Medical Developments International

ASX:MVP

FY24 HALF YEAR RESULTS

29 February 2024

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Non-IFRS Financial Information

This presentation uses non-IFRS information including underlying revenue, underlying EBIT and underlying adjustments.These measures are key performance measures used by MVP, the investment community, and peers with similar business portfolios. MVP uses these measures for its internal management reporting as it better reflects what MVP considers to be its underlying performance. Underlying revenue and EBIT are used to measure segment performance and have been extracted from the segment information disclosed in the Half Year Consolidated Financial Report.

Executive summary

Positive operational momentum through 1H24, positive FDA feedback provides greater clarity on next steps in US

1H FY24 results[1]

- Group revenue up 9% to $15.1m driven by positive momentum in Pain Management (Europe and Australia)
- Pricing and efficiency benefits of $6.0m p.a. delivered
- Underlying EBIT improved by $0.3m
- Free cashflow improved by $3.5m

Key operational / commercial progress

- Efficiency and cash management measures are yielding results
- Good momentum for Penthrox® demand in Australian hospital emergency departments with volume +4% at significantly higher pricing
- Partner negotiations well progressed for Penthrox® distribution in France and Switzerland
- Growing market share in US respiratory segment, with US revenue growth of ~48% in 1H FY24

US market entry

- Positive FDA feedback providing greater clarity on the next steps in connection with non-clinical study requirements and device development
- Deeper understanding of US market potential, sales channels, potential partners and opportunities to maximise value
- Funding options for the non-clinical studies are being explored. While partner funding may be an option, this may not provide the best long-term outcome for shareholders

1. Versus prior corresponding period. All growth numbers are against this benchmark unless otherwise stated.

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FY24 Half Year

FY24 Half Year Results

Revenue
$15.1m
+9%[1]

Pain management revenue
$9.6m
+26%[1]

Respiratory revenue
$5.5m
-10%

Underlying EBIT[2]
$7.8m (loss)
+4%[2]

Reported NPAT
$10.9m (loss)
(pcp $2.7m gain)

Free cashflow
$8.3m (outflow)
+3.5m

1. Excluding Contract termination revenue of $18.9 million in the pcp (refer to the Half Year Consolidated Financial Report).
2. Before underlying adjustments of $5.1 million loss (pcp $11.5 million gain). Refer to page 16 for a summary of Underlying Adjustments.

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FY24 Half Year

1H FY24 strategic and operational highlights

Good progress has been made on key BAU[1] initiatives

	FY24 strategic priorities	Achievements / progress to date
	**Improve margins through pricing and operational efficiency**	• $6.0m p.a earnings benefit from pricing and efficiency improvements delivered in 1H24 • Additional efficiency savings of $3.0m p.a to be realised in FY25, of which $2.3m p.a has been implemented in the last few months[2]
	**Increase penetration of Penthrox® in Australian hospital emergency departments (EDs)**	• Encouraging lead indicators in hospital emergency department segment • Protocol listings for Penthrox® in 44 new hospitals over last year • Higher penetration with 176 purchasing hospitals in 1H FY24 versus 130 in 1H FY23
 In progress	**Review go-to-market model for Europe**	• Partner negotiations well advanced for Penthrox® distribution in select markets • Direct markets of France and Switzerland likely to transition to partners, subject to final agreement on terms
 In progress	**Drive continued growth in Respiratory**	• Lower prevalence of respiratory conditions has softened demand in all Australia • 1H FY24 revenues up 48% versus 1H FY23 in priority US market driven by market share growth

1. BAU: business as usual
2. Expect the impact of this cost out initiative to be cash flow neutral in FY24 with full benefits to be realised in FY25

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FY24 Half Year

Positive momentum on Penthrox® US market entry

Greater clarity provided by the regulatory body enabling MVP to progress towards Penthrox® market entry

Recent developments

- Positive meeting with the USFDA in October 2023, providing clear guidance on next steps:
  - Non-clinical reproductivity studies[1] required to include women of childbearing potential ('WOCBP') in the Phase III Clinical Trial
  - Support for MVP's proposal to use the Next Generation Device as part of Phase III Clinical Trial
  - Pathway to using existing clinical trial data in New Drug Application
- Engagement of advisors to evaluate the commercial assessment of the US acute pain market and to provide strategic guidance on the partner search for Penthrox® commercialisation
- Refer page 17 in the Appendix for further details regarding USFDA engagement and feedback

