Prolysis' small molecule inhibitors may not be sufficiently novel to provide for patent allowance.

DNA Gyrase, Topoisomerase Program

Prolysis has developed a set of compounds that dually target a region on two key bacterial enzymes, known as DNA gyrase and topoisomerase IV which are crucial for unwinding/disassembly of bacterial DNA (and therefore replication). Bacterial DNA gyrase and topoisomerase IV are well-characterised, clinically validated targets. The fluoroquinolone antibiotic class exert their antibacterial activity through inhibition of the catalytic subunits of both these enzymes. The fluoroquinolone market is heavily dominated by ciprofloxacin and levofloxacin, which together command US\$3.3 billion of global sales, according to one market research group. As with the majority of the older antibiotics, resistance continues to emerge.

Development of inhibitors against the so called ATPase sites for each has been troublesome. The advantage of the Prolysis compounds is they simultaneously inhibit both bacterial enzymes, owing to a region common to both, namely the ATPase binding subunit. This has been attempted by others, however in Prolysis' case, this has led to a series with potent Gram-positive antibacterial activity and a low resistance frequency.

We note in the literature that Vertex Pharmaceuticals (NASDAQ:VRTX) has also published information relating to a potent class of inhibitors, able to bind both ATPase regions of gyrase and topoisomerase with significant effect, and there exists a number of other natural product drugs including coumarins, such as novobiocin (withdrawn from the market) that are also able to dually inhibit.

Vertex has attempted a similar strategy to Prolysis, seemingly w/out success.

According to Vertex, such an approach means the likelihood of bacterial resistance is low (1 in 10^{14} bacteria). Vertex's lead drug VX-883, was slated to commence a Phase 1 clinical trial in 2007 subject to successful pre-clinical development. However, we note no such trial has been initiated, suggesting this program failed pre-clinically, or further optimisation work is being carried out. Given the published efficacy data, it is more likely VX-883 failed toxicology studies, though we have been unable to confirm this aspect. Achillion (NASDAQ:ACHN) is also in late pre-clinical stage of development for its dual action gyrase/topoisomerase inhibitor, though we note this inhibitor does not target the ATPase region.

Cell Division Inhibitor (CDI) Program

The CDI program is our preferred program.

This is our preferred program. We have analysed Biota's statements, and found that the series of compounds ("hits") derived from Prolysis are targeting a bacterial protein essential for cell division called FtsZ, and more particularly the compound generated is PC190723. Bacterial cell division is of considerable interest as a new antibacterial target. The process involves a large number of conserved proteins that are essential for the viability of bacteria. Novel inhibitors of bacterial cell division are expected to be highly selective and free of undesirable side-effects in man.

PC190723 is a potent *in vitro* and *in vivo* inhibitor of *Staphylococcus aureus* and MRSA, as shown by Prolysis in Sept 2008. We have analysed potential competitive inhibitors against FtsZ in either pre-clinical or clinical development. We note a series of small molecule FtsZ inhibitors developed by Merck in 2003, and a second class called Zantrins, though we could find no evidence such compounds have progressed into clinical development.

Indeed, the Zantrins were not considered suitable as therapeutic drugs. Others seem confined to the research laboratory at this juncture. Based on our comparisons, Prolysis' PC190723 appears more potent and effective than previous inhibitors, though we note resistant *S. aureus* mutants can be created than render this inhibitor ineffective. We understand improved compounds have since been created which are proving less sensitive to resistance mutants emerging. Moreover, with Biota's expertise in medicinal chemistry, oral forms of these compounds may result, which is likely to generate significant interest among potential partners in our view.

MaxThera, Inc. – Promising, though Skinny on IP

MaxThera acquisition comprised US\$1.2m cash and US\$0.3m in BTA scrip.

