Medical Developments Int Ltd (MVP)

China Pathway Open - Update

27 June 2019

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Summary

Medical Developments International (MVP) has three operating segments:

- Pharmaceuticals (59% of FY18 sales) - is engaged in the manufacture and sale of the Penthrox "green whistle" emergency pain relief device and methoxyflurane drug;
- Medical Equipment ("Space Chambers" and other asthma / respiratory care devices)(37% of sales);
- Veterinary Equipment (4% of sales).

The two main segments are both undergoing strong international expansion.

We forecast Penthrox sales to go from $8.1m in FY18 to $126m for the 38 approved countries to date, under a 12 year roll out scenario. Approvals to be sought in a further 50+ countries including the USA, China and Russia could take this to $260m of annual sales (not in our forecasts).

What has changed?

- **China approval process** - MVP has received feedback from the Chinese FDA that they require 2 bridging studies based on the existing European studies (including the important Phase 4 PAS study already underway) plus one animal study. These will take approximately 12 months to complete. No major new clinical trials appear to be required.
- MVP in planning to lodge its IND application before end-August. Marketing approval could be end 2020, approximately 6 months earlier than expected.
- **US approval process** – MVP management and technical staff met with the FDA earlier this month and are waiting for the FDA's written response. MVP expects its clinical program to be confirmed, and the total US approval costs to be approximately US$15m (unchanged on previous guidance).
- **Valuation** - We value the US opportunity for Penthrox at A$100m or ~$1.50 per share, and the China opportunity at A$52m or $0.80 per share. We apply a 50% risk weighting on the US opportunity and 40% on China.

Recommendation – 12-mth Price Target $6.45

We maintain our Accumulate recommendation for the long-term growth potential of a global roll-out of Penthrox.

Our valuation range is $5.39 to $7.52 per share, with a mid-point of $6.45 based on our updated Sum of the Parts / DCF valuation.

Our unrisked valuation including 3 "blue sky" opportunities is $8.60 / share.

Recommendation	**Accumulate**
Risk Rating	**High**
12-mth Target Price (AUD)	**$6.45 (was $6.40)**
Share Price (AUD)	$5.21
12-mth Price Range	$3.48 - $5.91
Forecast 12-mth Capital Growth	23.8%
Forecast 12-mth Dividend Yield	0.8%
12-mth Total Shareholder Return	**24.6%**
Market cap ($m)	341.3
Net debt (net cash) ($m)(Jun 19e)	(21.6) (net cash)
Enterprise Value ($m)	319.8
Gearing (Net Debt/ Equity)	N/a – Net cash
Shares on Issue (m)	65.5
Sector	Healthcare
Average Daily Value Traded ($)	$561,000
ASX 300 Weight	n/a

Financial Forecasts & Valuation Metrics

Years ending Jun $m	17(a)	18(a)	19(e)	20(e)	21(e)
Sales revenue	18.3	17.5	21.2	25.6	30.9
Sales growth	19%	-5%	21%	21%	21%
EBITDA	3.8	2.2	3.6	4.9	6.4
NPAT	1.8	0.2	1.2	1.8	2.2
EPS (cents)	3.1	0.4	1.8	2.8	3.3
EPS growth	16%	-87%	344%	51%	20%
DPS	4.0	4.0	4.0	4.0	4.0
P/E	165.9	1,264.4	284.6	188.6	157.1
EV/Ebitda	80.7	142.5	89.6	67.3	53.6
Yield	0.8%	0.8%	0.8%	0.8%	0.8%
Franking	100.0%	100.0%	100.0%	100.0%	100.0%
Net debt / equity	Net Cash	40.2%	Net Cash	Net Cash	6.9%

Source: PhillipCapital estimates

MVP SHARE PRICE PERFORMANCE

Clinical Trials Update

Clinical Studies/ Regulatory - The PK study (Pharmacokinetic study – which characterises how the drug moves through the human body; 56 patients in Europe) has been completed.