Key takeaways

- ✓ Potential for all adults to be included in Phase III Clinical trial and launch populations
- ✓ Pathway to removing need for second pivotal clinical trial, resulting in a reduction in time to registration and cost
- ✓ Planning underway to identify avenues to remove IV access restrictions post-launch
- ✓ Deeper understanding of US market potential, sales channels, potential partners and opportunities to maximise value
- ✓ Funding options for the non-clinical studies are being explored. While partner funding may be an option, this may not provide the best long-term outcome for shareholders

1. Non-clinical studies to encompass FEED, EFD and PPND studies - FEED: Fertility and Early Embryonic Development; EFD: Embryo-Fetal Development; PPND: Pre and Post Natal Development. Likely time to complete trials is 18-24 months.

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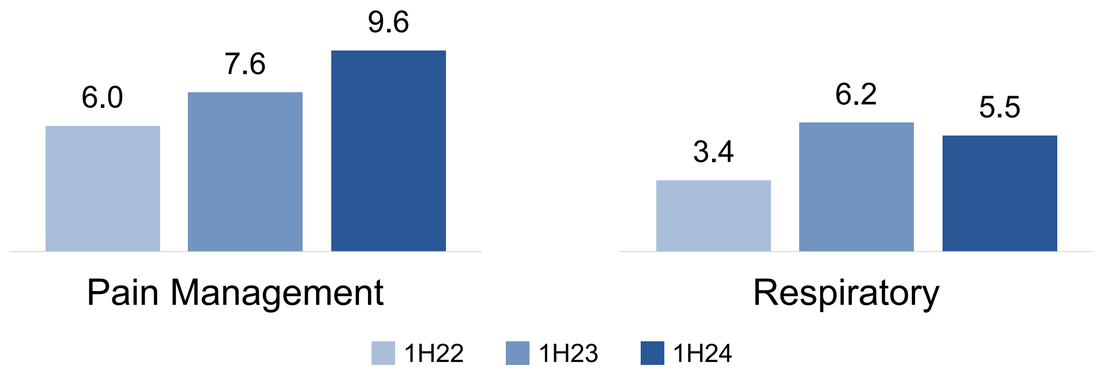
Results summary

$million	1H23	1H24	Change $m
Revenue[1]	13.9	15.1	1.2
Underlying EBIT	(8.1)	(7.8)	0.3
Underlying Adjustments (before tax)[2]	11.5	(5.1)	(16.6)
Reported EBIT	3.4	(12.9)	(16.3)
NPAT	2.7	(10.9)	(13.6)

Segment revenue[3]

($million)



Commentary

- Group revenue up 9%
- Continued growth of Penthrox® in key markets; higher prices
- Robust Respiratory revenue growth in US, softer demand in other regions
- Lower cost to serve in Europe
- Underlying EBIT improved
- Non-cash Underlying Adjustment of $5.1m (loss before tax) relating to share-based payment expense adjustments arising on transition to new remuneration arrangements for the CEO

1. 1H23 excludes Contract termination revenue of $18.9 million (refer to the Half Year Consolidated Financial Report).
2. Underlying adjustments are detailed on page 16 in the Appendix.
3. Excludes other segment revenues relating to discontinued businesses (FY23: $0.1 million; FY22: $0.2 million).

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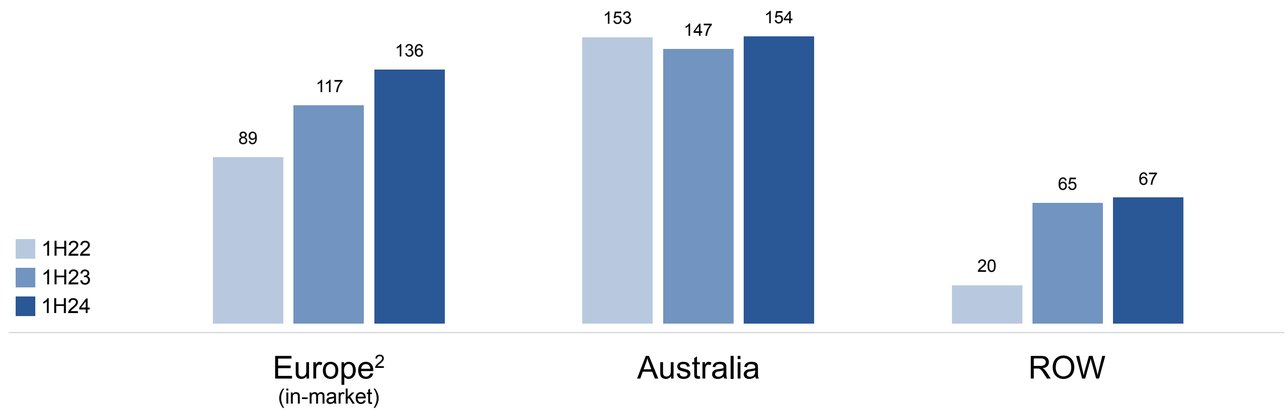
Pain Management segment revenue

