Medical Developments International

29 February 2024

ASX ANNOUNCEMENT

FY24 HALF YEAR RESULTS

POSITIVE MOMENTUM

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

[1] Excludes Contract termination revenue of $18.9 million (refer to the Half Year Consolidated Financial Report)
[2] Refer to the Half Year Consolidated Financial Report

KEY ACHIEVEMENTS

- **Group revenue up 9% to $15.1m**
  - Good momentum for Penthrox demand in Australian hospital emergency departments with volume +4% at significantly higher pricing; European demand +16%
  - Growing market share in US respiratory segment, with US revenue growth of +48%
- **Free cashflow improved by $3.5m**
  - Pricing and efficiency benefits of $6m p.a. delivered
- **Review of operating model in Europe complete**
  - Partner negotiations well progressed for Penthrox distribution in France and Switzerland
  - Demand in France remains firm
- **Positive momentum on Penthrox US market entry**
  - Greater clarity provided by USFDA on 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

Medical Developments International (ASX: MVP) today announced a net loss after tax of $10.9 million for the half year ended 31 December 2023, compared to a profit of $2.7 million in the prior corresponding period (pcp). The Board elected not to declare a dividend.

Medical Developments International Limited ABN 14 106 340 667
4 Caribbean Drive Scoresby Victoria 3179 Australia **Postal Address** PO Box 9004 Scoresby Victoria 3179 Australia
Telephone +61 3 9547 1888 **Fax** +61 3 9547 0262 **Web** www.medicaldev.com

Reported earnings included a net loss from Underlying Adjustments of $5.1 million before tax (pcp $11.5 million gain), 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. This is a non-cash adjustment. No benefit was received by the CEO.

HALF YEAR PERFORMANCE

CEO, Brent MacGregor, said, "*Our FY24 half year results demonstrate positive momentum. Demand for Penthrox continues to grow, and our Respiratory business, despite seasonally weaker demand in most markets, has delivered robust growth in the US. We have delivered $6 million per annum earnings improvements through pricing and efficiency, and both Underlying EBIT and operating cashflows are improving.*"

Group revenue was up 9% on the pcp at $15.1 million. The Pain Management segment delivered revenue growth of 26%, with higher volumes and improved pricing, particularly in Australia. Good momentum in hospital emergency departments in Australia delivered 4% volume growth. Underlying demand in Europe was up 16%. In France, demand remained firm despite the scale-back of promotional activity in FY23, with volume in line with the pcp. Volume in the UK and Ireland was up 18%. Volumes into other markets were down 5% following inventory stocking for the relaunch of Penthrox in Canada in the prior year.

Revenue in the Respiratory segment was down 10% due to weaker respiratory conditions in some markets which softened demand for our suite of products. Revenue in the US was up 48% reflecting continued strong market share growth in our target strategic market.

EBIT improved 4% in the period. Earnings benefits from higher overall volumes, pricing and efficiency more than offset investment in the Australian Penthrox field team and other capability changes in FY23, and non-capital costs associated with reviewing the European operating model and progressing US market entry planning.

Free cashflow improved by $3.5 million, with improved earnings, strong working capital management, and lower capital expenditure. Monthly operating cashflows are improving, as business efficiencies are delivered.

FY24 PRIORITIES

Improve margins through pricing and efficiency

The Group delivered $6 million per annum earnings benefits from pricing and efficiency in the period. This includes a reduction in costs in Europe following the scale-down of promotional activity in France and the transition of regional support to Melbourne, lower supply chain costs and higher pricing for Penthrox in Australia.

The Group has commenced further efficiency programs, which will deliver $3 million per annum earnings benefits in FY25. Implementation of the program is expected to be cashflow neutral in FY24.

Increase penetration of Penthrox in Australian hospital emergency departments

The Group's expansion of Penthrox into Australian hospital emergency departments is delivering encouraging lead indicators. Penthrox has been listed on protocols in 44 new hospitals over the last year, and the total number of purchasing hospitals has increased by 46 to 176 hospitals.

Review go-to-market model for Europe
The Group has completed a detailed review of its go-to-market model for Europe. Subject to final agreement on terms, direct markets of France and Switzerland are likely to transition to partners. Negotiations are well progressed.

Progress Penthrox US market entry
In October the Group had a positive meeting with the USFDA, where the regulatory agency provided guidance on next steps, including:

- non-clinical studies required to include women of childbearing potential ('WOCBP') in the Phase III Clinical Trial;
- support for the Group's proposal to use its next generation device in the Phase III Clinical Trial; and
- the pathway to using existing clinical trial data in the New Drug Application.

This guidance will enable the Group to potentially broaden the Phase III trial population to include all adults, and potentially remove the need for a second pivotal trial, resulting in a reduction in time to registration and cost. Ultimately, broadening the trial population should have a positive impact on the eventual product label at market launch. Completing the non-clinical studies is an important next step in the pathway to market entry.

The Group is exploring funding options for these studies. Over the last 12 months the Group has deepened its understanding of the US market potential, sales channels, potential partners, and opportunities to maximise value. While partner funding may be an option, it may not provide the best long-term outcome for shareholders.

Mr MacGregor said, *"Our work on business efficiencies and volume expansion is driving improved cashflows, and further work we have underway will accelerate this change. We remain on track to deliver positive operating cashflows by the end of FY25.*

"We now have much greater clarity on how to unlock value in Europe, with a partner supported strategy a cost-effective way to realise the volume potential we see here.

"The clarity we have received from the USFDA on the next steps toward US market entry provides positive momentum to our work here. Completing the non-clinical studies will potentially broaden the Phase III trial and launch populations and enhance the value proposition of Penthrox."

FY24 OUTLOOK

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

~END~

Authorised for release by the Board of Directors.

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4 Caribbean Drive Scoresby Victoria 3179 Australia **Postal Address** PO Box 9004 Scoresby Victoria 3179 Australia
Telephone +61 3 9547 1888 **Fax** +61 3 9547 0262 **Web** www.medicaldev.com

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Enquiries

Anita James
Chief Financial Officer
+61 (3) 9547 1888

About Medical Developments International Ltd
MVP is an Australian company delivering emergency medical solutions dedicated to improving patient outcomes. MVP is a leader in emergency pain relief and respiratory products. The Company manufactures Penthrox®, a fast-acting non-opiod trauma & emergency pain relief product. It is used in Australian Hospitals including Emergency Departments, Australian Ambulance Services, the Australian Defence Forces, Sports Medicine and for analgesia during short surgical procedures such as change of burns dressings, biopsies and dental procedures as well as in other medical applications.