

Medical Developments Int Ltd (MVP)

FY19 Results and Outlook – Catalysts Approaching

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Wayne Sanderson
wsanderson@phillipcapital.com.au
+61 3 8633 9930

Summary

Medical Developments International (MVP) has three operating segments:

- Pharmaceuticals (69% of FY19 revenue) - is engaged in the manufacture and sale of the Pentrox “green whistle” emergency pain relief device and methoxyflurane drug;
- Medical Equipment (“Space Chambers” and other asthma / respiratory care devices)(28% of revenue);
- Veterinary Equipment (3% of revenue).

The two main segments are both undergoing strong international expansion.

We forecast Pentrox sales to go from \$11.9m in FY19 to \$128m for the 41 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 \$240m of annual sales (not in our forecasts).

What has changed?

- FY19 Results were marginally below our forecasts due to a delay in launching Pentrox in Germany, Italy and Spain all now expected in 2020.
- FY19 was still a very commendable year with revenue up 20% overall to \$20.9m (Pentrox sales up 47% to \$11.8m, amortisation of up-front licence fees up 12% to \$2.4m, but Medical Equipment down -8% to \$5.9m and Vet Equipment down 18% to \$0.6m).
- Ebitda was \$3.1m up 31% (Vs our forecast of \$3.6m).
- Reported NPAT was \$1.0m (vs \$0.2m pcp and our forecast of \$1.2m).
- The \$20.8m up-front licence fee received from Daiichi Sankyo for China Thailand and Vietnam has been taken to the Balance Sheet as unearned revenue.

Change in Estimates

- We have lowered our near term estimates by -13% and -10% at the ebitda level to push back Germany Italy and Spain launches by one year.
- However we have rolled forward and extended our modelling for the global Pentrox roll out.
- Our updated Sum of the Parts / DCF valuation range is \$6.39 (risk weighted) to \$10.00 (unrisked) per share, with a mid-point of \$8.19. We set our 12-mth price target at \$8.20 (previously \$6.45).
- We value the US opportunity for Pentrox at A\$136m or ~\$2.07 per share, and the China opportunity at A\$61m or \$0.93 per share. We apply a 50% risk weighting on the US opportunity and 40% on China.

Recommendation – 12-mth Price Target \$8.20

MVP shares have under-performed the market the last 12 months. We see a number of catalysts approaching (AGM update, US update, Germany Spain & Italy launches) so upgrade to a Buy (was Accumulate). Our revised price target implies 59% total shareholder return (TSR).

Recommendation

Buy

Risk Rating	High
12-mth Target Price (AUD)	\$8.20 (was \$6.45)
Share Price (AUD)	\$5.17
12-mth Price Range	\$3.48 - \$6.50
Forecast 12-mth Capital Growth	58.6%
Forecast 12-mth Dividend Yield	0.8%
12-mth Total Shareholder Return	59.4%
Market cap (\$m)	339.2
Net debt (net cash) (\$m)(Jun 19e)	(25.4) (net cash)
Enterprise Value (\$m)	313.8
Gearing (Net Debt/ Equity)	N/a – Net cash
Shares on Issue (m)	65.6
Sector	Healthcare
Average Daily Value Traded (\$)	\$655,000
ASX 300 Weight	n/a

Financial Forecasts & Valuation Metrics

Years ending June \$m	18(A)	19(e)	20(e)	21(e)	22(e)
Sales revenue	17.5	20.9	25.7	30.3	38.1
Sales growth	-5%	20%	23%	18%	26%
EBITDA	2.3	3.1	4.2	5.7	8.3
NPAT (reported)	0.2	1.0	1.3	1.4	3.4
NPAT (adjusted)	0.3	0.7	1.3	1.4	3.4
EPS (adjusted)	0.6	1.0	1.9	2.2	5.2
EPS growth	-81%	72%	89%	large	large
DPS	4.0	4.0	4.0	4.0	4.0
P/E	882.8	512.0	270.8	236.8	99.7
EV / Ebitda	135.2	102.6	75.6	56.9	38.2
Yield	0.8%	0.8%	0.8%	0.8%	0.8%
Net debt / equity	40.2%	net cash	net cash	net cash	net cash

Source: Phillip Capital estimates

MVP SHARE PRICE PERFORMANCE



Change in Estimates

We review MVP's FY19 result in detail in this report. We have made a number of changes to our forecasts as follows:

- We push back our launch dates for Germany, Spain and Italy by one year.
- We increase our Australian revenue forecasts slightly following better than expected performance here.
- We increase amortisation of registration costs expense, based on new modelling.
- Extending our Pentrox global roll-out timetable & other modelling changes.

These changes lower our near-term Ebitda forecasts by 13% for FY20 and 10% for FY21. EPS is lowered even more because of the depreciation adjustment.

Changes in Estimates Years ending June \$m	FY19	FY20e			FY21e			FY22e
		Old	New	Change	Old	New	Change	New
External sales	18.5	22.2	22.9	3.2%	27.0	27.3	1.1%	33.6
Amortisation of Upfronts	2.4	3.4	2.8	-18.0%	3.9	3.0	-24.1%	4.5
Sales revenue	20.9	25.6	25.7	0.3%	30.9	30.3	-2.1%	38.1
Sales growth	20%	23%	23%		21%	18%		26%
EBITDA (excl FX gain)	3.1	4.9	4.2	-13.3%	6.4	5.7	-10.2%	8.3
Ebitda growth	32%		39%			35%		44%
Depreciation & Amortisation of Regn costs	-2.3	-2.8	-2.8	0.7%	-3.2	-4.0	24.1%	-4.2
EBIT	0.8	2.1	1.4	-32.0%	3.2	1.8	-44.5%	4.1
NPAT (reported)	1.0	1.8	1.3	-30.4%	2.2	1.4	-34.9%	3.4
NPAT (norm)	0.7	1.8	1.3	-30.4%	2.2	1.4	-34.9%	3.4
EPS (norm)	1.0	2.8	1.9	-31.7%	3.3	2.2	-33.7%	5.2
DPS	4.0	4.0	4.0	n/a	4.0	4.0	n/a	4.0

Source: Phillip Capital estimates

Valuation & Recommendation

We have revised our 10 year DCF forecasts and assumptions, which capture the expected ramp up of Pentrox sales to international markets.