The Phase 4 Post Authorisation Safety study (PAS) in the UK - should finish recruitment of 1,000 Penthrox patients in August 2019. Final data should be available a couple of months later. Interim data for the first 500 patients has already been received, and has been passed on in an updated dossier to the US FDA.

China application process

MVP recently received confirmation from the Chinese Food and Drug Administration (CFDA) regarding the Penthrox application process. The CFDA confirmed that a pre-IND meeting will not be required.

- MVP is aiming to submit the Chinese IND (Investigative New Drug) application before end-August, and have the IND officially "opened" by October.
- The CFDA require two small Phase 3 bridging studies based on the existing European studies and one bridging PK study. These would take approximately 12 months to complete.
- MVP expects the costs will be within earlier estimates of US$7m for the entire China approval process. No major new clinical trials appear to be required.
- MVP is seeking approval for BOTH trauma pain management AND minor surgical procedures (eg dental work). MVP believe the inclusion of the latter could more than double the addressable market for Penthrox.
- MVP could receive marketing approval for Penthrox in China within 18 months if things go according to plan (end 2020). This would be approximately 6 months earlier than previous expectations (approval mid 2022 - see diagram over).

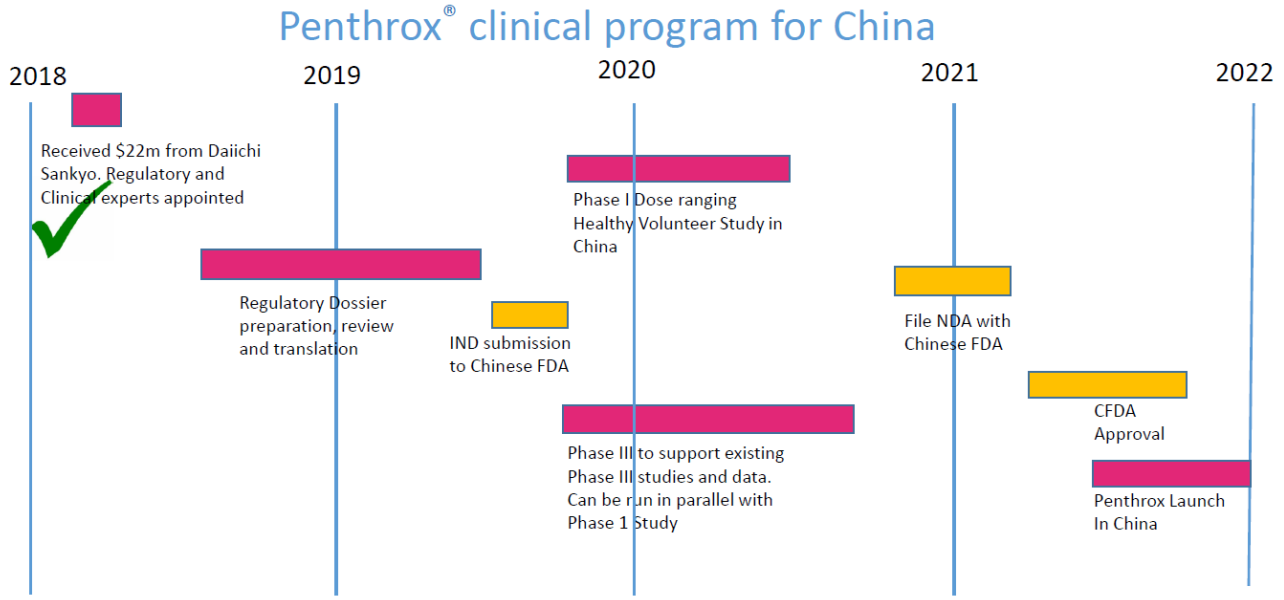
Background

With a population of 1.4 billion people, China represents a large market opportunity for MVP and Penthrox. CEO John Sharman says that about 70% of the market for pharmaceuticals is in the 20 largest cities, so launching a product like Penthrox might be more manageable than most people would expect. We show below a table of the Top 20 cities by population according to Wikipedia.

