

Biota Holdings Limited

Influenza franchise update



Wilson HTM
INVESTMENT GROUP

1 August 2008

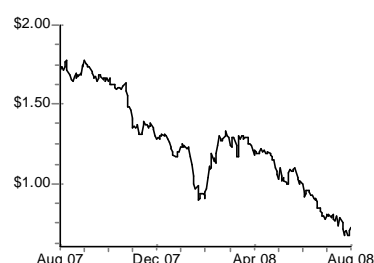
\$0.75

BUY

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Price Performance



Security/Capital Details

ASX Code	BTA
Market Cap	\$129 M
Issued Shares	181.0 M
Avg Mth T'over	9.27 M
12 Mth High – Low	\$1.78 - \$0.67

Key Data/Ratios – FY 2008

Cash	\$60M
EBIT / Sales	\$40M
EV	\$69M
Interest Cover	x
ROE	2.0%
EPS Growth	-82.8%
PEG Ratio	-1.10 x
NTA / Share	\$ 0.32
DCF	\$ 1.32
12 Mth Price Target	\$ 1.42

BUY: Total return +10% or more over a 12 month period

HOLD: Total return expected to be between +10% to -10% over a 12-month period

SELL: Total return expected to be -10% or more over a 12 month period

TOTAL RETURN OR TSR = capital growth in share price + expected dividend yield in that period

Year to June	NPAT (Rep) \$M	EPS (Norm) c	EPS Growth %	PER x	P/CF x	EV/EBITDA x	DPS c	Div Yld %	Franking %
2007a	20.2	11.4	280.3	10.6	10.3	8.0	0.0	0.0	0
2008e	1.4	2.0	-82.8	40.8	67.2	201.6	0.0	0.0	0
2009e	15.0	9.3	375.0	8.6	9.0	6.8	0.0	0.0	0
2010e	13.6	8.6	-7.8	9.3	27.2	8.0	0.0	0.0	0

Equities Research – Biota Holdings Limited

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Recommendation

Mixed signals from within the BTA influenza franchise this week with a soft quarterly Relenza royalty number and positive Phase II clinical data from the LANI (2nd generation) influenza drug program. LANI now sits as the dominant asset within the BTA influenza franchise. The BTA price has been weak of late, but with litigation risk gone it is a different stock. The stock continues to trade below its cash & royalty aggregate and the market seemingly ignores LANI – a program that Daiichi-Sankyo will now take into the Phase III clinic. We have incorporated another modest upgrade to our price target, which is now 142 cps. We reiterate our BUY recommendation.

Key Points

- We have reviewed our Relenza modelling in light of a weak quarterly result, but remain confident about the outlook over FY09-13. We estimate that a further \$150M of royalties are receivable over this period, but warn investors that the timing of Relenza royalties is always unpredictable.
- The lead compound in the LANI project, CS8958, has successfully completed a Phase II trial in Japan. Daiichi-Sanyko will take this product into Phase III clinical trials later this year, during the Northern Hemisphere influenza season.
- In Phase II, CS8958 had acceptable safety and tolerability and was efficacious in reducing symptoms in adult patients with naturally acquired influenza A or B infections. It was statistically indistinguishable from Tamiflu which is given twice daily for 5 days.
- We believe this dosing feature will attractively differentiate CS8958 in the seasonal influenza market. None of the available neuraminidase inhibitor drugs (Relenza, Tamiflu) are effective when given just once – both drugs require twice daily treatment for 5 days. CS8958 will be formulated as a once-only, inhaled, disposable product.
- CS8958 now sits as the dominant asset with the BTA influenza franchise. Our timeline expectations are for a Japanese product launch in 2010/1 and a US launch in 2012.
- We have applied a modest upgrade to our valuation, capturing the following elements:
 - Base year for our DCF Relenza valuation is now FY09 which reduces the value (reflecting the fact that the product is closer to patent expiry);
 - Small downward adjustments to forward estimates of Relenza order filling, based on updated information;
 - De-risking the Phase II development stage for CS8958 has increased the value of LANI.
- Price target is now set at 142 cps. BUY retained.



Update - BTA Influenza Franchise

Mixed signals from within the BTA influenza franchise this week with a soft quarterly Relenza royalty number and positive Phase II clinical data from the LANI (2nd generation) influenza drug program. LANI now sits as the dominant asset within the BTA influenza franchise. The BTA price has been weak of late, but with litigation risk gone, the asset pipeline should now get noticed. The stock continues to trade below its cash & royalty aggregate and seemingly ignores LANI – a program that Daiichi-Sankyo will now take into Phase III clinical trials. We have incorporated another modest upgrade to our price target, which is now 142 cps. We reiterate our BUY recommendation.