Sum of the Parts / DCF Valuation	Unrisked	Unrisked	Risk	Risk	Risk	Midpoint
	NPV	Value	Factor	NPV	Value	
	\$m	Per Share	Applied	\$m	Per Share	
1. Base Valuation of company (Pharma includes 41 countries approved to date)	248.4	\$3.79	n/a	248.4	\$3.79	
2. Further Countries to be approved: (50 new countries, could be more)(excludes US & China)	191.1	\$2.92	40%	76.5	\$1.17	
3. China Opportunity	60.7	\$0.93	40%	24.3	\$0.37	
4. US Opportunity	135.7	\$2.07	50%	67.9	\$1.04	
5. Mundipharma milestones (could be others) (assume A\$52m max received in FY24, & 80% margin, 27.5% tax)	19.3	\$0.29	10%	1.9	\$0.03	
Subtotal (Base case)	655.2	\$10.00		418.9	\$6.39	\$ 8.20
Blue Sky Opportunities :						
6. Pentrox into new segments (Assume adds 10% to Pharma sales, from FY23)	26.5	\$0.40	20%	5.3	\$0.08	
7. Value of new "flow" manufacturing technology (External use - New drug applications - Guestimate)	30.0	\$0.46	0%	0.0	\$0.00	
Valuation (Optimistic case)	711.7	\$10.86		424.2	\$6.47	\$ 8.67

Source: Phillip Capital estimates

Assumptions: 10 year DCF model; WACC 10.0%, Terminal Growth Rate 4.0% (except we use 5.0% for China)

Our "Base case" valuation range has increased slightly to \$6.39 to \$10.00, with a midpoint of \$8.20 (previously \$6.45). We set our 12-mth price target at this level.

Our "Optimistic case" adds a further \$0.08 to \$0.86 per share for the "blue sky" opportunities of MVP possibly being successful at taking Pentrox into new market segments (ie. Beyond the accident & emergency department, into cancer treatment, burns patients, minor surgical procedures and possibly home use), and our guestimate of the value of the new "continuous flow" manufacturing technology.

Share price Catalysts & Recommendation

MVP's share price has largely tracked sideways over the last 12-months, with a 12-mth total shareholder return of around 2%. We attribute this to delays in the planned launches into the major European markets of Germany, Italy and Spain (partly due to Brexit issues) and on-going uncertainty over the status of the US application process.

Reuters Code	Company	Price \$	Market Cap \$m	TSR -1 Month	TSR -3 Mths	TSR -12 Mths	P/E FY1e	P/E FY2e	EV/Revenue FY1e	EV/EBITDA FY1e
RMD.AX	Resmed Inc	19.16	27,330	-0.8%	9.2%	31.7%	33.8x	29.8x	6.9x	22.0x
FPH.AX	Fisher & Paykel Healthcare	17.60	10,022	13.5%	15.7%	38.1%	42.7x	37.9x	9.1x	27.0x
NAN.AX	Nanosonics Ltd	6.87	2,060	9.3%	33.3%	118.2%	156.1x	88.5x	19.0x	114.1x
MYX.AX	Mayne Pharma Group Ltd	0.59	931	14.7%	19.4%	-52.0%	21.9x	15.5x	2.2x	8.7x
PNV.AX	Polynovo Ltd	2.44	1,610	7.1%	43.7%	300.0%	3641.8x	281.4x	63.2x	1470.7x
AVH.AX	Avita Medical Ltd	0.67	1,243	10.2%	56.6%	556.6%	NaN	NaN	47.2x	NaN
SPL.AX	Starpharma Holdings Ltd	1.12	414	-0.4%	-15.4%	-25.0%	NaN	NaN	21.1x	NaN
	Average of the above			7.6%	23.2%	138.2%	779.3x	90.6x	24.1x	328.5x
	Median of the above			9.3%	23.2%	118.2%	156.1x	88.5x	21.1x	114.1x
MVP.AX	Medical Developments Intl	5.17	339	6.0%	-13.6%	2.8%	270.8x	236.8x	12.5x	75.6x

Source: Phillip Capital forecasts for MVP; Refinitiv consensus forecasts for all others. NaN means no available number.

Catalysts

We see a number of important catalysts approaching:

- AGM on Wednesday 30 October in Melbourne.
- German launch now expected early 2020 (January???)
- Spanish launch shortly thereafter (early 2020).
- Italian launch (mid-2020). These are three big European markets.
- Progress with numerous other country approvals and launches (FY20 expected to be a big year of activity and launches).
- Results from the Post Authorisation Safety Study (PAS) in the UK covering 1,000 patients, and further Pharmacokinetics and toxicology studies completed (~ next 6 months).
- Lodging amended IND submission with the US FDA and getting "clinical hold" lifted / Re-starting US IND approval process.
- Progress on trials to support China application.
- Possible licencing deal for MVP's new "continuous flow" drug manufacturing technology which MVP believes has significant commercial potential to reduce the cost of making large volume drugs such as Lidocaine (numbing drug commonly used by dentists), Diclofenac (Voltaren – pain and anti-inflammatory drug), and potentially some other large volume drugs. MVP owns the technology, which was developed in conjunction with CSIRO. MVP's CEO John Sharman was quite excited by the potential of this technology at the 2018 AGM. MVP has flagged a possible licencing deal for FY20.
- Progress with new inhaler devices – we have seen images of a "selfie" model (see below) which should have significant improvements over the current device which is now 30 years old. Other models / dosages may also be under development which could extend the use of Pentrox. Timing 1-2 years.