Rank	Name	Designation	Province	Popln
1	Shanghai	NCC	n/a	20,217,700
2	Beijing	NCC	n/a	16,446,900
3	Chongqing	NCC	n/a	11,871,200
4	Guangzhou	NCC	Guandgong	10,641,400
5	Shenzhen		Guangdong	10,358,400
6	Tianjin	NCC	n/a	9,562,300
7	Wuhan	NCC	Hubei	7,541,500
8	Dongguan		Guangdong	7,271,300
9	Hong Kong		n/a - Special administrative region	7,055,071
10	Foshan		Guangdong	6,771,900
11	Chengdu	NCC	Sichuan	6,316,900
12	Nanjing		Jiangsu	6,238,200
13	Shenyang		Liaoning	5,718,200
14	Hangzhou		Zhejiang	5,578,300
15	Xi'an	NCC	Shaanxi	5,399,300
16	Harbin		Heilongjiang	5,178,000
17	Suzhou		Jiangsu	4,083,900
18	Qingdao		Shandong	3,990,900
19	Dalian		Liaoning	3,902,500
20	Zhengzhou	NCC	Henan	3,677,000
	Total (2010 data)		11%	157,820,871
	Total China (2017 data)			1,386,000,000

Source: Wikipedia.org, according to 2010 Census. Total from 2017. NCC = National Central Cities

China Ambulance – The ambulance system is hospital based (especially large teaching hospitals) and city based. Ambulance is a major part of Penthrox's Australian and NZ business, so will be an important area for MVP's China distributor (Daiichi Sankyo) to focus on, as well as hospitals.



Source: CEO roadshow presentation 4/3/19

We have valued MVP's China opportunity at A$52m or $0.80 per share using conservative roll-out assumptions on a DCF basis. We apply a 40% risk weighting to this to arrive at our Sum of the Parts valuation of $5.39 per share (refer page 5).

