Medical Developments International

5 September 2023

ASX ANNOUNCEMENT

Transcript of FY23 Full Year Investor Presentation

Enclosed is the transcript of the briefing to shareholders and the investment community held on Thursday 31 August 2023 following release of the FY23 Full Year results.

Investor can also access the presentation slides of that webcast at MVP-FY23-Full-Year-Results-Investor-Presentation.pdf (medicaldev.com)

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Authorised for release by the Board of Directors.

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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 trauma & emergency non-opioid 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.

Medical Developments International

FY23 Full Year Results Presentation
31 August 2023 at 10:00 AEST

Presented by:
Gordon Naylor – Company Chair
Brent MacGregor – Chief Executive Officer
Anita James – Chief Financial Officer

Start of Transcript

Gordon Naylor: Good morning and welcome to today's investor briefing for our full year financial results. I am Gordon Naylor, Company Chair. I am joined today by Brent MacGregor, our Chief Executive Officer, and Anita James, our Chief Financial Officer.

I'll make some introductory remarks and then pass over to Brent and Anita who will run you through the slides. There'll be plenty of time for questions at the end of the presentation.

This financial year has been one of consolidation for Medical Developments.

Following the successful capital raise a year ago and completion of the primary investment phase, we're very focused on managing the cash resources of the company.

France was a difficult decision to make, but management acted appropriately to adjust course. Our other markets are developing well with strong sales growth across both the pain and respiratory franchises. This is a pleasing result, following our efforts to focus the business and build capability.

Even though we have excluded it from the underlying results, I would also commend Brent and his team for stopping the clinical trial in China. This was burning cash without any realistic prospect of a commercial outcome. A careful resolution of the situation has also preserved our strategic optionality in this region.

In addition to improving financial performance, strategic efforts are mainly directed toward US market entry. With this in mind, I am very happy to welcome Dr Russell Basser to the Board. Russell brings a great depth of experience and expertise in the US clinical and regulatory environment. These capabilities will be invaluable to the company as we thoughtfully progress toward US market entry.

Finally, we've worked very hard through the year to strengthen our governance systems for the company and to better align management incentives with the interests of shareholders. We'll have more on this at the AGM.

Brent MacGregor: Thank you, Gordon.

Today I will share with you the highlights of our results and our key achievements in FY23. I will then hand over to Anita to take you through the group financials in more detail, before returning to talk to you about our FY24 priorities and outlook. As Gordon mentioned, we will be pleased to take questions at the close of the presentation.

Moving first to slide 3.

We are proud of our achievements in FY23 and the progress we are making in delivering our growth strategy with our lead Penthrox business as well as with our Respiratory franchise.

Over the last two years a key priority has been to build the capability in the Company needed to execute our growth agenda. Our capability build is complete, and we are already seeing encouraging results. I will touch on some highlights in the coming slides.

We have stated previously our target of delivering positive operating cashflows by the end of FY25. This target remains a key goal with a step change in profitability expected in the year ahead. Later in the presentation I will take you through some of the key initiatives that will deliver this change.

Entering the US market for Penthrox remains our longer-term target. Market entry here represents a significant value creation opportunity. Our market entry plans are advancing and later in the presentation I will share with you our expectations for the year ahead as well as exciting insights we have gained on the value opportunity here.

I feel the Company is now at an inflection point. I am proud of the progress we have delivered to date and excited about the opportunities we have ahead.

Moving first to slide 4 and the financial highlights of the period.

At a headline level we have delivered revenue growth of 47%, with revenue at $32.3 million. This included 54% growth in our Penthrox business and 43% growth in the Respiratory business.

Underlying EBIT loss of $18.3 million, and finally, net loss after tax of $5.6 million, which is strongly improved over the prior year. This included a gain from underlying adjustments of $10.3 million before tax, mostly related to closing out the clinical program in China and the costs associated with a comprehensive assessment of the commercial opportunity for Penthrox in the US.

Overall, we have increased the penetration of Penthrox in global markets, and our Respiratory segment is reflecting the gains we are making in growing market share, particularly in the US.

These results show encouraging progress.

Moving ahead to slide 5, and operational highlights for the year.

We made some encouraging progress in our commercial strategy to increase penetration of Penthrox and grow share in our Respiratory segment.

In Australia, we deployed a field team to capture the growth opportunity for Penthrox in hospital emergency departments as well as driving further penetration in existing segments.

Our partner markets for Penthrox performed well. We saw good growth in underlying demand in Europe and we expanded our market reach, with the relaunch of Penthrox in Canada. Early feedback from this market has been very positive, and we are looking forward to seeing growth as we go forward.

In France, we delivered Penthrox volume growth of 33%. This was encouraging, but less than our expectations, considering the investment we made in that market. Our progress was slowed by challenging conditions across the healthcare system. In light of market conditions spend here has been scaled back. I will speak to this later in the presentation.

Our focus on growing market share in our Respiratory business delivered great results once again. Sales in the US were up 59%, mostly on share gains. A very pleasing outcome.