As noted, Biota has acquired the IP assets and drug development programs of MaxThera for US\$1.2m cash and US\$0.3m in Biota shares, with a deferred consideration of 12% for MaxThera holders of any upfront/milestone payments Biota may secure via direct licensing of the two drug development programs acquired. We note Oscient Pharmaceuticals Corp (in chapter 11 bankruptcy) entered into a license and contribution Agreement with MaxThera, Inc. in 2005, who were granted an exclusive license to certain patent rights relating to legacy anti-infective technology, covering inhibitors of a key bacterial enzyme phosphopantetheine adenyl transferase (PPAT) and a second enzyme Enolpyruvyl transferase (EPT, or MurA).

PPAT is the lead program, with little competitive threats apparent.

PPAT is essential for survival of bacteria, including *Staphylococcus aureus*, which is the causative agent of many complicated bacterial infections, with multi-drug resistance a key attribute for methicillin resistant *Staphylococcus aureus* (MRSA). Therefore, PPAT represents a potential new target for antibiotic therapy. We have found little evidence of competitive threats in developing PPAT inhibitors, and no PPAT inhibitors are currently in clinical development. Moreover, there appears to be scant evidence in the literature (particularly since 2007) on studies investigating PPAT or derivation of small molecule inhibitors against this target. This may indicate a high degree of failure to derive such inhibitors by others or possibly some questions over the target (PPAT).

Based on the patent applications filed by MaxThera (see below), there is little *in vivo* evidence presented on the potency of the PPAT inhibitors in animal models of infection. Some *in vitro* evidence on the inhibitory potential of the compounds has been investigated. However, we understand from Biota that there are some very early indicators of *in vivo* (animal) efficacy for the early compounds. In our view, the early stage nature of the program, the lack of validation of PPAT via third parties either clinically or even pre-clinically in literature searches is suggestive that its program represents a high-risk/ high reward play for Biota.

EPT inhibitor has made it to market, called fosfomycin.

EPT (MurA) inhibitors are not novel. EPT plays a vitally important role in a broad range (gram +/-) bacterial species for formation of the bacterial cell wall, and as such has been targeted by a number of researchers over an extended period. Despite this, there is only one commercial antibiotic, fosfomycin (marketed as Monurol™ in the US), that has resulted from targeting EPT/MurA, which has suffered from bacterial resistance, and as such is rarely used for sustained treatment of infections.

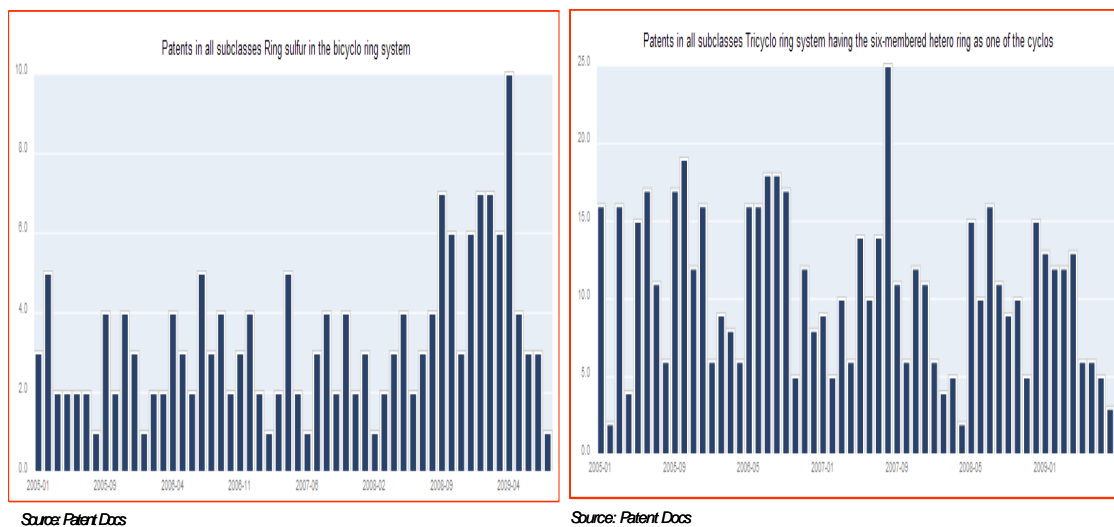
We were unable to locate any current clinical trials utilising EPT/MurA inhibitors to treat bacterial infections. Fosfomycin is currently approved in uncomplicated urinary tract infections of women. MaxThera's EPT program is earlier stage than that of PPAT, with no lead compound yet selected, according to Biota. As such, we consider in a similar light to PPAT: high risk/ high reward.