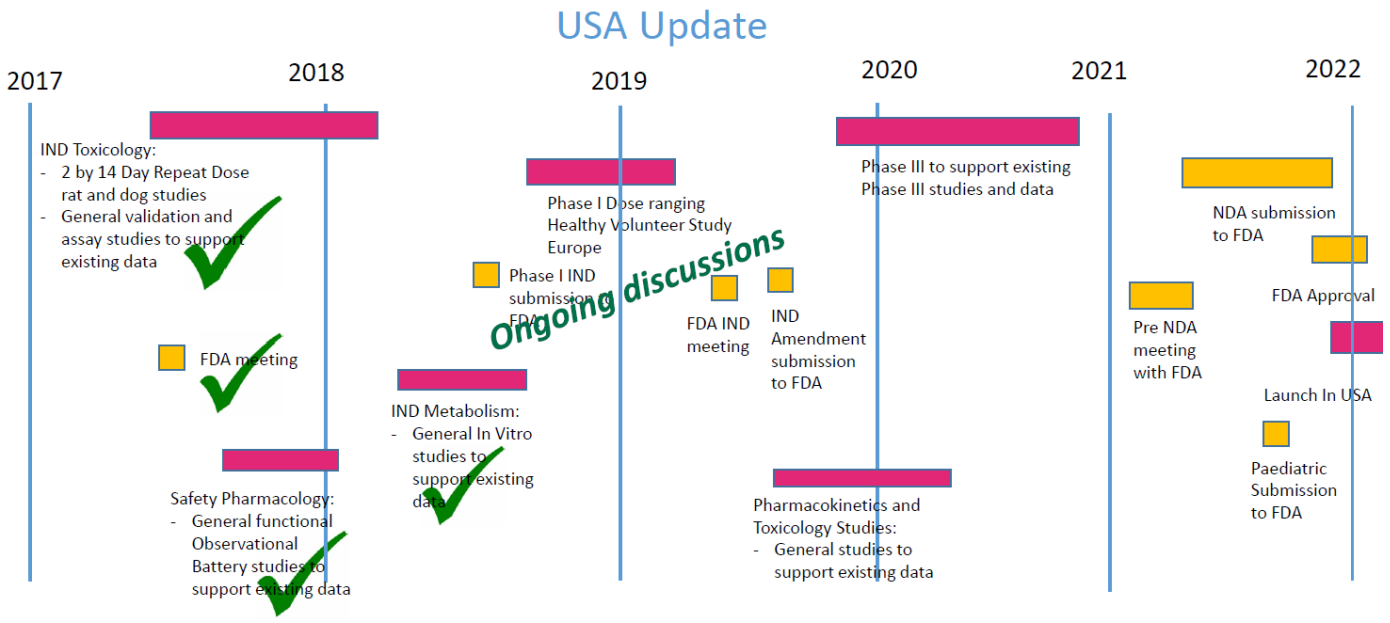
US application process

MVP management and technical staff met with the FDA earlier this month (June) and are waiting for the FDA's written response.

MVP expects its clinical program to be confirmed, and total US approval costs to be approximately US$15m (unchanged on previous guidance). MVP has already invested approximately US$4m in this process to date. MVP expect this process, if restarted, will take approximately 2-3 years. We show a diagram of MVP's previous planned timetable for getting US approval on the next page.

Background: The clinical trial program for Penthrox to seek approval for the USA was put on "clinical hold" by the FDA in July 2018, causing the share price to tumble by approximately 39% from $5.85 before the announcement on 25/7/18 to a 2018 low of $3.55 in August 2018. MVP shares have since recovered most of that fall, but are still 11% lower than before the announcement. Therefore we think the share price could bounce a further ~10% or so should the US IND application process be allowed to restart. The All Ordinaries index (XAO) is also 5.5% higher since that date (6716 points vs 6366 points).

The US has an estimated 140m Accident & Emergency department addmissions per annum. A proportion of these would be highly suited for Penthrox (eg. Car accidents, gun shot wounds, broken bones, dislocations, bad sprains etc). Our modelling for the US assumes a potential peak penetration of 1.5% of the US population, or approximately 5.0m units per annum. This would be equivalent to 3.6% of the 140m A&E admissions. The USA is probably MVP's biggest and most attractive market opportunity. Potential drug reimbursements and ability to pay for treatment are also very favourable.



Source: CEO roadshow presentation 4/3/19

Valuation & Recommendation

MVP looks very expensive on near term price earnings and EV/ sales multiples, compared to other medical device and pharmaceutical stocks. Also, it is difficult to find a good comparison for MVP.

MVP's current modest level of profit has little relevance to its 5-10 year future earnings potential, as the Pharmaceutical segment (Penthrox) is in the early stages of a 38+ country geographic expansion. Also the Medical Equipment segment (Asthma Devices) has only recently gained US FDA approval and listings in >15,000 US Pharmacies including WalMart, Kmart, Costco, Price Chopper, Sam's Club and Independent Pharmacy CoOp. So we consider a P/E based valuation is not appropriate at this early stage of the company's international development.

DCF / Sum of the Parts Valuation

We have valued MVP using a discounted cash flow method, and broken this down further into a sum of various components.

- We have chosen to value the US and China opportunities separately, so investors can consider the likelihood of MVP getting regulatory approvals to enter, and conducting a successful product launch in these large markets.
- Our base valuation for MVP is $5.38 per share, which includes a 40% risk weight on the 50+ country roll out (ex China & the US), a 40% risk weight on the China opportunity and 50% on the US opportunity. We previously used a 40% risk weighting for the US in our initiation report in November. We think a slightly more optimistic weighting is now justified given that 6 million doses of Penthrox have been sold worldwide, that the UK and France roll-outs are 3 years + and 2.4 years in without any safety issues arising of which we are aware.
- If MVP is successful in gaining approval in these new markets, our valuation rises to $7.52 per share.
- In addition, there are several "blue sky" opportunities that MVP is working on which we have considered (see items 6 & 7 in the table below). These could take our valuation to around $8.61 per share (unrisked).
- We value MVP shares in a range of $5.39 to $7.52 per share, as there are many moving parts, and a wide range of valuation outcomes as MVP executes on its strategy.
- We set our 12-month price target at the midpoint of $6.45, recognising that a wide range of outcomes are possible on a high growth, small cap stock such as MVP.