Pentrox[®] Inhaler Developments

Selfie Inhaler

The Pentrox[®] Selfie inhaler is the next generation of inhalers under development at MDI.

It is a fully integrated pain relief system which delivers 3ml of Pentrox[®] to patients in a quick and easy manner.

The Selfie inhaler will be suitable for patients in emergency, clinical, military and may lead to further development of home use devices.

The Selfie system is undergoing initial trials and production is planned for launch in 2020/early 2021.

MVP plans to invest up to \$5m in plant, equipment and production facilities to cater and promote the global expansion of Pentrox.



Source: CEO roadshow presentation 4/3/19

FY19 Results

The key features of MVP's FY19 result were as follows:

- Operating cash flow was \$21.3m (v \$1.8m) up \$19.5m or 11 fold due to MVP receiving \$20.8m in upfront licence fees from Daiichi Sankyo of Japan for China, Thailand and Vietnam in the year (v \$1.0m in the pcp).
- Operating revenue up 20% to \$20.9m, comprising external sales up 21% to \$18.5m and up-front payments being amortised over the licence period of each country of \$2.4m up 12%. The China licence fee received is capitalised to the balance sheet and will be amortised to revenue once Pentrox launches there.
- Within external sales, Pentrox was up 40% as new countries ramped up, Medical devices was down -8% and Vet Equipment was down 18%. We review each division in more detail below.
- The gross margin declined by 2.9% in absolute terms. We expect this small decline to continue as international sales of both Pentrox (and also asthma devices) through distributors ramp up. MVP will be giving up some margin to share with these distributors, in order to achieve higher sales volumes.
- Ebitda was up 31% to \$3.1m as revenues rose at 20% which was faster than the +10% rise in costs. (We exclude a \$0.4m FX gain on the Daiichi licence fee here).
- Depreciation & amortisation expense increased by 27% as MVP starts to amortise previously capitalised product registration costs for each market now being entered.
- Reported NPAT was \$1.0m (v \$0.2m) up 327%, but this is coming off a low base.
- NPAT (normalised to exclude FX gains & losses) was \$0.7m (v \$0.3m) up 90%, but again off a low base.
- In our opinion the reported and normalised NPAT figures do not yet reflect the true earnings potential of the company, because Pentrox is still in the early stages of its international / global launches.

MVP - FY19 Results Review							PCR	Difference	Comments	
Years ended June \$m	1H18	2H18	FY18	1H19	2H19	FY19	Change	Est	%	
External Sales	6.8	8.5	15.3	8.3	10.1	18.5	21%	18.4	0%	Pentrox revenues +40%; Med Devices -8%, Vet Equip -18%
Amortisation of milestones	1.0	1.1	2.2	1.2	1.2	2.4	12%	2.8	-14%	Amortisation of Pentrox milestones and upfront licence fees received
Op. Revenue	7.8	9.7	17.5	9.5	11.4	20.9	20%	21.2	-2%	Pentrox revenues +40%; Other divisions lower
Cost of Goods Sold	(2.2)	(2.9)	(5.1)	(3.2)	(3.4)	(6.7)	31%	(6.4)	5%	
Gross Profit	5.6	6.8	12.4	6.3	7.9	14.2	15%	14.8	-4%	
Gross Profit Margin	71.5%	70.2%	70.8%	65.9%	69.7%	67.9%	-2.9%	70.0%		GP margin down slightly, but still very strong
Other Income	0.0	0.0	0.0	0.0	0.0	0.0		0.0		
Cash Operating Expenses	(4.7)	(5.3)	(10.0)	(5.0)	(6.1)	(11.1)	11%	(11.2)	-1%	Costs rising slower than revenue - a good sign
EBITDA	0.9	1.5	2.3	1.2	1.8	3.1	31%	3.6	-15%	Pentrox +23%; Med Devices +13%, Vet Equip -25%, Unallocated costs 8% lower
Ebitda Margin	11.2%	15.1%	13.3%	13.0%	16.0%	14.6%	1.3%	17.0%		Good margin improvement, especially in the 2H
Depreciation & Amort	(0.7)	(1.1)	(1.8)	(1.1)	(1.2)	(2.3)	27%	(2.3)	0%	Capitalised regulatory costs are amortised once each new country is launched
EBIT	0.1	0.4	0.5	0.1	0.7	0.8	46%	1.2	-36%	Strong % increase, but off a low base
Ebit Margin	1.8%	4.1%	3.1%	1.4%	5.8%	3.8%	0.7%	11.2%		
Net Interest Income (Expense)	(0.0)	(0.1)	(0.1)	0.1	0.3	0.4	NM	0.4	-6%	MVP has net cash of \$25m
Share of Assoc NPAT (NLoss)	0.0	0.0	0.0	0.0	0.0	0.0		0.0		
Pre-tax profit	0.1	0.3	0.4	0.2	1.0	1.2	189%	1.6	-28%	Strong % increase, but off a low base
Income Tax Credit (Expense)	0.0	(0.1)	(0.1)	(0.1)	(0.5)	(0.5)	784%	(0.4)	14%	Milestones received are taxable
Tax Rate	7.6%	-23.4%	-14.4%	-29.0%	-46.7%	-43.9%	-29.5%	-27.5%		
Minorities (share of loss)	0.0	0.0	0.0	0.0	0.0	0.0		0.0		
NPAT (reported)	0.1	0.1	0.2	0.1	0.9	1.0	327%	1.2	-12%	Strong % increase, but off a low base
Adjustments	0.0	0.1	0.1	0.0	-0.4	-0.4	NM	0.0	NM	Adjustments to exclude FX gains & losses
NPAT (adjusted)	0.1	0.2	0.3	0.1	0.5	0.7	90%	1.2	-45%	
EPS - Reported (cents)	0.2	0.2	0.4	0.2	1.4	1.6	288%	1.8	-11%	Strong % increase, but off a low base
EPS - Normalised (cents)	0.2	0.4	0.6	0.2	0.8	1.0	72%	1.8	-44%	Strong % increase, but off a low base
DPS (cents)	2.0	2.0	4.0	2.0	2.0	4.0	0%	4.0	0%	Uncovered dividend being paid out of reserves. Shows confidence by the Board.
Franking	100%	100%	100%	100%	100%	100%		100%		Milestones received are taxable