Relatively skinny IP position, representing 4 filed applications, none issued.

We have examined issued or pending US patents owned by MaxThera, and have identified only two patent applications, one for each of the compounds targeting both PPAT and EPT (MurA), which have yet to be prosecuted to issue and represent a risk to Biota that its patent rights may be narrow in scope or found not to be novel. However, using the PCT application process, MaxThera has filed four patent applications, all of which relate to PPAT inhibitors.

For both PPAT and EPT patents, molecularly related compounds have been filed from 2005-2009 that could potentially impact on novelty (see below left for PPAT, below right for EPT). It is

uncertain whether such related compounds have any applicability to either PPAT or EPT.



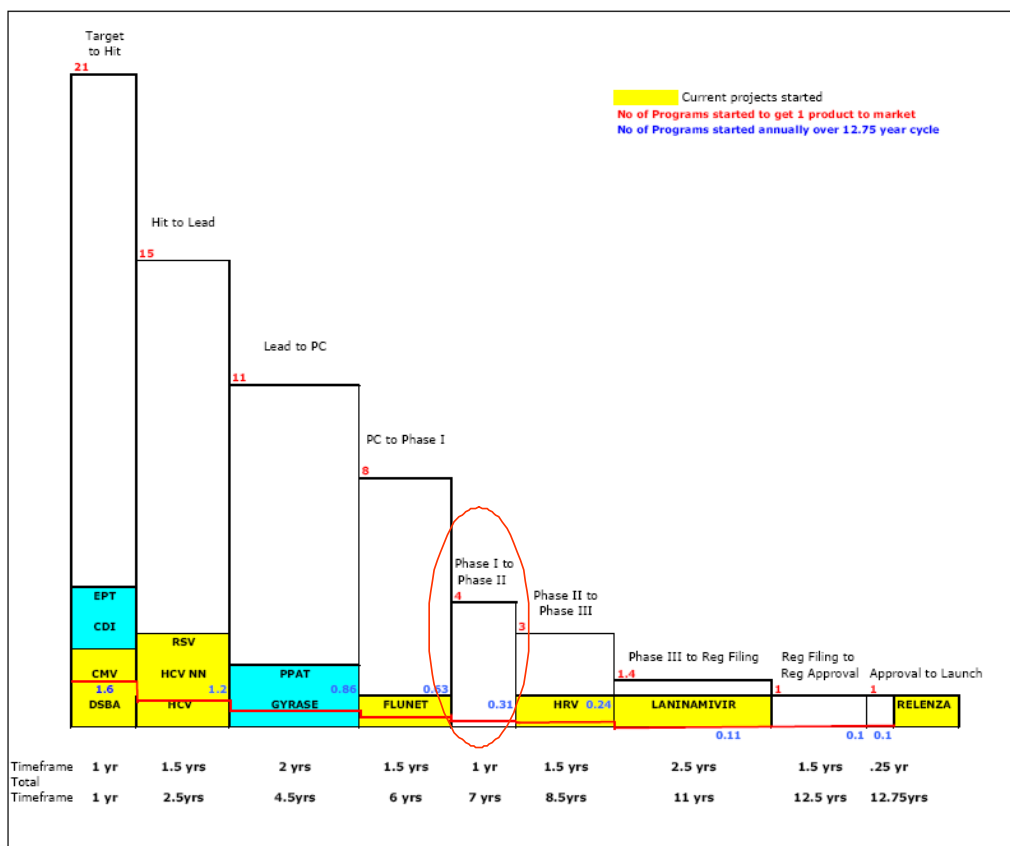
MaxThera has not been able to attract US venture funding.