Longer-term growth for Penthrox will be accelerated by label expansion, new product development, and importantly, US market entry. We have several initiatives underway.

We have been undertaking a trial in the UK, which has been underway for a couple of years now, specifically focused on demonstrating the safety and efficacy of Penthrox in children. We are very pleased to report that this trial has now closed, with our submission expected in the year ahead. We hope to see an outcome that will reduce the age indication below 18 years of age in Europe, thereby expanding our addressable market. We will keep you informed of progress.

We have continued work on our next generation Penthrox inhaler, nicknamed Selfie internally. We are very proud to have been selected as recipients of funding of up to $1.5 million under the Clinical Translation and Commercialisation Medtech program, otherwise referred to as CTCM, to support investment in this device over the next 2 years. Selfie is critical to our US market entry plans.

And finally, as previously mentioned, we advanced planning for entry into the US market in earnest.

Overall, an encouraging year. I will speak to how we will continue the momentum after Anita has taken you through the financials for the period in more detail. Anita.

Anita James: Thank you, Brent and good morning, everyone.

Firstly, to recap on the headlines of our FY23 performance: revenue was up 47% at $32.3 million, with both Penthrox and Respiratory performing well. Both volumes and pricing were improved. Underlying EBIT was lower at a loss of $18.3 million, with higher gross margin supporting investment in commercial, leadership and functional capability that is underpinning delivery of our growth agenda. Underlying adjustments were a net gain of $10.3 million. This mostly reflects the cessation of clinical trial preparations in China which we announced with our first half results, and costs associated with the comprehensive commercial market assessment for Penthrox in the US. Further details on underlying adjustments can be found in the appendix to the presentation. Reported EBIT and NPAT were strongly improved, because of these adjustments.

Moving ahead to revenue in our Pain Management segment on slide 8.

Our topline performance for the year illustrates good growth for Penthrox.

Revenue in the Pain Management segment was up a pleasing 54%, with a very strong 2nd half, which included the recognition of a shipment to our UK partner that had been deferred from the first half.

Pricing was improved, with increases achieved across all products in Australia by the end of the period and in several partner markets.

Volumes in all markets were up.

In Europe demand was stronger despite economic challenges. European in-market volumes were up 39%. This included growth in France of 33% and 34% in the UK and Ireland. Volumes in the Nordics, Central Europe, Switzerland, and Belgium were also up.

In Australia, volume was up 6%. This reflected solid demand from the ambulance sector and growing penetration in emergency departments and procedural segments.

Volumes into other markets were up almost three-fold, driven by inventory stocking for the relaunch of Penthrox in Canada.

Moving ahead to slide 9 and our respiratory segment.

Revenue in this segment was up 43%, a strong result that reflects pleasing market share gains, particularly in the US, strong partner engagement and solid underlying demand. Inflationary pressures were managed through disciplined pricing.

Overall, encouraging results.

Moving ahead to slide 10, and the key changes to underlying EBIT in the period.

Our earnings reflect the outcomes of our growth agenda. These are illustrated on the chart.

Firstly, we have expanded gross margin. Higher volumes and improved pricing increased gross margin by $5.4 million in the period, with increases in both the Pain and Respiratory segments. A very encouraging result.

Secondly, we have invested in capability to deliver our growth ambitions. This included $3.4 million in commercial and marketing resources to drive the penetration of Penthrox in hospital emergency departments, $1.2 million to underpin our growth in the US respiratory market, and $2.5 million relating to leadership and functional capability.

As Brent mentioned, we have completed the capability build and we expect to see our resourcing levels steady through FY24.

Other cost changes impacted EBIT by $1.9 million, including one-off contract termination costs in France, relating to our scale-down in Europe resourcing, and inflationary impacts.

We said at the time of the capital raise that we expected our investments to underpin growth in our portfolio and that we would return to profitability as our volumes and margins improved. It is encouraging to see progress this period. Brent will speak to the improvement in earnings we expect in the year ahead.

Moving ahead to slide 11, our balance sheet and cashflow.

Our closing cash balance is at $25 million.

Operating cash outflows were $17 million in the period, reflecting earnings and working capital investments of $2.6 million.

Pleasingly, our working capital to sales percent is in line with the prior year with strong customer collections and good inventory management.

Capital expenditure for the year was around $8 million, which included spend on the development of Selfie, the UK paediatric trial and market registration activities in the US and China.

We expect spend in the year ahead to be approximately $5m. Spend on US registration activities will be limited to planning activities. Funding for the clinical program will be provided by one or more partners.

I will now hand over to Brent to speak further on our priorities for the period ahead. Brent.

Brent MacGregor: Thank you, Anita.

In FY24 we will deliver an improvement in earnings and cashflow while advancing plans for US market entry.

These priorities are reflective of the competencies in our organisation and our expectation that we will fully leverage this capability to deliver results. These results will come not just from commercial performance, but also from disciplined operational efficiency that will drive needless costs from our operation. I will provide a little more detail on the following slides.