Source: MVP accounts

Cash Flow Statement

As noted above, Operating cash flow was \$21.3m (v \$1.8m) up \$19.5m or 11 fold due to MVP receiving \$20.8m in upfront licence fees for China (v \$1.0m) in the year.

Investing cash flow was an out-flow of \$9.5m (v \$10.7m out-flow) as follows:

- Plant and equipment (chiefly at Scoresby) \$1.5m (v \$2.1m)
- Investment in intangible assets \$8.4m (v \$8.6m)
 - Product development \$1.5m (v \$1.1m)
 - Patents & trademarks \$0.1m (v \$0.3m)
 - Capitalised country registration costs \$6.8m (v \$7.3m)

Cash flows from financing was \$13.0m (v \$7.9m) with \$23.8m of new capital raised, with external debt now eliminated apart from \$0.2m owed to CSIRO for the development program of a new manufacturing method for Pentrox ("Continuous flow" technology).

Balance Sheet

- MVP had net cash of \$25.4m at end-June 2019 (v net debt of \$8.5m at end-June 2018). The big improvement was due to the \$23.8m of new capital raised, the \$20.8m up-front licence fee for China, Thailand and Vietnam from Daiichi Sankyo of Japan, less the continued investment in getting country registration approvals and on-going R&D.
- Total assets were \$84.8m (v \$49.6m) up \$35m with cash up \$25m and Intangibles up \$7m being the major changes.
- Total liabilities were \$40.2m (v \$28.5m) up \$11.7m which included \$31.4m (v \$13.0m) of revenue received in advance that will be progressively amortised to revenue as Pentrox is launched into new countries.
- Shares on issue increased by 10.7% to 65.5m.
- Net assets per share improved to \$0.68 per share (v \$0.36).
- Net tangible assets per share was \$0.06 per share (v negative \$0.20 per share).

Divisional Reviews

Pharmaceutical division (Pentrox)

This division recorded a very strong result with operating revenue for accounting purposes up 40% to \$14.3m (v \$10.2m). This excludes all of the \$20.8m non-refundable up-front licence fee received from Daiichi Sankyo which has been capitalised to the balance sheet as “Other liabilities - Revenue received in advance” (refer note 19 of MVP’s FY19 accounts).

External revenue was \$11.9m up 47% and up-front licence fee amortisation income was \$2.4m up 12%.

Ebitda was \$5.3m up 23%. The Ebitda margin was 37.2% (v 42.5%) down 5.3% in absolute terms. We expect this gradual decline to continue as international sales of Pentrox through distributors ramp up. MVP will be giving up some margin to share with these distributors, in order to achieve higher sales volumes.

MVP - FY19 Results Review - Pharmaceutical Division (Pentrox)								PCR	Difference	Comments
Years ended June \$m	1H18	2H18	FY18	1H19	2H19	FY19	Change	Est	%	
External Sales	3.7	4.3	8.1	5.2	6.7	11.9	47%	11.8	1%	Strong sales growth in Europe +401%, UK +68%, & Aust ambulance +38%
Amortisation of milestones	1.0	1.1	2.2	1.2	1.2	2.4	12%	2.8	-14%	
Operating revenue	4.8	5.5	10.2	6.4	8.0	14.3	40%	14.6	-2%	Strong sales growth in Europe +401%, UK +68%, & Aust ambulance +38%
External sales growth	0%	0%	-11%	38%	55%	47%		46%		
Ebitda	2.2	2.1	4.4	2.5	2.8	5.3	23%	6.0	-11%	Strong growth, but lagging revenue growth due to sharing margin with distributors Ebitda margin down 5 points, expected to continue
Ebitda margin	47.1%	38.5%	42.5%	39.4%	35.5%	37.2%	-5%	41.0%		
Depreciation & Amortisation	-0.6	-1.4	-1.4	-0.9	-1.4	-1.8	27%			Amortisation of capitalised Registration costs rises as each new country is launched
EBIT	1.7	0.7	2.9	1.6	1.4	3.5	20%			
Ebit margin	34.9%	12.6%	28.7%	25.4%	17.7%	24.6%				
Segmental Assets	29.6	35.0	35.0	38.3	44.2	44.2	26%			\$9.2m increase includes \$8.4m spend on capitalised intangibles (registration costs)
Return on Assets (Ebit)	11.3%	3.9%	8.4%	8.4%	6.4%	8.0%				

Source: MVP accounts

Australia showed surprisingly good growth and MVP’s distributors in the UK (Galen) and Europe (Mundipharma) appear to be making good progress, and getting some solid traction:

Global

- Pentrox sales +47% worldwide
- 1,058 customers in total.