The lack of US venture funding of MaxThera, while concerning in our view, has probably allowed Biota to acquire the two early stage programs at a relatively modest upfront cost. MaxThera had historically received approximately US\$2.8m in US govt funding, and based on the lack of developmental initiatives since 2007, has probably been capital constrained.

Analysis of Biota's R&D Pipeline – Room For Further Acquisitions?

Phase 1 drugs remains an acquisition goal for Biota.

With the acquisition of MaxThera and Polylis, Biota has essentially reloaded its pre-clinical pipeline with four programs, two at target/hit and two at lead stage (collectively, all pre-clinical), as shown in blue highlight below. Examining the pipeline, we note a deficiency in Phase 1 assets. Our view on the FLUNET program is it remains at least 1-2 years from a Phase 1 clinical trial. We believe Biota will consider acquiring Phase 1 clinical assets, provided the "right" opportunity presents.



Apparently low anti-viral assets to consider.

Most likely will be another anti-bacterial asset purchase.

Room to move, though mgt likely to wait for certainty over Relenza.

Examining what we consider the Phase 1 virology sweet spot for Biota, namely small molecule inhibitors of cytomegalovirus (CMV), influenza, human rhinovirus (HRV), respiratory syncytial virus (RSV) and hepatitis C virus (HCV) we make the following observations: zero active Phase 1 programs in CMV, HRV and influenza; several active Phase 1 studies in RSV albeit held by major pharmaceutical companies; and two programs in HCV we consider potentially accessible by Biota's business development team. On this basis, we consider it unlikely Biota will acquire anti-viral programs at Phase 1 over the near term, but potentially will make an offer over transition drugs that have progressed from pre-clinical but have yet to commence a human Phase 1 clinical study. While difficult to ascertain with any degree of confidence, there are likely to be many such opportunities.

In our view, if Biota was to acquire an additional active program at Phase 1 over the near term, it will most likely represent small molecule drugs targeting bacterial species, versus a strict virology product. We believe this will depend on the next 2Q of Relenza royalties which provides greater certainty to Biota's operating cash flows for FY10 (TC est. \$80.3m) and therefore deployment for upfront asset licensing, which will likely be materially higher (US\$5-US\$15m) at Phase 1 and follow on milestones, or outright acquisitions.

Changes to Forecasts

We present changes to our FY10-FY12 forecasts resulting from the acquisitions and expected expenditure on the programs over the same period, below. We note our forward P&L does not include upfront/milestone expectations from either LANI or HRV at this juncture.

Changes to Forecasts

	FY10E			FY11E			FY12E		
	Previous	Revised	Change	Previous	Revised	Change	Previous	Revised	Change
Relenza Volumes (m)	76.9	76.9	0.0%	31.1	31.1	0.0%	31.6	31.6	0.1%
Relenza Royalties (A\$m)	134.5	134.5	0.0%	54.4	54.4	0.0%	55.3	55.3	0.1%
EBITDA	113.6	106.9	-5.9%	40.9	22.0	-46.1%	49.8	25.2	-49.5%
Reported NPAT	89.0	72.1	-19.0%	28.7	17.8	-38.0%	38.0	23.5	-38.1%
Reported EPS (c)	50.9	40.6	-20.2%	16.4	9.9	-39.4%	21.7	13.1	-39.5%
Adj. NPAT	89.0	84.5	-5.1%	28.7	17.8	-38.0%	38.0	23.5	-38.1%
Adj. EPS (c)	50.9	47.6	-6.5%	16.4	9.9	-39.4%	21.7	13.1	-39.5%

Source: Taylor Collison estimates

Outlook

From our perspective, Prolysis represents the better of the two acquisitions for Biota, despite higher (non-cash) cost, owing to a greater general commercial interest in the bacterial targets presented, superior validation from a related clinical perspective and stronger IP build. Given the difficulty in valuing early stage, pre-clinical assets, we have elected to value both Maxthera, Inc. and Prolysis Limited at cost, representing a technology value of A\$1.6m and A\$10.8m, respectively.