DCF / Sum of the Parts Valuation	Unrisked NPV $m	Unrisked Value Per Share	Risk Factor Applied	Risked NPV $m	Risked Value Per Share	Midpoint
1. Base Valuation of company (Pharma includes 38 countries approved to date)	252.4	$3.85	n/a	252.4	$3.85	
2. Further Countries to be approved: (50 new countries, could be more)(exclude US & China)	71.1	$1.09	40%	28.5	$0.43	
3. China Opportunity	52.3	$0.80	40%	20.9	$0.32	
4. US Opportunity	99.5	$1.52	50%	49.7	$0.76	
5. Mundipharma milestones (could be others) (assume A$52m max received in year 6, & 80% margin)	17.0	$0.26	10%	1.7	$0.03	
Subtotal	492.4	$7.52		353.3	$5.39	$6.45
Blue Sky Opportunities :						
6. Penthrox into new segments (Assume adds 10% to Pharma sales, from FY21)	23.2	$0.35	20%	4.6	$0.07	
7. Value of new "flow" manufacturing technology						
7a. Internal use - Assume reduces Pharma Divn COGS from 30% to 27% from FY20	18.7	$0.29	10%	1.9	$0.03	
7b. External use - New drug applications - Guestimate	30.0	$0.46	0%	0.0	$0.00	
Total Valuation	564.4	$8.61		359.8	$5.49	$7.05

Source: Phillip Capital estimates
Assumptions: 10 year DCF model; WACC 10.0%, TGR 4.0% except we use 5.0% for China

Company Description

Medical Developments International Limited (MVP), is an Australian based healthcare company. The Company operates through three segments: Pharmaceuticals, Medical Devices and Veterinary products.

Pharmaceuticals (59% of FY18 sales) - is engaged in the manufacture and sale of "Penthrox" (methoxyflurane), a generic pharmaceutical product which provides pre-hospital and emergency pain relief, by being inhaled by the patient through an associated delivery device (the Penthrox inhaler, also known as the "green whistle"). Penthrox has been manufactured in Australia by MVP since 2002, and MVP is the only known manufacturer of the drug. Sales have expanded from Australia and New Zealand, into several major new markets including Ireland (Nov 2015), the United Kingdom (Jan 2016), and France (Feb 2017), with approvals now received for 38 countries and a number of launches now in progress (Germany, Spain, Italy and Mexico expected early 2020).

Medical Devices (37% of Sales) – This segment is engaged in the sale of medical devices that improve respiratory care. These include anti-static valved holding chambers ("Space Chambers") for the delivery of asthma and COPD medications, "Breath Alert" breathing flow meters, and finger-tip pulse oximeters for measuring oxygen levels in the blood. Sales are approximately 50/50 Australia and a growing list of 20 countries in North America, Europe and Asia.

Veterinary Products (4% of sales) - is engaged in the sale of veterinary products within Australia, Europe and the United States. The Company offers a range of products in the areas of pain management, and asthma and resuscitation.

MVP has been profitable every year since listing, and has only had one capital raising since the IPO being the recent $24.5m placement and SPP in Aug/ Sep 2018 (at $4.00 per share). MVP has funded its own growth internally, and with upfront licence payments (non-refundable) received for Penthrox.

Investment Thesis

MVP's Penthrox "green whistle" emergency pain relief product (the inhaler device plus the fast-acting methoxyflurane generic drug) is a remarkable 30 year old product in the midst of major international roll-out.