Australia (the first major market launch for Pentrox)

- Pentrox was launched with the Victorian Ambulance service in 1975 (44 years ago). Ambulance sales are still around 75% of the Australian sales, with hospitals, dentists, clinics and other emergency services the balance.
- Ambulance sales +38% in FY19 - quite incredible after 44 years. MVP still handles these sales directly. MVP has now appointed Mundipharma as its new distributor for the rest of its Australian business which it believes is still under-penetrated.
- The strategy is to expand the use of Pentrox beyond the ambulance and emergency department, into new areas requiring pain relief such as cancer wards, burns patients etc.

UK market (the second major market launch for Pentrox)

- Launched January 2016 in UK (and November 2015 in Ireland), so now 3 years and 9 months in.
- Now used in nearly all ambulances and hospitals in Ireland. Recommended for use for all UK ambulances by the UK national ambulance body (JRCALC) in September 2017, but so far only a 3 of the UK’s 13 regional ambulance trusts have adopted Pentrox. Several are reviewing it.

- MVP sales into the UK & Ireland up 68%.
- Now 540 customers (v 385 in FY18) +40%
- Pentrox selling to 125 hospitals (per 29/10/18 AGM statement) and listed in 7 major Trauma centres (per MVP presentation 4/3/19).
- Our comment – Although Pentrox seems to be getting reasonable traction with hospitals and clinics, it looks to us that Ambulance has been underwhelming so far. We understand that UK sales are still below New Zealand’s level of around A\$1.0m.

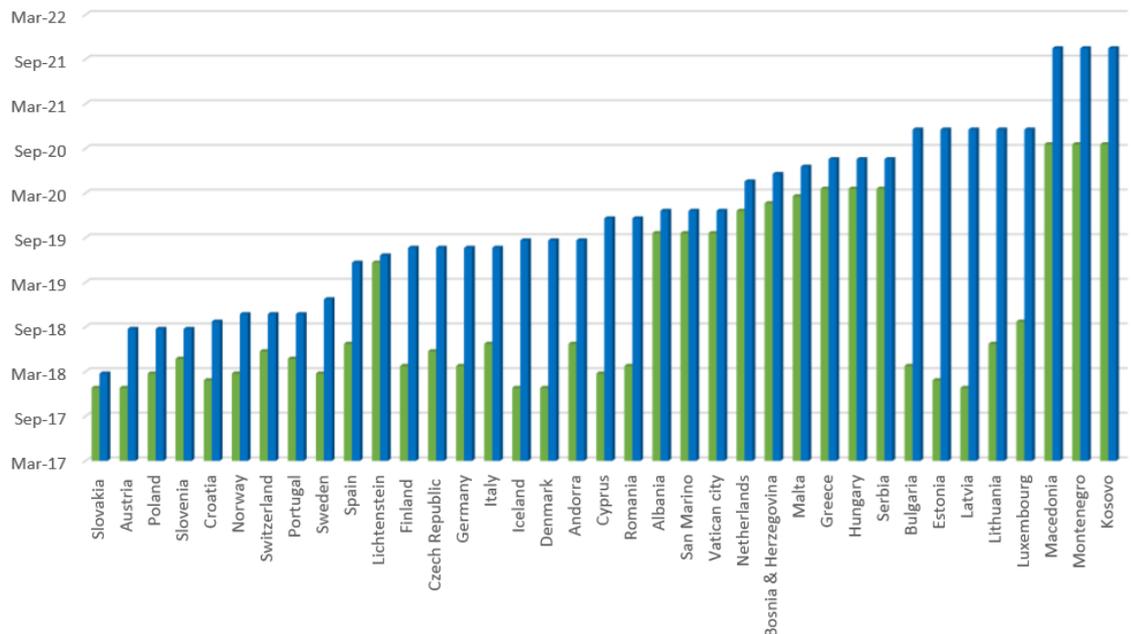
France (the third major market launch for Pentrox)

- Launched February 2017, so now 2 years and 8 months in.
- Now 359 customers (v 248 in FY18) +111 or +45%.
- 121 hospital formulary approvals (per 10/9/18 presentation) and targeting 350.
- Pentrox appears to be getting much better traction in France than in the UK. This augurs well for the rest of Europe.

Europe (including France)

- Sales up 401% (but off a low base).
- Almost 400 new customers in Europe (including +111 in France as above).
- Regulatory approval now received in 27 European countries. Sales have been made into 13 of the 41 countries in Europe & UK.
- Launches planned for the remaining 28 countries including the main markets of Germany, Italy and Spain. Pre-launch marketing and education by Mundipharma already well underway.
- NB MVP has already sold product to Mundipharma ahead of these launches.