Relenza model revisited

Relenza had a weak quarter in Q2CY2008 with just \$6M of sales, resulting in royalties of only \$400,000 to BTA. That prompted us to review our underlying assumptions about the dynamics of the international stockpiling market and GSK's activities in supplying product. This is a difficult product to model because transparency is poor. Relenza is not a product that is sold in a continuous fashion – large orders are placed in a sporadic fashion by governments as a way of protecting against the threat of future pandemics. The information we have about initial orders placed to date are simply summarised:

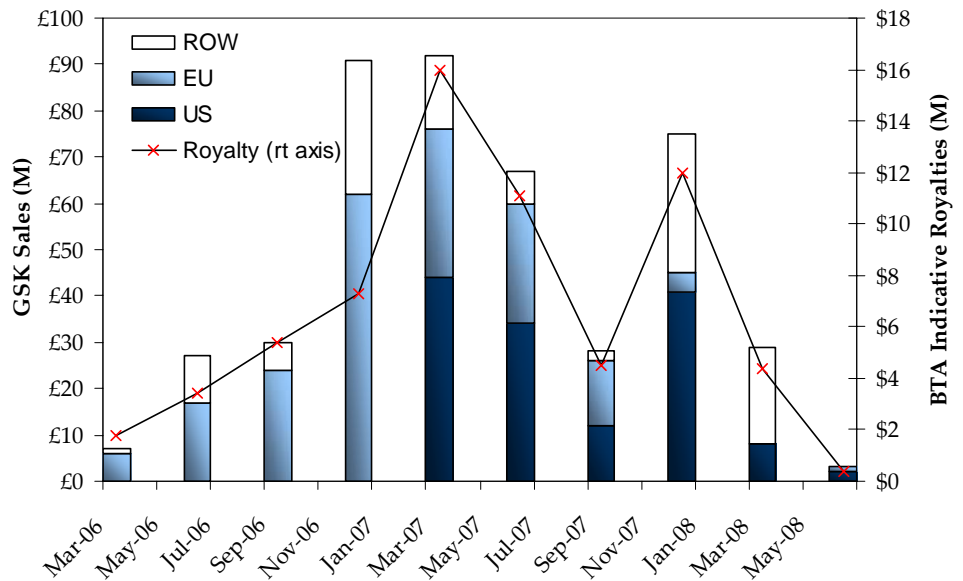
- US – 21 million courses
- EU – 19.1 million courses
- ROW – 1.55 million courses

Approximately 41.5 million courses ordered in aggregate, the supply of which began in early 2006. Since that time, GSK has reported sales revenue of £141M in the US, £186M in the EU and £122M in the ROW. With almost zero presence in the seasonal retail market, we assume that 100% of this reported revenue is from supplying government Relenza stockpiles. Our drug pricing assumptions, which are consistent with BTA's best estimates (pricing is not disclosed by GSK) are US\$24/course in the US, €22/course in the EU and US\$36/course in the ROW.

We estimated the number of courses represented by GSK's sales using historical FX rates. Taking the US as an example – GSK has collected £141M or approximately US\$268M. At US\$24/course – these sales numbers reflect the placement of 11 million courses, or about half the original order target. Similar analyses reveal that approximately 55% of the European orders have been booked as sales by GSK and that there has been an oversupply in the ROW geographies. The latter point suggests that some additional orders (probably from Japan) have also been filled.



Figure 1: Correlation between GSK quarterly Relenza sales and indicative royalties reported by BTA. In aggregate, GSK has taken £449M in Relenza sales over the stockpiling period to date.



Source: WHTM Research

On balance, we remain comfortable with our model as far as the aggregate amounts of Relenza orders are concerned. Europe appears to be slightly ahead of the supply schedule in our model. We estimate that there are still 18.9 million courses of Relenza to be filled from the start of 2HCY2008 and that it will take to the end of 2HCY2009 to complete the orders – the majority of that business to come from the US. In aggregate, that represents a further \$154M of royalties to be received out to the middle of FY2013. The timing of those royalty flows is less certain – as exemplified by the current quarter. Historically, Q1 and Q4 of the Australian financial year are weak; even the stockpiling market displays some degree of seasonality. We remain of the view that Relenza royalties will average \$26-30M a year, though warn investors to expect considerable variability on both quarterly and annual bases.