In the last 5 years, major pharmaceutical distributors have paid $41m in upfront licence fees and early milestones to secure their territory licences for Penthrox including: Galen Pharmaceuticals $1.6m for the UK/Ireland; Mundipharma $16.4m for Europe; Purdue $1.5m for Canada; and Daiichi Sankyo $21m ($7m net of estimated costs) for China Thailand and Vietnam. This is a strong sign of confidence in Penthrox.

Approvals have now been received for approximately 38 countries including Germany, Italy and Spain. Product launches are underway or imminent with quality pharmaceutical distributors noted above.

We forecast Penthrox sales to grow from $8.1m in FY18 to $126m for the 38 approved countries over the next 12 years. Approvals to be sought for a further 50+ countries including the USA, China and Russia could take this to $260m in annual sales (not in our forecasts).

The product is proven with over 6 million doses sold over 30+ years in Australia, 14 years in New Zealand, 3+ years in the UK and 2+ years in France.

MVP's Medical Equipment division (asthma devices) is also expanding internationally with new ranging in >15,000 US pharmacies including Walmart, Kmart and Costco.

Medical Developments (MVP:$5.21)

PROFIT AND LOSS ($m)

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
Sales revenue	18.3	17.5	21.2	25.6	30.9
EBITDA	3.8	2.2	3.6	4.9	6.4
Depreciation	1.3	1.8	2.3	2.8	3.2
EBITA	**2.5**	**0.4**	**1.2**	**2.1**	**3.2**
Goodwill amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	**2.5**	**0.4**	**1.2**	**2.1**	**3.2**
Interest exp (income)	-0.0	0.1	-0.4	-0.4	0.2
Pre-tax profit	**2.5**	**0.3**	**1.6**	**2.5**	**3.0**
Tax expense	0.6	0.1	0.5	0.7	0.8
Tax rate (%)	*26.1%*	*19.3%*	*27.5%*	*27.5%*	*27.5%*
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
NPAT	**1.8**	**0.2**	**1.2**	**1.8**	**2.2**
NPAT pre-g'will	**1.8**	**0.2**	**1.2**	**1.8**	**2.2**
Significant items	0.0	0.0	0.0	0.0	0.0
Reported NPAT	1.8	0.2	1.2	1.8	2.2

BALANCE SHEET ($m)

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
Cash	1.7	0.8	31.5	18.1	3.8
Receivables	5.2	4.3	5.2	6.3	7.6
Inventories	2.4	3.2	3.9	4.7	5.7
Other	0.5	0.5	0.4	0.4	0.4
Current assets	**9.9**	**8.7**	**41.0**	**29.5**	**17.4**
Net PPE	6.6	8.1	9.8	11.4	13.3
Investments	0.0	0.0	0.0	0.0	0.0
Intangibles	24.2	31.6	36.9	49.0	59.9
Other	1.1	1.1	5.8	7.0	8.5
Non-current assets	**31.9**	**40.8**	**52.5**	**67.4**	**81.7**
Total assets	**41.8**	**49.5**	**93.5**	**96.9**	**99.2**
Current payables	2.7	3.2	3.9	4.7	5.7
Debt	0.4	9.3	9.9	8.6	6.8
Provisions	0.7	0.6	2.8	3.4	4.1
Other	16.5	15.5	40.5	40.5	40.5
Total liabilities	**20.4**	**28.5**	**57.1**	**57.1**	**57.0**
Equity	15.0	16.1	40.4	40.4	40.4
Reserves	0.3	0.7	0.7	0.7	0.7
Retained profits	6.3	4.2	2.9	2.1	1.7
Minorities			0.0	0.0	0.0
Total s/h funds	**21.6**	**21.0**	**44.0**	**43.2**	**42.8**
Total funds emp.	**42.0**	**49.5**	**101.1**	**100.3**	**99.8**

CASHFLOW ($m)