Europe launch plan

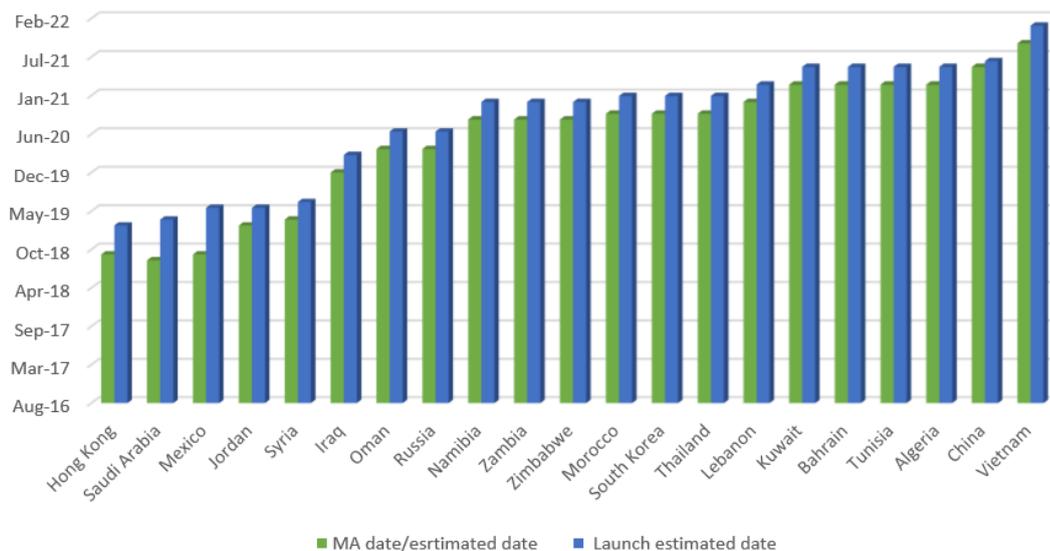


Source: MVP presentation 4/3/19 (NB Launch dates appear to have slipped).

Rest of World

- Regulatory approval and launches in Hong Kong and Saudi Arabia achieved in FY19.
- Approval in Jordan achieved. Presume launch in FY20.
- MVP working towards approval and launch in a further 19 countries including Mexico (refer 4/3/19 presentation).

Rest Of the World launch plan



Source: MVP presentation 4/3/19 (NB Launch dates appear to have slipped).

Medical Equipment

This division reported an 8% decline in revenue to \$5.9m, but a 13% improvement in Ebitda to \$0.6m as follows:

MVP - FY19 Results Review - Medical Devices Division (Asthma devices)							Change	PCR Est	Difference %	Comments
Years ended June \$m	1H18	2H18	FY18	1H19	2H19	FY19				
Operating revenue	2.7	3.7	6.5	2.8	3.1	5.9	-8%	6.0	-1%	Sales down as UK distributor over-ordered previously
External sales growth	-67%	-345%	-3%	2%	-16%	-8%		-7%		
Ebitda	-0.024	0.531	0.507	0.073	0.500	0.573	13%	0.5	15%	Stronger 2H Closed UK Ebitda margin down 12 points
Ebitda margin	-0.9%	14.2%	7.8%	2.6%	15.9%	9.7%	23%	8.3%		
Depreciation & Amortisation	-0.077	-0.192	-0.192	-0.117	-0.192	-0.249	30%			Amortisation of capitalised Registration costs rises as each country is launched
EBIT	-0.101	0.339	0.315	-0.044	0.308	0.324	3%			
Ebit margin	-3.7%	9.1%	4.9%	-1.6%	9.8%	5.5%	12%			
Segmental Assets	9.3	10.0	10.0	9.1	10.0	10.0	0%			
Return on Assets (Ebit)	-2.2%	6.8%	3.2%	-1.0%	6.2%	3.2%				

Source: MVP accounts

We understand that the revenue decrease was due to the UK distributor over-ordering in the FY18 year in anticipation of winning a large new pharmacy account which so far has not eventuated.

MVP is confident that the business will continue its strong growth trend.

We were pleased to see the Ebitda margin improve to 9.7% (v 7.8%) suggesting that MVP can continue to make reasonable margins whilst utilising large international distributors to grow its global reach and volumes.

Veterinary Products

This division reported an 18% sales decline and a 25% decline in Ebitda as follows:

MVP - FY19 Results Review - Veterinary Equipment Division										
Years ended June \$m	1H18	2H18	FY18	1H19	2H19	FY19	Change	PCR Est	Difference %	Comments
Operating revenue	0.3	0.5	0.8	0.4	0.3	0.6	-18%	0.6	3%	Sales down as a launch order with a large US customer in FY18 was not repeated
External sales growth	0%	0%	11%	20%	-43%	-18%		-21%		
Ebitda	0.134	0.110	0.244	0.120	0.064	0.184	-25%	0.200	-8%	As above Ebitda margin down due to lower sales
Ebitda margin	44.8%	24.1%	32.3%	33.3%	24.8%	29.8%	-8%	33.3%		
Depreciation & Amortisation	-0.011	-0.037	-0.037	-0.013	-0.037	-0.025	-32%			
EBIT	0.123	0.073	0.207	0.107	0.027	0.159	-23%			Ebit margin down due to lower sales
Ebit margin	41.1%	16.0%	27.4%	29.7%	10.5%	25.7%	-6%			
Segmental Assets	1.0	1.1	1.1	1.1	1.1	1.1	-1%			
Return on Assets (Ebit)	23.9%	13.0%	18.5%	20.1%	4.9%	14.4%				

Source: MVP accounts

We understand that the revenue decrease was due to timing, with a launch order for a large US customer in the FY18 year not repeating.

We are a little concerned that MVP may be gradually losing its competitive advantage in this division, as it spends little on R&D. Management assures us this is not the case.

This is the smallest of MVP's three divisions, so it probably doesn't matter much in the overall scheme of things.

Unallocated Costs

These were up 9% to \$3.0m after adjusting for the \$0.4m FX gain on the Daiichi Sankyo up-front licence fee.