With Europe and ROW order filling slightly ahead of our estimates we have taken that surplus out of our forward order filling expectations and this has resulted in a ~5% reduction in future royalties, in aggregate. Our revised estimates are provided in Figure 2. Note that the royalty revenues reported in any given financial year reflect an April year end. For example in FY08, BTA will receive approximately \$28M royalties in cash, but report a revenue line of \$20.5M after other adjustments (product returns, over/underpayments) are accounted for.

Figure 2: Forecast Relenza royalties FY09-15 after adjustments to our international stockpile building and replenishment models

	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15
Relenza royalty (cash)	\$ 28.0	\$ 19.6	\$ 29.6	\$ 27.9	\$ 30.0	\$ 32.9	\$ 13.4	\$ -
BTA revenue line estimates (April yr end)	\$ 20.5	\$ 21.3	\$ 27.6	\$ 28.2	\$ 29.6	\$ 32.3	\$ 17.3	\$ 2.7

Policy makers in both Europe and the US have called for substantial increases in influenza drug stockpiles. European policy is to increase the proportion of Relenza in stockpiles relative to that of Tamiflu. US policy objectives seek to increase their stockpile from the current target of 81M courses to 190M courses. In addition to this, GSK and Roche are both targeting major corporations for drug stockpiling, to protect their workforces.



Changes to the Relenza valuation

We are now valuing the Relenza asset with FY09 as our base year, which necessarily leads to a lower valuation than when we initiated coverage in FY08. Relenza is a wasting asset on account of finite patent life. We continue to discount Relenza at 10% pa and in so doing, we derive an FY09 valuation of \$114.8M or 66 cps. Looking ahead 12 months, the Relenza asset contributes 60 cps to our target price.

LANI Phase II Data

In our May 2008 BTA initiation of coverage report we flagged the importance of the LANI program to our view of BTA's valuation. In fact, this program comprised more than half the value we ascribed to BTA at that time. Investors will recall that BTA co-owns the LANI program with Daiichi-Sankyo. LANI is a program which seeks to develop longer acting neuraminidase inhibitor drugs against influenza. The commercial arrangements are split between geographies – Daiichi agrees to pay BTA an undisclosed royalty on sales in Japan. Daiichi pays BTA no milestone payments because it is funding Phase II and Phase III development. The rest of the world (ROW) rights are likely to be partnered jointly by BTA and Daiichi – and in this case, any milestones and royalties are shared 50:50 by the parties.

The very strong position we took on the LANI program was based on the putative dosing benefits of CS8958 – this molecule has been designed to be a once-only inhaled drug for influenza treatment and once-weekly for prophylactic use. Both Relenza and Tamiflu are dosed twice daily for 5 days to be efficacious. If patients do not comply with the full course of treatment, these drugs do not work. Clearly a one-dose product takes patient compliance out of the equation – and that will be very attractive to primary care physicians and in the emergency setting, where the majority of influenza prescriptions originate. Government and corporate stockpiling bodies should also take note of this product, because the dosage form means less physical storage capacity, a tenth of the transport and distribution challenge and most importantly – superior compliance and efficacy. Tamiflu has already demonstrated to the world what a successful influenza drug can achieve (\$1.84 billion in CY2007). Our attraction to this program was also based on the distinct lack of competition we observed. Peramivir (Biocryst/Shionogi) was the only competing Phase II neuraminidase inhibitor in the pipeline at the time of initiation.

CS8958 – Clinical development and the future

Phase II LANI trials commenced in November 2007, targeting the northern hemisphere's influenza season. Two studies were planned – one in Japan, one elsewhere in Asia – and the objective was to test the effectiveness of CS8958 in adult patients with naturally acquired influenza A or B. Enrolment was reasonably brisk – the Japanese arm completed enrolment in February 2008. The second Phase II study completed enrolment in April 2008 and flagged that data would be available mid-2008.

Data from the first Phase II trial reported on 31 July 2008 showing that once-only inhalation of CS-8958 was statistically indistinguishable from Tamiflu (given twice daily for 5 days). This is the key result we were looking for, but that needs to be confirmed by the second Phase II study (which should report in ~2 months' time) and in Phase III studies.