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
EBIT	2.5	0.4	1.2	2.1	3.2
Net interest recd (paid)	-0.0	-0.1	0.4	0.4	-0.2
Dep'n and amort'n	1.3	1.8	2.3	2.8	3.2
Tax refund (Tax paid)	-4.3	0.0	-3.8	-0.7	-0.8
Upfronts & Milestones recd	7.4	1.0	20.8	4.2	2.8
(Inc)/dec in working cap	2.8	0.7	-0.9	-1.1	-1.3
Other	-5.5	-2.0	2.2	0.6	0.7
Operating cashflow	**4.0**	**1.8**	**22.3**	**8.3**	**7.6**
Investing activities					
Capital expenditure	-4.4	-2.1	-2.7	-2.8	-3.2
Intangibles (Capit Regn Cos	-4.3	-8.6	-6.6	-13.7	-12.8
Investments	0.0	0.0	0.0	0.0	0.0
Divestments	0.0	0.0	0.0	0.0	0.0
Financing activities					
Equity raised	2.0	0.4	24.3	0.0	0.0
Change in loans	-0.1	8.8	0.6	-1.4	-1.8
Dividends paid	-1.2	-1.2	-2.5	-2.6	-2.6
Other non-op flows	-0.0	-0.0	-4.7	-1.2	-1.4
Net chg in cash	**-4.0**	**-0.9**	**30.7**	**-13.4**	**-14.3**

LIQUIDITY AND LEVERAGE RATIOS

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
Net debt (Net cash) ($m)	-1.3	8.5	-21.6	-9.5	3.0
Net debt / equity (%)	**-5.8%**	**40.2%**	**-49.0%**	**-22.1%**	**6.9%**
Interest cover (x)	(614.8)	3.2	(3.1)	(5.3)	16.2

PROFITABILITY RATIOS

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
EBITDA / sales (%)	20.7%	12.7%	16.9%	19.2%	20.8%
EBITA / sales (%)	**13.4%**	**2.5%**	**5.9%**	**8.3%**	**10.5%**
Return on assets (%)	6.5%	1.0%	2.2%	3.0%	3.7%
Return on equity (%)	9.0%	1.1%	3.7%	4.2%	5.1%
Return on funds emp (%)	14.4%	1.8%	4.8%	7.6%	8.1%

GROWTH RATES (% over pcp)

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
Sales		-4.8%	21.2%	21.2%	20.5%
EBITDA		-41.4%	60.5%	38.2%	30.2%
EBITA		-82.1%	180.7%	71.9%	52.0%
Pre-tax profit		-87.8%	444.1%	54.3%	20.0%
NPAT pre-g'will		-86.6%	388.6%	54.3%	20.0%
EPS		-86.9%	344.3%	50.9%	20.0%

MULTIPLES AND PER SHARE DATA

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
EPS cents	3.1	0.4	1.8	2.8	3.3
DPS	4.0	4.0	4.0	4.0	4.0
Franking	100%	100%	100%	100%	100%
Payout ratio	127%	971%	218%	145%	121%
CFPS	6.9	3.0	34.4	12.5	11.5
NTA	-0.04	-0.18	0.11	-0.09	-0.26
PER	165.9	1264.4	284.6	188.6	157.1
Div yield (%)	0.8%	0.8%	0.8%	0.8%	0.8%
P/CF	75.1	171.6	15.1	41.6	45.4
P/NTA	-118.8	-29.1	48.6	-59.4	-20.2
EV/EBITDA	80.7	142.5	89.6	67.3	53.6
EV/EBITA	124.4	718.2	258.3	156.0	106.5

WORKING CAPITAL RATIOS (% of sales)

Year ending Jun	17(a)	18(a)	19(e)	20(e)	21(e)
Current receivables	28.5%	24.6%	24.6%	24.6%	24.6%
Current inventory	13.2%	18.3%	18.3%	18.3%	18.3%
Current payables	14.9%	18.5%	18.5%	18.5%	18.5%
Current provisions	1.9%	2.0%	12.0%	12.0%	12.0%
Non-current provisions	2.1%	1.2%	1.2%	1.2%	1.2%

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Buy	Accumulate	Hold	Reduce	Sell
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