Revenue up 26%, higher volumes and pricing

$million	1H23	1H24	Change %
Europe	1.8	2.6	44%
Australia	4.0	5.8	45%
Rest of World	1.2	1.1	(8%)
Product revenue[1]	**7.0**	**9.5**	**36%**
Milestone and other revenue	0.6	0.1	(83%)
Pain Management	**7.6**	**9.6**	**26%**

Penthrox® Units

(000s)



Commentary

Europe

- In-market volumes up 16%
- UK and Ireland in-market volumes up 18% with momentum continuing
- Volume in France holding firm despite withdrawal of in-market resources
- Growth in all other markets

Australia

- Volumes up 4% with growing penetration in emergency departments
- Higher average prices

Rest of World (ROW)

- Stronger volume into New Zealand, Asia, South Africa and Mexico more than offset lower volume into Canada following inventory stocking for relaunch of Penthrox® in FY23

1. Prior year excludes Contract termination revenue of $18.9 million (refer to the Half Year Consolidated Financial Report).
2. European volumes reflect “in-market” sales units, which may differ from units sold to distribution partners in the period (and recognised in revenue). The Company believes this measure improves the transparency of underlying demand.

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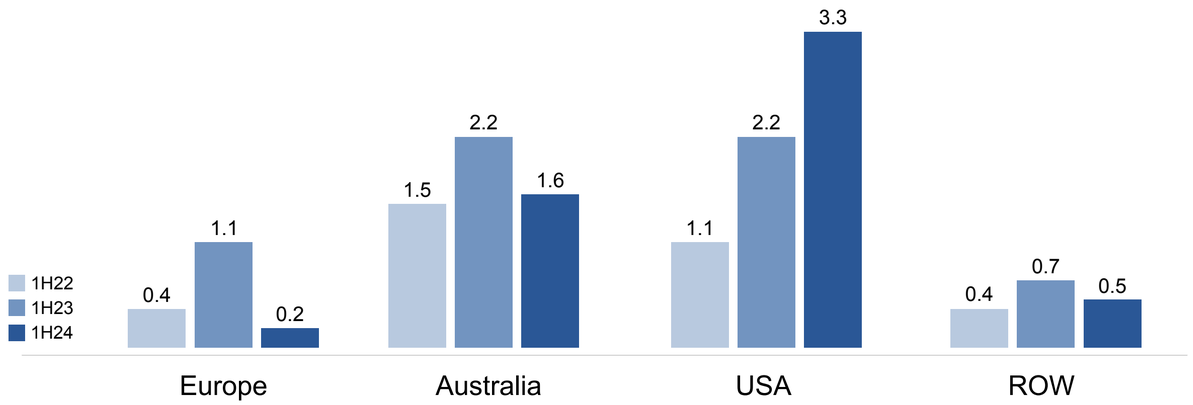
Respiratory segment revenue

Weaker underlying demand globally, share growth in US drives 48% growth

$million	1H23	1H24	Change %
Europe	1.1	0.2	(82%)
Australia	2.2	1.6	(27%)
USA	2.2	3.3	48%
Rest of World	0.7	0.5	(28%)
Respiratory	**6.2**	**5.5**	**(10%)**

Revenue

($million)



Commentary

Europe

- Lower demand from UK, Germany and Italy due in part to inventory stocking in the prior year

Australia

- Softer demand arising from lower incidence of respiratory conditions, particularly during winter
- Market share maintained

USA

- Strong partner engagement continues to drive market share growth
- Continued expansion into pharmacy banner / wholesaler and GPO groups