We will deliver $6 million in incremental earnings benefits through pricing and operational efficiencies.

Further pricing improvements, mostly for Penthrox, are expected to deliver around $2 million to the top line. In line with our pricing strategy in Australia, we will implement further price changes from those implemented in FY23 and will benefit from a full 12 months of the FY23 changes.

We are actively working on new pricing arrangements with partners in several of our global markets.

Operational efficiencies will reduce costs by around $4 million. This includes cost savings in Europe. From July, direct promotional activity in France has been significantly reduced, and regional management costs have been scaled back. Most activities previously managed in Europe will be managed through our team in Melbourne.

Improved processes and capability throughout our supply chain will deliver savings in production labour and freight.

And we will benefit from scale efficiencies as our volumes grow.

These savings will deliver a step change in earnings and improve our gross margins.

Moving first to our Australian growth strategy on slide 15.

Our focus in this market is to drive our commercial effort into the hospital and procedural segments.

The Australian market for Penthrox has historically been focused on the ambulance services. 75% of our volumes today are into this segment, despite this segment being only 30% of the addressable market.

Penthrox in the emergency department offers compelling advantages, including both patient and efficiency benefits.

To support penetration here, we have deployed a field team to target the hospitals, enhanced our medical department to support access, and launched activities to position Penthrox in these settings.

Volume growth in FY23 reflected early progress in our drive to increase penetration. In addition, the team has made progress in working with hospitals and buying groups to list Penthrox on hospital formularies and to generate protocols in all states.

From experience in other markets, we know the selling cycle can take several months, but with some early wins already made, we expect to see sales momentum accelerate in the year ahead.

Moving ahead to slide 16, and the go-to-market model for Europe.

As I mentioned earlier, our progress in France in the period was not as strong as we had planned. While volume growth of 33% was encouraging, the rate of growth was less than we had forecast relative to our level of investment.

In light of operating conditions and slower than planned growth, spend in France has been scaled back. This decision is very much to having an eye to our profitability. Supply to existing customers, which is a list more than 300 strong, will be maintained through a scaled down region team with greater oversight from head office here in Melbourne.

Strong product 'stickiness', as we call it, is expected to underpin stable demand as we revisit our go-to-market approach.

Our approach may include a partner supported strategy that is delivering encouraging growth in the UK, Ireland, the Nordics and Austria. That assessment is underway.

Our decision in France will influence our approach in other European markets, including Germany, Italy and Spain.

We will provide an update on our assessment in the coming months.

Now to the US, on slide 17.

We are advancing our plans for market entry to the US. This will ultimately be transformational for the Company and is a primary strategic focus for the business. We have several streams of work underway.

Firstly, a partner search.

The Company announced in April it would commence a search for partner organisations to undertake the clinical and non-clinical programs required for US market entry and to launch Penthrox in this market.

The US is the world's largest market for pharmaceuticals and it is clear that delivering value from Penthrox here will be best achieved through the support of one or more partners. An experienced adviser has been appointed to support the search for suitable partner

organisations, the fund and development program and ultimately to commercialise Penthrox.

A comprehensive market assessment on the commercial opportunity for Penthrox in the US was completed in the period. This assessment will inform partner discussions and development of the go-to-market strategy. I will share some insights from this assessment on the following slide.

Secondly, in FY24 we will advance planning for the clinical program. We expect this to commence in FY25. We will continue work to simplify the Phase III protocol and plan trial logistics.

And finally, we will continue development of our next generation device. This is an important stream of work as it will be this device that we use at launch. We are assessing the possibility of using this device in our clinical program as well.

Now moving to slide 18, with some high-level insights from the commercial market assessment in the US we completed in the period.

The commercial assessment for Penthrox in the US identified a large and attractive opportunity for Penthrox.

On the assumption of a label at launch similar to Europe, the study estimated an addressable market in the range of US$300 and US$400 million 5-years post launch.

This is based on an addressable market of 20 million adult patients in acute pain and trauma, with 75% of these patients in emergency departments and EMS segments. Pricing in the identified segments is expected to range between US$35 and US$75 per unit, depending on the segment.

A further 10 million adult patients in outpatient procedures, and children, could potentially be reached in the future with label expansion.

These estimates exceeded our initial expectations and provides us with confidence that the unwavering commitment of the Company to pursue entry in the US will deliver significant value.

So, this brings me to my final slide and the outlook for FY24.

The Company expects underlying EBIT in FY24 to improve on FY23, driven by:

- Higher Penthrox volumes in Australian hospital emergency departments.
- Share growth in the Respiratory segment; and
- Incremental margin improvements of $6 million from pricing and efficiency.

As Anita mentioned earlier, we expect capital expenditure in FY24 to be approximately $5 million.

Ultimately, our performance in FY23 has solidified our foundation such that we can continue to execute our strategy, in a sustainable manner, that increases our confidence to reach cashflow positivity by FY25.

I will stop there, and we'll open the floor for questions.

I'm also told we had some issues with audio, and apologies for that. Let's keep pushing forward. **End of Transcript**