MVP - FY19 Results Review - Unallocated costs										
Years ended June \$m	1H18	2H18	FY18	1H19	2H19	FY19	Change	PCR Est	Difference %	Comments
Unallocated	-1.5	-1.4	-2.9	-1.5	-1.2	-2.7	-8%	(3.2)	-17%	
Adjust for FX gains (losses)	0.0	0.1	0.1	0.0	-0.4	-0.4				
Adjusted Unallocated costs	-1.5	-1.3	-2.8	-1.5	-1.6	-3.0	9%	-3.2	-5%	Unallocated costs 5% below expectations, after adjusting for FX gain

Source: MVP accounts

China Update

- IND (Investigative New Drug) application submitted in China in August 2018.
- 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 Pentrox.
- MVP could receive marketing approval for Pentrox in China within 18 months if things go according to plan (end 2020).

Background

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

China Ambulance – The ambulance system is hospital based (especially large teaching hospitals) and city based. Ambulance is a major part of Pentrox'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

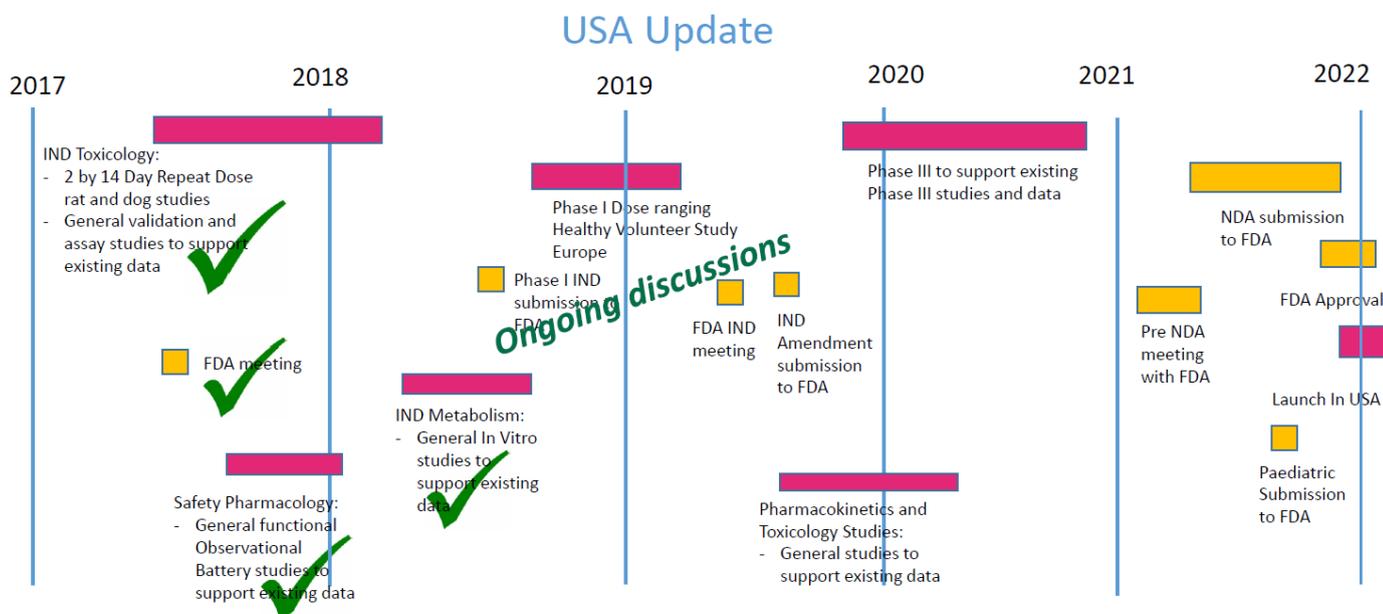
Penthrox US Approval Process

MVP expects its proposed US 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 40% from \$5.85 before the announcement on 25/7/18 to a 12-mth low of \$3.48 in February 2019. Now at \$4.98, MVP shares have recovered \$1.50 of that \$2.37 fall (~63%), but are still 15% lower than before the announcement. Therefore we think the share price could bounce a further ~15% or so should the US IND application process be allowed to restart. The All Ordinaries index (XAO) is also 6.2% higher since that date (6758 points vs 6366 points).

The US has an estimated 140m Accident & Emergency department admissions 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.

Our forecasts assume a US launch in January 2023, but we have isolated this item separately in our Sum of the Parts valuation table.



Source: CEO roadshow presentation 4/3/19

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 41 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 \$11.9m in FY19 to \$130m for the 41 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 around \$240m 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.