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EBIT bridge

Volume and pricing drive margin expansion

Commentary

Pricing and efficiency

- Stronger pricing in Pain Management, particularly for Penthrox® in Australia
- Supply chain efficiencies and lower cost to serve in Europe

Volumes

- Growth in Penthrox® volumes in most markets, Canada volumes lower following stock build in prior year
- Growth through share gains in US Respiratory market offset by seasonally softer demand in other regions

Penthrox® expansion strategy

- Investment in Australian Penthrox® field team, leadership and functional capability appointed throughout FY23

Other changes

- Non-capital costs relating to European operating model review and US market entry
- Lower milestone income following true-up in prior year
- Inflationary impacts

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Balance sheet and cashflow

Free cashflow improved $3.5 million

$million	1H23	1H24	Change
Underlying EBITDA	(6.6)	(6.3)	0.3
Non-cash items	(0.1)	0.6	0.7
Change in working capital	(1.5)	(0.6)	0.9
Change in other assets and liabilities	(0.7)	(0.3)	0.4
Interest paid	(0.1)	(0.1)	0.0
Operating cash flow	**(9.0)**	**(6.7)**	**2.3**
Capital expenditure	(2.8)	(1.6)	1.2
Free cashflow	**(11.8)**	**(8.3)**	**3.5**
Working capital / sales (%)	**22%**	**15%**	**7%pts**

Commentary

Working capital

- Working capital to sales % improved
- Strong customer collections
- Increased inventory investment to support stronger sales in the US Respiratory market
- Outflows include one-off payments for the PwC commercial market assessment completed in FY23 ($1.9m) and contract termination costs in France following the scale down of investment at the end of FY23 ($0.8m)

Capital expenditure

- Plant and equipment ($0.7m), mostly relating to manufacturing projects
- Intangible assets ($0.9m), mostly relating to development of the Next Generation Device, the UK paediatric trial, and planning for US registration

Cash

- Closing cash balance of $15.7m

Closing remarks and outlook

Positive operational momentum to continue

$6.0m p.a. earnings benefit realised from pricing and efficiency with a **further $3.0m p.a. cost savings** to be delivered in **FY25,** of which $2.3m p.a. has been implemented to date[1]. MVP is on track to be operating cashflow positive by the end of FY25

Positive engagement with the USFDA and deeper understanding of the US market is providing clarity on the pathway to US launch. Funding options for non-clinical studies are being explored

The Company expects **underlying EBIT in FY24 to be strongly improved on FY23**, driven by higher average Penthrox prices and lower costs

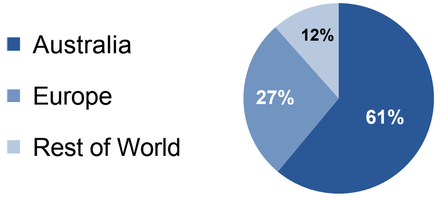
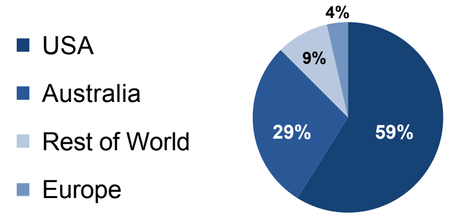
1. Expect the impact of this cost out initiative to be cash flow neutral in FY24 with full benefits to be realised in FY25

APPENDICES

Appendices

Business overview

The Pain Management segment generates the majority of Group revenue, driven by demand for Penthrox® in Australia and Europe

	Pain Management	Respiratory
		
Description	Manufactures Penthrox®, an inhaled, needle-free, non-opioid analgesic	Supplies pharmacies, medical clinics and hospitals with a range of respiratory devices which are designed to assist patients to manage asthma and COPD[1]
1H FY24 revenue	$9.6m (~64% of total revenue)	$5.5m (~36% of total revenue)
1H FY24 revenue breakdown by geography		

1. Chronic Obstructive Pulmonary Disease

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Appendices

Penthrox® overview

Efficacy, safety and administration benefits of Penthrox® deliver positive patient outcomes and lower overall customer costs[1-5]

- Inhaled **needle-free** analgesic[1]
- **Non-opioid**[1]
- **Portable**, **self administered** device[1]
- **Effective pain relief** within **6–10 breaths**[1-4]
- **Established safety profile** with over **9 million uses**
- **Well tolerated,** with the majority of adverse events mild and transient[1,2]
- **Approved for use in children in Australia**[1]
- **Efficiency benefits** of Penthrox in hospital emergency departments illustrated in British study[5]