It was particularly encouraging to read that Daiichi-Sankyo will support Phase III studies for CS8958 on the strength of this Phase II study. This is a significant decision because it instils faith in both the clinical result and the commercial opportunity. Phase III drug development requires an order of magnitude greater commitment than Phase II; primarily because the manufacturing and regulatory status for Phase III drug material needs to be identical to that intended for on-market use. The first Phase III study will target the next Autumn/Winter influenza season in the Northern Hemisphere. Phase II began in November and reported in July – we would expect to see similar timing for the Phase III.



The Phase III program does face a seasonal risk, though – the autumn/winter period has to be bad enough to ensure enough people contract influenza and present for recruitment. The Phase II trial benefited from an “early” winter, which enabled rapid recruitment. We note that Phase III will be conducted using more centres, including multiple Asian countries, which will help mitigate this risk. Phase II comprised several hundred patients. We would expect the Phase III study to enrol >500 patients and if successful, will support registration in Japan as a therapeutic agent. Further studies may be required to approve the drug as a prophylactic drug. These trials will take substantially longer to conduct than the acute, therapeutic trial we have just witnessed. At least two further Phase III studies will be required to approve the drug in the US. There is no reason to change the LANI commercialisation timeline we put forth in our May report. Phase II completion came in line with our expectations and we would expect Daiichi to hit their target and begin dosing the first Phase III towards the end CY2008. The product is likely to reach the Japanese market first, possibly as soon as late CY2010 for therapeutic use. Our outlook for the US market is longer term, looking to a product launch in 2012.

CS8958 – commercialisation options

For CS8958 to get to market, it is likely that a third party will become involved to complete the development and marketing in geographies outside Japan. Daiichi could elect to commercialise worldwide, but we view that as unlikely. Potential partners really only include major pharma with established businesses and experience in the antiviral space – GSK, Roche, Schering, Novartis, Sanofi. The seasonality of the market, to our mind, is not a problem for Pharma to understand. It characterises more than one multibillion dollar market – look to the influenza vaccine markets and the RSV market as good examples. Parties looking to understand the potential of the retail influenza market need look no further than Tamiflu, which dominates the market. Even now, amid rising concern about the safety of that drug, Tamiflu is at an all time high as far as prescription rates are concerned.

Most of the retail market (~60%) exists within Japan, so the uncertainty around ROW (rest of the world) partnering is not that much of a concern to us at this stage. The ROW is clearly an opportunity and there are really only 3 players worth considering at this point. It is unlikely that Relenza will play a role in the seasonal market once CS8958 becomes available. The prospects of generic Relenza entering this market is low. To get a generic Relenza approved under an abbreviated new drug application (ANDA) or equivalent regulatory submission, the developer will be tied to using GSK’s inhaler device, which is widely recognised as sub-optimal. Generic versions of Tamiflu are more likely, given the oral dosing feature.

Earlier this week Biocryst Pharmaceuticals announced positive Phase II data for peramivir as a treatment for influenza. They have partnered the Japanese rights for this drug with Shionogi (Japan). Their Phase II data set came from a study where patients were given peramivir intravenously. Follow-up studies using a subcutaneous delivery are planned. Shionogi, too, has committed to Phase III studies of this drug. So it is fair to say that the Daiichi/BTA and Shionogi/Biocryst programs are level pegging in terms of development.

We favour the Daiichi/BTA compound for several reasons. Firstly, the mode of delivery is more convenient (inhalation versus intravenous) – particularly in the emergency medicine setting. Intravenous drugs in an ER setting demand more resources, equipment and nursing contact. Second, peramivir is an old drug that has failed on several occasions in the past – perhaps not all of them due to the route of administration. That said, the peramivir program is being watched with interest – as are prescription rates/trends within the seasonal influenza market.

Changes to the LANI valuation

The only change we have made to our LANI valuation is to remove the time and risk from the Phase II option. Investors will recall that we modelled the value of LANI using our options methodology, identifying four key events in the timeline: a) Phase



