

28 October 2014

### **ASX ANNOUNCEMENT**

### Chairman's and CEO's Address to Shareholders

### ADDRESS BY CHAIRMAN – MR. DAVID WILLIAMS

FY14 was an important year for us and we achieved some significant milestones in terms of the future of our business. I would like to highlight just four of these milestones:

- 1. We lodged our Marketing Authorisation Application ("MAA") for approval to sell Penthrox in the United Kingdom, France, Ireland and Belgium. We have made good progress with the regulatory authorities and we hope to have a decision from them before the end of the financial year.
- 2. The work we have done to date preparing our regulatory dossier has potential to be "company making" not only through an approval to sell penthrox in Europe but by using the dossier to apply for registration in other jurisdictions. The "Regulatory Dossier" we developed for Europe has already been customised and used to lodge applications to sell Penthrox in Singapore, Israel, and South Africa. Importantly, we received approval from South African authorities in June 2014 and I am delighted to advise the first shipment of Penthrox to South Africa occurred earlier this month.
- 3. We have had significant success in our search for quality partners to promote Penthrox and our medical devices outside of Australia. Recently we signed a significant deal with Galen Inc. to distribute Penthrox in the United Kingdom and Ireland and other deals with PSUK Ltd and Medel Spa to distribute our respiratory range of medical devices in the UK and Italy. This has involved upfront payments with other milestone payments to come. There are other proposals to represent us which we are negotiating.
- 4. Our new range of asthma inhalers are now registered in the US and whilst we have so far had a small number of sales, we are in discussion with a number of companies to supply large quantities direct. However, in Europe and elsewhere our business is growing well and sales in Europe are significantly more than for the same period last year.

Operationally, FY14 was challenging, however we are seeing a strong improvement in trading performance in the first quarter of FY15 with sales up almost 22% and EBIT up by a greater percentage year on year.



Our ambition is to turn our company into an international Pharmaceutical and Medical Device company of substance. As Chairman and the major shareholder I have never been more passionate about the future of the business and I am hopeful that we will be able to reflect on FY15 as the beginning of big things for MVP.

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

#### 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 on improving the performance of our company. We are looking forward to a very exciting FY15 and beyond.

As our Chairman stated earlier our ambition is to make Penthrox a main stream analgesic of choice in markets around the world and our company a meaningful international Pharmaceutical and Medical Device.

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 and we have achieved a number of key strategic milestones this year, moving us closer to achieving our ambition.

Our portfolio of business opportunities is substantial and deliverable and we are looking forward to the years ahead.

#### **Penthrox**

### The Future

We believe we are on track to receive positive feedback from the European regulatory authorities regarding the approval of Penthrox for sale in the United Kingdom, France, Ireland and Belgium before the end of this calendar year. If successful, we will be in a position to add additional European Union member countries to our list of approved markets within three to six months. This will give us a real opportunity to rapidly expand the markets in which Penthrox might be sold.

We have recently signed major licensing deals to distribute Penthrox in the United Kingdom, Ireland, Mexico and Singapore. We expect more licensing deals to be executed during FY15.



The rate of our cash investment into clinical trials and the preparation of our Regulatory Dossier is slowing because we have largely finished the body of work required to complete it. We have already used our Regulatory Dossier to make submissions to the United Kingdom, France, Belgium, Ireland, Israel, Singapore, Saudi Arabia and Russia during FY14 and are preparing applications in Hungary, Mexico, Malaysia and Hong Kong which we hope will be lodged in the next few months.

Our CSIRO project is making good progress. We expect to complete this project during FY15 and when successfully completed, it will revolutionise our manufacturing process and transform the 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 delivered a number of new initiatives in the Australian market which are delivering sales and should deliver sales growth during FY15 and beyond.

We have successfully signed major deals to distribute our range of respiratory devices in the United Kingdom, Italy, Netherlands, Belgium, Luxemburg, Greece, Singapore and Hong Kong. This adds to our established networks in 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. European sales are almost four times (4x) higher than for the same period last year and we expect sales to grow for the rest of FY15 and beyond.

To facilitate sales growth in the USA, we recently appointed a General Manager – North America and added products from our range of respiratory masks and our portable nebuliser to our USA approved products. We are working on a number of deals to distribute our products in the USA and we expect our USA business to generate significant sales in the years 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. Our new range of anti-static respiratory devices will be available for sale during FY15 and will be leaders in their field.

We continue to develop a range of next generation Penthrox products which will be used in a number of markets around the world. As part of this project we are focused on new innovative



ways to deliver Penthrox. This project is expected to provide MVP with valuable intellectual property into the future.

# **Trading update**

Our business has recovered strongly in the first quarter FY15. Sales of Penthrox are up almost 40% and we have achieved good growth in our domestic Ambulance business. Our Middle East and New Zealand businesses are performing strongly.

Gross margin is significantly better for the first quarter FY15 compared with the same 3 months of FY14 and EBIT is four times higher compared to the first three months of FY14.

We expect our R&D tax concession refund to be circa \$290,000 for FY14 and the stronger trading performance to continue.

#### Conclusion

Our Respiratory Device business is recovering and will 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. With the completion of our Regulatory Dossier and a number of licensing deals successfully completed during FY14, the opportunities for a quantum change in the performance of our company is fast approaching.

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

### End.

Further information:

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## **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.

# **Respiratory Devices**

MVP's Space Chamber and Space Chamber Plus devices deliver category leading performance for Asthma and COPD sufferers. Both devices have MVP's patented Cross Valve technology which allows patients to manage their disease more effectively and deliver medication more efficiently. In the course of obtaining FDA approval, a number of independent clinical laboratory trials were conducted at world recognised facilities proving the Space Chambers' performance as "best practice".

# **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 minor 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.