The iconic ***Green Whistle***

Over **9 million** used worldwide

1. Penthrox® (methoxyflurane) Approved Product Information 06 October 2023.
2. Coffey F, et al. STOP!: a randomised, double-blind, placebo-controlled study of the efficacy and safety of methoxyflurane for the treatment of acute pain. Emerg Med J 2014;31:613-618.
3. Grindlay J & Babl FE. Review article: Efficacy and safety of methoxyflurane analgesia in the emergency department and prehospital setting. Emerg Med Australasia 2009;21:4-11.
4. Penthrox® (methoxyflurane) Consumer Medicine Information August 2023.
5. Young L, et al. Service Evaluation of Methoxyflurane Versus Standard Care for Overall Management of Patients with Pain Due to Injury. Adv Ther (2020) 37:2520–2527

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Reconciliation between underlying EBITDA and net loss after tax

$million	1H23	1H24
Underlying EBITDA	**(6.6)**	**(6.3)**
Depreciation and amortisation expense	(1.5)	(1.5)
Underlying EBIT	**(8.1)**	**(7.8)**
Share-based payment expense arising from cancellation of options[1]	-	(5.1)
Contract termination revenue - Pain Management segment[2]	18.9	-
Impairment losses - Capitalised Registration Costs[3]	(7.4)	-
Total underlying adjustments	**11.5**	**(5.1)**
Reported EBIT	**3.4**	**(12.9)**
Net interest	0.1	0.2
Net loss before tax	**3.5**	**(12.7)**
Income tax benefit	(0.8)	1.8
Net loss after tax	**2.7**	**(10.9)**

Notes

FY24

1. An acceleration of share-based payment expense of $5.1m relating to the cancellation of all share options held by the CEO upon joining the Group LTI program as part of new CEO remuneration arrangements approved by shareholders at the 2023 Annual General Meeting.

FY23

2. Contract termination revenue arising from the termination of agreements for the distribution of Penthrox® in China ($18.5m), and other countries where revenue opportunities are not being pursued ($0.4m).

3. Impairment of capitalised registration costs following the cessation of market activities in China of $6.5m, and an additional $0.9m in other countries where revenue opportunities are not being pursued.

USFDA engagement: growing clarity on clinical pathway

IND approval March 2022	USFDA Feedback October 2023
Trial patient population restricted to males ≥ 18 years of age and post menopausal women with no IV access	• Positive results from 2 of the 3 required development and reproductive toxicity non-clinical studies would enable WOCBP (with pregnancy test as part of the protocol) to enroll in the Phase III trial.
Green light to commence clinical development (standard USFDA requirement of 2 pivotal trials)	• Confirmation that use of pre-existing Phase III clinical data may be possible • Clarity on non-clinical program required before commencement of Phase III • Further USFDA engagement planned to clarify additional non-clinical work that may be required before NDA • Support for MVP's proposal to use the Next Generation Device as part of Phase III clinical trial • Clarification on pathway to demonstrate bio-equivalence with the Next Generation Device, including a human factor study

Appendices

US market overview

The US pain market is highly attractive and Penthrox® is well positioned to capitalise on the structural opportunities uniquely presented by the US market

Key industry trends

- ✓ The opioid epidemic has led to a **growing shift in prescriber preferences away from opioids**, creating opportunities for new, innovative products to gain a foothold in the market
- ✓ Opex pressure and price sensitivity are common in the acute care market, **which is beneficial for low holistic cost solutions such as Penthrox®**
- ✓ **Crowded emergency rooms** have increasingly led patients to on-demand sites of care (e.g., urgent care)
- ✓ Commercialisation success in this market largely depends on **overcoming fragmentation in highly diverse end user channels, adapting treatment protocols, and changing prescriber habits by building awareness and buy-in amongst healthcare practitioners**

Penthrox® value proposition

- ✓ Increased quality of care and patient satisfaction
- ✓ Faster administration
- ✓ Reduced staffing needs for administration / monitoring
- ✓ Quicker dispositioning of patients, particularly vs. prolonged procedural sedation
- ✓ Reduced need to establish IV[1] access
- ✓ Higher patient satisfaction
- ✓ Higher provider satisfaction
- ✓ Fewer DEA[2] regulations

1. IV: Intravenous.
2. DEA: Drug Enforcement Administration.