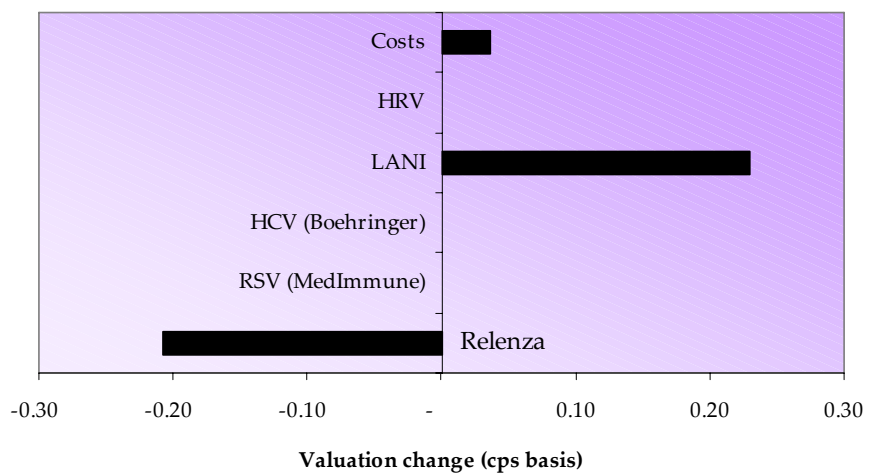
II; b) partnering; c) Phase III and d) product approval. Success in Phase II means we set the Phase II risk to zero, having previously risked this phase of development at 80% chance of success. The other risk factors are unchanged. The project timing is also unchanged as BTA has reached this milestone within the timeframe they said they would. Further, with a multinational involved in Phase III, we expect this program will stay on track. In value terms, this adjustment has lifted our valuation of LANI from \$112M to \$143M – adding 23 cps.

Overall BTA Valuation

A number of important events have occurred since we initiated coverage of BTA in May; not all of them helpful. The share price was weak through June due to tax selling and a number of large holders forced to sell their interests. A number of long term holders of the stock chose to exit after the (in their opinion) disappointing litigation outcome with GSK.

The following diagram summarises how our position has changed with respect to this stock over the June-July period. The early (and unexpected) resolution of the GSK litigation was a net positive in our view because it reduced the amount of forecast expenditure in the business. None of the litigation settlement of \$20M is captured in our valuation directly, although it will improve their cash position. The loss of value in Relenza in cps terms is primarily the effect of switching to FY09 as the base case for our Relenza DCF. But there is a small (~5%) adjustment in the number of Relenza orders remaining to be filled, using historical GSK sales as our guide. The reduction in Relenza value is netted out by an increase in our LANI valuation having passed Phase II successfully.

Figure 3: Net changes in our BTA valuation for the events of June-July 2008 in cps terms.



Our outlook for the stock remains positive. The next result we're looking for will come from the HRV program, which should commence dosing its Phase II trial this quarter. Investors will recall that we did not rate that program very highly in our initiation of coverage report. We do not expect to review that position until efficacy Phase II efficacy data becomes available, possibly by the end of CY2008. From there our focus will switch to the RSV program, partnered with MedImmune, which comes due for Phase I data by the end of this year or early 2009. That too is a key program for us, because success there will trigger Phase II studies and a milestone payment, which might be in the \$10M range. Our target price for BTA is upgraded to 142 cps and our BUY recommendation is retained.

Biota Holdings Limited (BTA : \$0.75)

INVESTMENT FUNDAMENTALS

Yr Ending June	2006A	2007A	2008E	2009E	2010E
EPS Reported (c)	-6.3	11.2	0.8	8.3	7.5
EPS Normalised (c)	-6.3	11.4	2.0	9.3	8.6
EPS Growth (%)	N/A	280.3%	-82.8%	375.0%	-7.8%
PER Normalised (x)	-19.1	10.6	40.8	8.6	9.3
DPS (c)	0.0	0.0	0.0	0.0	0.0
Payout (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	0%	0%	0%	0%	0%

VALUATION DATA

Yr Ending June	2006A	2007A	2008E	2009E	2010E
EV / EBITA (x)	-12.5	8.6	-369.9	7.2	8.6
EV / EBITDA (x)	-13.4	8.0	201.6	6.8	8.0
CFPS (c)	-4.3	11.6	1.2	8.9	2.9
Price / CF	-28.0	10.3	67.2	9.0	27.2
Book Value / Share (\$)	0.3	0.4	0.4	0.4	0.5
Price / Book (x)	4.6	3.0	2.1	1.9	1.7

PROFIT & LOSS (\$m)