The next 12 months offer some enticing news flow for investors in Biota. As we have flagged previously, we expect demonstrably stronger 2Q Relenza royalties (\$38.1m) owing to a full quarterly production run-rate for Diskhaler (90m annual capacity) and potential FDA approval for the new Rotahaler format, with capacity of 100m expected by year's end. Our milestone chart is shown across.

Biota 12 Month Milestone Chart	Timing
Announcement of LANI Phase 1 (UK) studies	4Q CY09
GSK 4Q09 Royalties	Feb-10
Regulatory filings of LANI in Japan	before 2Q 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
GSK 3Q10 Royalties	Oct-10

Source: Taylor Collison estimates

Given the surprisingly rapid development of FLUNET to formal pre-clinical /Phase 1 stage and the demonstrable interest in government funding of new influenza drugs we have increased our valuation of FLUNET to \$50m, or \$0.28 per share. We have not adjusted our valuation assumptions on the remainder of the Biota pipeline, though out of our modelling probably see most upside to the risk-adjusted HRV valuation of \$51m upon a licensing transaction. We have reduced our valuation/PT by 8cps to \$2.66 as a result of the acquisitions and additional R&D spend and are forecasting an FY10 adj. NPAT of \$84.5m, down 5.1% from previous estimates. We maintain our Market Perform recommendation

Maintain Market Perform recommendation.

Biota Holdings Limited - Summary of Forecasts

BTA \$2.72

PROFIT & LOSS SUMMARY (A\$'000)

Period	FY08A	FY09A	FY10E	FY11E	FY12E
Relenza Royalties	20,544	45,000	134,522	54,417	55,333
Partnering (Licence) Income	5,871	4,426	7,467	10,667	12,000
Research income (inc Grants)	15,042	10,966	6,020	1,420	700
Total Revenue	44,989	63,334	150,678	72,178	82,162
<i>Growth (pcp)</i>	-21.5%	40.8%	137.9%	-52.1%	13.8%
Net Gain on GSK Settlement	0	12,756	0	0	0
Net Operating Revenue	3,592	60,280	134,186	59,961	69,625
R&D Expenses	(10,287)	(13,348)	(24,617)	(32,973)	(38,364)
EBITDA	(9,897)	43,997	106,925	22,038	25,162
Depreciation	(933)	(1,184)	(1,108)	(1,463)	(1,471)
Amortisation	(1,681)	(3,931)	(4,750)	(3,265)	(387)
EBIT	(12,511)	38,882	101,068	17,310	23,304
Net Interest	3,202	2,935	2,645	4,949	6,099
Pre-Tax Profit	(9,309)	41,817	103,712	22,259	29,403
Tax Expense	2,820	(3,636)	(19,230)	(4,452)	(5,881)
Minorities	0	0	0	0	0
NPAT Normalised *	8,761	20,343	84,482	17,807	23,523
NPAT Adj.	(6,489)	38,181	84,482	17,807	23,523
<i>Growth (pcp)</i>	n/a	n/a	121.3%	-78.9%	32.1%
Net Adjustments	0	0	(12,400)	0	0
Reported Profit	(6,489)	38,181	72,082	17,807	23,523

PER SHARE DATA

Period	FY08A	FY09A	FY10E	FY11E	FY12E
Adjusted EPS (c)	(3.5)	21.7	47.6	9.9	13.1
<i>Growth (pcp)</i>	n/a	n/a	119.7%	-79.1%	32.1%
Reported EPS (c)	(3.5)	21.7	40.6	9.9	13.1
<i>Growth (pcp)</i>	n/a	n/a	87.4%	-75.5%	32.1%
Dividend (c)	0.0	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%	0%
Gross CF per Share (c)	2.6	18.4	45.2	14.0	15.6
NTA per share (c)	28.0	50.3	88.9	99.9	113.3