CONTACT INFORMATION

CEO					
John Miles	+61 3 8633 9838	jmiles@phillipcapital.com.au			
Research					
Wayne Sanderson	+61 3 8633 9930	wsanderson@phillipcapital.com.au			
Corporate Finance					
Sharon Cardy	+61 2 9233 9611	scardy@phillipcapital.com.au			
Institutional Sales					
Enzo Salvatore	+61 3 8633 9924	esalvatore@phillipcapital.com.au	Chris Walker	+61 3 8633 9928	cwalker@phillipcapital.com.au
Institutional Execution					
Craig Stephens	+61 3 8633 9881	cstephens@phillipcapital.com.au			
Private Wealth					
Enzo Salvatore	+61 3 8633 9924	esalvatore@phillipcapital.com.au	Mark Wiseman	+61 3 9618 8228	mwiseman@phillipcapital.com.au
Ben Roper	+61 7 3338 3835	broper@phillipcapital.com.au	Michael Cori	+61 2 9233 9648	mcori@phillipcapital.com.au
Bo Xin	+61 7 3338 3840	bxin@phillipcapital.com.au	Nick Katiforis	+61 3 8633 9847	nkatiforis@phillipcapital.com.au
Chris Forte	+61 3 8633 9841	cforte@phillipcapital.com.au	Nigel Ormiston	+61 7 3149 8630	normiston@phillipcapital.com.au
Chris Walker	+61 3 8633 9928	cwalker@phillipcapital.com.au	Patricia Harrison	+61 2 9994 5505	pharrison@phillipcapital.com.au
Daniel McFarlane	+61 3 8633 9917	dmcfarlane@phillipcapital.com.au	Patrick Trindade	+61 3 8633 9926	ptrindade@phillipcapital.com.au
Dinesh Magesan	+61 7 3338 3831	dmagesan@phillipcapital.com.au	Prasanna Wickramatunge	+61 3 9618 8270	pwickramatunge@phillipcapital.com.au
David Dwyer	+61 2 9233 9643	ddwyer@phillipcapital.com.au	Rob Hughes	+61 3 8633 9846	rhughes@phillipcapital.com.au
David Thang	+61 3 8633 9923	dthang@phillipcapital.com.au	Sam Sheffield	+61 7 3338 3837	ssheffield@phillipcapital.com.au
Howard Elton	+61 3 9618 8233	helton@phillipcapital.com.au	Shane Langham	+61 7 3338 3838	slangham@phillipcapital.com.au
Jim Yong	+61 7 3338 3839	jyong@phillipcapital.com.au	Sue McDonald	+61 3 9618 8211	smcdonald@phillipcapital.com.au
Joel Christie	+61 7 3338 3834	jchristie@phillipcapital.com.au	Xiaoming Huang	+61 3 8633 9912	xhuang@phillipcapital.com.au
Josh Graham	+61 3 92339645	jgraham@phillipcapital.com.au			
Kate Hanrahan	+61 3 8633 9909	khanrahan@phillipcapital.com.au			
Lachlan Owen	+61 3 8633 9842	lowen@phillipcapital.com.au			
Funds Management					
Jessica Bell	+61 3 8633 9998	jbell@phillipcapital.com.au	Monica (Mengnu) Yu	+61 3 8633 9810	my@phillipcapital.com.au
Glenn Tan	+61 3 8633 9905	gtan@phillipcapital.com.au	Zane (Zheng) Song	+61 2 9233 9640	zsong@phillipcapital.com.au

CONTACT INFORMATION (Regional Member Companies)

SINGAPORE

Phillip Securities Pte Ltd

Raffles City Tower
250, North Bridge Road #06-00
Singapore 179101

Tel +65 6533 6001

Fax +65 6535 6631

www.phillip.com.sg

HONG KONG

Phillip Securities (HK) Ltd

11/F United Centre 95 Queensway
Hong Kong

Tel +852 2277 6600

Fax +852 2868 5307

www.phillip.com.hk

INDONESIA

PT Phillip Securities Indonesia

ANZ Tower Level 23B,
JI Jend Sudirman Kav 33A
Jakarta 10220 – Indonesia

Tel +62-21 5790 0800

Fax +62-21 5790 0809

www.phillip.co.id

THAILAND

Phillip Securities (Thailand) Public Co. Ltd

15th Floor, Vorawat Building,
849 Silom Road, Silom, Bangrak,
Bangkok 10500 Thailand

Tel +66-2 6351700 / 22680999

Fax +66-2 22680921

www.phillip.co.th

UNITED KINGDOM

King & Shaxson Capital Limited

6th Floor, Candlewick House,
120 Cannon Street,
London, EC4N 6AS

Tel +44-20 7426 5950

Fax +44-20 7626 1757

www.kingandshaxson.com

MALAYSIA

Phillip Capital Management Sdn Bhd

B-3-6 Block B Level 3 Megan Avenue II,
No. 12, Jalan Yap Kwan Seng, 50450
Kuala Lumpur

Tel +603 2162 8841

Fax +603 2166 5099

www.poems.com.my

JAPAN

Phillip Securities Japan, Ltd.

4-2 Nihonbashi Kabuto-cho Chuo-ku,
Tokyo 103-0026

Tel +81-3 3666 2101

Fax +81-3 3666 6090

www.phillip.co.jp

CHINA

Phillip Financial Advisory (Shanghai) Co. Ltd

No 550 Yan An East Road,
Ocean Tower Unit 2318,
Postal code 200001

Tel +86-21 5169 9200

Fax +86-21 6351 2940

www.phillip.com.cn

FRANCE

King & Shaxson Capital Limited

3rd Floor, 35 Rue de la Bienfaisance 75008
Paris France

Tel +33-1 45633100

Fax +33-1 45636017

www.kingandshaxson.com

UNITED STATES

Phillip Futures Inc

141 W Jackson Blvd Ste 3050
The Chicago Board of Trade Building
Chicago, IL 60604 USA

Tel +1-312 356 9000

Fax +1-312 356 9005

INDIA

PhillipCapital (India) Private Limited

No. 1, C - Block, 2nd Floor, Modern Center,
Jacob Circle, K. K. Marg, Mahalaxmi
Mumbai 400011

Tel: (9122) 2300 2999

Fax: (9122) 6667 9955

www.phillipcapital.in

TURKEY

PhillipCapital Menkul Degerler

Dr. Cemil Bengü Cad. Hak Is Merkezi
No. 2 Kat. 6A Caglayan
34403 Istanbul, Turkey

Tel: 0212 296 84 84

Fax: 0212 233 69 29

www.phillipcapital.com.tr

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