Yr Ending June	2006A	2007A	2008E	2009E	2010E
Sales Revenue	11.6	55.8	20.5	21.3	27.6
EBITDA	-12.6	19.2	0.4	11.2	9.1
Depreciation	1.0	1.2	0.7	0.6	0.6
EBITA	-13.6	18.0	-0.2	10.6	8.5
Amortisation	0.0	0.3	2.1	1.9	1.9
EBIT	-13.6	17.7	-2.4	8.7	6.6
Net Interest Expense	-2.3	-2.5	-3.8	-6.2	-7.0
Pre-tax Profit	-11.3	20.2	1.4	15.0	13.6
Tax	0.0	0.0	0.0	0.0	0.0
Tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Minorities / pref divs	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0
Net Profit	-11.3	20.2	1.4	15.0	13.6
Abn's / Extraord's	0.0	0.0	0.0	0.0	0.0
Reported Net Profit	-11.3	20.2	1.4	15.0	13.6
Revenue Growth (%)	N/A	380.6%	-63.3%	3.9%	29.7%
EBIT Growth (%)	N/A	230.3%	-113.3%	469.6%	-24.1%
NPAT Growth (%)	N/A	278.5%	-93.0%	955.2%	-8.9%

PROFITABILITY RATIOS

Yr Ending June	2006A	2007A	2008E	2009E	2010E
EBIT / Sales (%)	-116.8%	31.7%	-11.5%	40.9%	23.9%
ROA (%)	N/A	84.8%	-7.7%	30.6%	24.4%
ROE (%)	N/A	34.1%	2.0%	20.6%	16.8%
ROFE (%)	N/A	356.2%	-2.5%	128.5%	77.2%

INTERIMS (\$m)

Half Yr	Dec 06	Jun 07	Dec 07	Jun 08	Dec 08
Yr Ending June	1H A	2H A	1H A	2H E	1H E
Sales Revenue	20.3	35.6	20.5	0.0	8.5
EBIT	2.9	14.7	4.4	-6.7	4.7
Net Profit	4.1	16.1	5.5	-4.1	7.7
EBIT / Sales (%)	14.5%	41.4%	21.3%		55.4%

BALANCE SHEET (\$m)

Yr Ending June	2006A	2007A	2008E	2009E	2010E
Cash	46.2	62.2	60.0	68.5	72.0
Receivables	5.9	9.4	5.3	3.3	4.3
Inventories	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Current Assets	52.1	71.5	65.3	71.8	76.3
Net PPE	5.5	4.9	5.5	6.4	7.6
Investments	0.0	0.0	0.0	0.0	0.0
Intangibles	0.0	13.7	11.6	9.7	7.8
Other	0.0	2.4	8.0	7.0	8.0
Non-current Assets	5.5	21.0	25.1	23.1	23.5
Total Assets	57.6	92.5	90.4	95.0	99.8
Current Payables	4.0	6.0	6.5	6.7	7.0
Current Debt	0.0	0.0	0.0	0.0	0.0
Non-Current Debt	0.0	0.0	0.0	0.0	0.0
Provisions	0.6	7.4	3.2	2.3	1.9
Other	6.0	7.5	11.5	10.2	4.0
Total Liabilities	10.7	20.9	21.1	19.2	12.9
Equity	158.0	161.7	159.1	153.1	153.1
Reserves	-0.1	0.6	0.8	0.8	0.8
Retained Profits	-111.0	-90.8	-90.6	-78.2	-67.1
Minorities	0.0	0.0	0.0	0.0	0.0
Total Equity	46.9	71.5	69.3	75.7	86.8
Total Funds Employed	0.7	9.4	9.3	7.2	14.9

CASHFLOW (\$m)

Yr Ending June	2006A	2007A	2008E	2009E	2010E
EBIT	-13.6	17.7	-2.4	8.7	6.6
Dep'n and Amort'n	1.0	1.6	2.8	2.5	2.5
Net Int Rec'd (Paid)	2.3	2.5	3.8	6.2	7.0
Tax Paid	0.0	0.0	0.0	0.0	0.0
Dec / (Inc) W'kg Cap	1.8	-4.7	5.9	2.2	-0.7
Other	6.8	4.0	3.4	0.0	0.0
Operating Cash Flow	-7.7	21.0	2.2	16.1	5.3
Capital Expenditure	-2.0	-0.9	-1.4	-1.5	-1.9
Asset Sales	0.1	0.0	0.0	0.0	0.0
Investments	0.0	-5.5	0.0	0.0	0.0
Other Inv. Flows	0.0	0.0	0.0	0.0	0.0
Investing Cash Flow	-1.9	-6.4	-1.4	-1.5	-1.9
Equity Raised	31.9	1.4	0.0	0.0	0.0
Inc / (Dec) in Loans	0.0	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0
Other Fin. Flows	-0.9	0.0	-3.0	-6.0	0.0
Financing Cash Flow	31.0	1.4	-3.0	-6.0	0.0
Net Cash Flow	21.4	16.0	-2.2	8.6	3.5

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