

27 October 2015

### **ASX ANNOUNCEMENT**

# Chairman's and CEO's Address to Shareholders

#### ADDRESS BY CHAIRMAN - MR. DAVID WILLIAMS

First, thank you all for coming and thank you for supporting MVP over the last few years.

Those of you who have shared the journey with us will know that in the last few months you have been joined on the share register by more than a dozen of Australia's leading institutional investors.

These investors like the MVP story and even though our market capitalisation is at a large multiple to FY15 earnings there are many investors who believe as we do that we are on the cusp of a global roll-out.

Perhaps I am too close to the company but as promising as the future for Penthrox looks I feel that some investors are focused only on Penthrox and are missing the upside that exists in our respiratory business.

In FY15 we achieved a number of significant milestones. In particular, I would like to highlight the following:-

- We now have a world class regulatory dossier for Penthrox which is capable of being approved by regulatory agencies around the world. The dossier will still need customising for some countries but the quality of the dossier and the credibility received from each new country registration are good signals for other countries. We are actively pursuing more registrations to sell Penthrox in new countries and hope to announce more in the near future.
- As a result of the work done to date we have agreed licencing deals with a number of globally recognised partners who will work with us to sell Penthrox in new countries. There are a number of these but two standout. First, Galen, who recently lodged its first forecast orders and which paid an upfront licencing fee to distribute Penthrox in the UK and Ireland. More recently, Mundipharma, a top 20 global pharmaceutical company, has made a significant upfront financial commitment to sell Penthrox in Europe. I am pleased to report that we received their first forecast order in the last few days. We expect both companies to contribute to our FY16 result starting from 2H FY16.
- Our respiratory business continues to grow throughout the world but for the first time our North American operations are well placed to deliver significant sales growth in the near term.
  We have recently signed our first significant distribution deal in North America and we anticipate strong growth in this market in H2FY16.



• The global expansion of Penthrox and the business generally requires us to develop a new manufacturing site. Accordingly MVP is moving its operations in the next few weeks to a new site in Scoresby and construction of our new manufacturing facility will commence during January 2016.

Our ambition remains to turn our company into an international pharmaceutical and medical device company of substance. As Chairman and the major shareholder I am passionate about our future and I am confident that FY16 will prove that we are indeed a global player.

Given our cash at bank with no debt, future milestone payments to be received and strong expected operations performance, shareholders have asked about our dividend policy. This is something the Board will consider at the half year after considering the usual things.

I would now like to invite John Sharman, our CEO, to talk about the year just past in more detail and our future prospects.

#### ADDRESS BY CEO - MR. JOHN SHARMAN

## An exciting future

I would like to thank the Board of Directors and our staff who continue to work tirelessly to improve the performance of our company. We are looking forward to a very exciting FY16 and beyond.

Penthrox has global application and the capacity to dominate specific analgesic markets around the world. Our respiratory and medical devices are leaders in many of the markets we operate in.

Our ambition is to globalise Penthrox and make it the main stream analgesic of choice in markets around the world and MVP a world class international Pharmaceutical and Medical Device company.

Our portfolio of business opportunities is substantial and deliverable. Our achievements to date demonstrate we are well on our way to delivering this ambition.

#### **Penthrox**

## The Future

It has been well documented we have invested heavily in creating a world class regulatory dossier. We have spent almost \$10 million to develop this asset and we continue to invest and work to improve it. This dossier is the cornerstone of our globalisation strategy and it will be used in our efforts to gain approval to sell Penthrox in the USA and elsewhere.



In terms of our future plans for Penthrox in the USA, we have recently signed up with one of the USA's best Regulatory Advisory firms who will guide and advise us through the FDA process and in this regard work has commenced.

Over the last two years we have signed major licensing deals to distribute Penthrox across Europe, in the United Kingdom, Ireland, Hungary, Mexico, Saudi Arabia, Hong Kong and Singapore. We expect more licensing deals to be executed during FY16.

Among the many highlights of these licencing deals our recent transaction with Mundipharma is the biggest deal we have done to date. Mundipharma paid circa AUD \$10 million upon signing of the Agreement, with a further \$4 million expected upon completion of the Marketing Authorisation approval process in France. We expect this to happen soon. In addition, Mundipharma will take control of the Regulatory Approval process in Europe, and will support the development of additional Penthrox products and clinical uses. We expect another circa AUD \$10 million to be paid by Mundipharma sometime within the next 15 months when we obtain approvals and reimbursement in Germany, Italy, Spain and France. Additional sales based milestone payments will also be achieved over time.