VALUATION MULTIPLES

Period	FY08A	FY09A	FY10E	FY11E	FY12E
Adjusted PE Ratio (x)	n/a	12.6	5.7	27.4	20.7
PE Ratio (x)	n/a	12.6	6.7	27.4	20.7
Dividend Yield (%)	n/a	0.0%	0.0%	0.0%	0.0%
EV/EBITDA (x)	n/a	8.9	3.1	14.0	11.2
EV/EBIT (x)	n/a	10.0	3.3	17.8	12.1

CAPITAL RAISING ASSUMPTIONS

Period	FY08A	FY09A	FY10E	FY11E	FY12E
Shares Issued (m)	0.0	0.0	0.0	0.0	0.0
Issue Price (A\$)	0.0	0.0	0.0	0.0	0.0
Cash Raised (A\$m)	0.0	0.0	0.0	0.0	0.0

KEY RATIOS

Period	FY08A	FY09A	FY10E	FY11E	FY12E
EBITDA/Sales Margin %	-22.0%	69.5%	71.0%	30.5%	30.6%
EBIT/Sales Margin %	-27.8%	61.4%	67.1%	24.0%	28.4%
Current ratio (x)	3.4	7.6	14.3	14.4	15.1
Net Debt : Equity (%)	-94.8%	-89.4%	-90.1%	-94.3%	-96.4%
ROE (%)	-9.6%	47.6%	65.4%	10.4%	12.3%
Dividend Payout Ratio (%)	n/a	0.0%	0.0%	0.0%	0.0%

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

BALANCE SHEET SUMMARY (A\$'000)

Period	FY08A	FY09A	FY10E	FY11E	FY12E
Cash	60,164	86,704	145,493	169,134	195,556
Receivables	4,270	8,067	15,068	13,714	12,324
Inventories	0	0	0	0	0
Other	0	0	0	0	0
Total Current Assets	64,434	94,771	160,561	182,848	207,880
Inventories	0	0	0	0	0
Property Plant & Equip	7,543	6,924	7,316	7,353	7,382
Intangibles	12,113	8,402	3,652	387	0
Other	5,168	1,532	1,532	1,532	1,532
Total Non-Current Assets	24,824	16,858	12,501	9,272	8,914
TOTAL ASSETS	89,258	111,629	173,062	192,120	216,795
Accounts Payable	12,023	5,631	6,027	7,218	8,216
Borrowings	0	0	0	0	0
Provisions	1,122	1,561	1,122	1,344	1,480
Other	6,059	5,262	4,102	4,102	4,102
Total Current Liab	19,204	12,454	11,251	12,664	13,798
Borrowings	132	0	0	0	0
Provisions	6,622	2,143	296	134	152
Other	0	0	0	0	0
Total Non-Current Liab	6,754	2,143	296	134	152
TOTAL LIABILITIES	25,958	14,597	11,547	12,798	13,950
TOTAL EQUITY	63,300	97,032	161,514	179,322	202,844

CASH FLOW SUMMARY (A\$'000)

Period	FY08A	FY09A	FY10E	FY11E	FY12E
EBIT (excl Abs/Extr)	(12,511)	38,882	101,068	17,310	23,304
Add: Depreciation	933	1,184	1,108	1,463	1,471
Amortisation	1,681	3,931	4,750	3,265	387
Change in Pay.	6,019	(6,392)	396	1,191	998
Less: Tax paid	2,820	0	(19,230)	(4,452)	(5,881)
Net Interest	3,202	2,935	2,645	4,949	6,099
Change in Rec.	5,080	(3,797)	(7,001)	1,354	1,389
Other	(4,090)	(8,191)	(8,196)	(3,205)	(233)
Gross Cashflows	4,815	32,483	80,289	25,141	27,922
Capex	(3,785)	(798)	(1,500)	(1,500)	(1,500)
Free Cashflows	1,030	31,685	78,789	23,641	26,422
Buy-Back/Cap. Return**	(3,022)	(5,145)	(20,000)	0	0
Net Cash Flow	(1,992)	26,540	58,789	23,641	26,422

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

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