Currently we have submitted marketing applications to regulatory authorities in Russia, Mexico, Israel and Saudi Arabia. We expect approvals to sell Penthrox in these countries to be granted during FY16 and beyond.

Our CSIRO project is making good progress. We have successfully, purchased, installed all our equipment and manufactured product which is now on "stability" trials. We expect final sign off from the TGA and other regulatory agencies around the world during FY16. This new manufacturing process will revolutionise our manufacturing of Penthrox and transform the capacity and cost base of our company. In addition to valuable intellectual property, this project will create ongoing options for innovation and growth which previously did not exist.

## **Respiratory Medical Devices**

The future

We continue to invest heavily in the product development of our Respiratory Device business. Our new range of anti-static devices is currently being assessed by the FDA and we expect they will be approved for sale before March 2016.

We recently signed our first large commercial distribution deal for our products in the United States. We are working on a number of additional deals to distribute our products in the USA and we expect our USA business to generate significant sales in the years ahead.



We now have partners and make sales in Australia, United States of America, United Kingdom, Netherlands, Belgium, Luxemburg, Greece, Singapore, Hong Kong, Germany, Switzerland, Austria, Canada, New Zealand, the UAE and Malaysia. Our international distribution network is establishing itself well and we are looking to sign additional distribution deals in the months ahead.

### Innovation, Research and Product Development

During the year MVP increased its investment, energy and focus in building its internal capacity for product innovation, development and research.

We continue to develop a range of next generation Penthrox products which will be used in a number of markets around the world. We recently successfully filed four international provisional patents. This is a major achievement for MVP and the result of years of research and development. The patent protection around our new delivery devices provides MVP with valuable intellectual property and competitive advantages into the future.

Our growth opportunities demand we develop a new manufacturing facility. This new facility will have the capacity to produce circa 25 million units of Penthrox per annum – a tenfold increase to our current capacity, which can be increased further. Importantly our facility is fully funded. We have already purchased all the equipment needed to roll out our new manufacturing technology which we created with the CSIRO which will deliver significant cost efficiencies and volume improvements.

## **Trading update**

Our business continues to perform well. We are on the verge of significant growth. We have received our first forecast orders from Mundipharma for Europe for delivery in H2FY16 and from Galen for the UK & Ireland.

Our North American and European respiratory business is poised to deliver significant sales growth over the coming months and years.

The distribution deals for Penthrox means we have almost AUD \$11 million in cash in our bank account. We expect another AUD \$5 million to be received within the next few months from Galen and Mundipharma. After that a further AUD \$10 million is to be paid by Mundipharma once it gets marketing approval and pricing reimbursement in Italy, Germany, Spain and France.

We expect our strong trading performance of FY15 to continue throughout FY16.



### Conclusion

Our Respiratory Device business is well placed to provide long term sustainable sales growth for our company.

Penthrox is a category leading drug in Australia and we expect it can dominate many of the trauma and minor surgical procedure markets around the world.

Many of the plans we put in place four and five years ago are coming to fruition. We have new manufacturing technology, we recently patented new delivery devices for Penthrox which will give us a strong competitive advantage well into the future. We have a new range of respiratory devices being approved in the USA and elsewhere and we are attracting new and significant licensing & distribution partners for both of these businesses.

I am looking forward to reporting our achievements to you in the coming months.

**Enquiries:** 

David Williams Chairman +61 (0) 414 383 593 John Sharman Chief Executive Officer +61 (3) 9547 1888



### **About Penthrox**

Penthrox is a fast onset, non-opioid analgesic indicated for pain relief by self-administration in patients with trauma and those requiring analgesia for surgical procedures. Penthrox has been used safely and effectively for more than 30 years in Australia with excess of 5.0 million units sold. There is growing interest in Penthrox being used in patients undergoing investigatory procedures, as well as operational procedures such as colonoscopy.

#### **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 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 Dental and Cosmetic surgery as well as in other medical applications. MVP is expanding internationally and manufactures a range of world-leading Asthma respiratory devices.