

28 October 2016

**ASX ANNOUNCEMENT**

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

**Address by Chairman – Mr. David Williams**

Let me open by thanking you all for coming and supporting MVP over the last few years.

Those of you who have shared the journey with us know of the significant achievements made in the last 12 months or so. While I view our share price as a weak and lagging indicator of our performance, the track is impressive against the market and other pharmaceutical companies. Our share price today is \$4.86, a year ago it was \$3.25, three years ago \$1.50 and five years ago 50 cents.

During the year, our Share Register was further enhanced by the introduction of another dozen or so domestic and international fund managers.

For the last several years we have been working on globalising our company, and in particular, our pharmaceutical product, Pentrox, and our respiratory medical devices. In FY16 we made significant advances to that end. For our Pentrox product we have had steady news of new country registrations and we have secured global pharmaceutical partnerships, including the likes of Galen and Mundipharma; and for our respiratory device businesses we have opened major channels in the USA and elsewhere.

We expect a flow of more good news through FY17 relating to new country registrations, new partnerships, new channels of distribution, new products and increased revenues. The story of Pentrox and medical devices gets better with time.

We have received almost \$15 million in upfront payments from our marketing partners in the last 12 months, and expect to receive in excess of \$10 million in additional milestone payments in the next 12 months.

The globalisation of our company required new manufacturing premises to cope with increased global demand and in November 2015 we moved to a new site in Scoresby. Construction has begun on a manufacturing facility within that site which will house our new technology to manufacture Pentrox. We expect this to be completed early in the New Year.

With upfront payments, milestone payments, revenue and profits comes dividends. We have almost \$8m in the bank and resumed paying dividends this year. Our share price growth is reflecting this even if it is a weak and lagging indicator of what we have achieved and where we are going.

Finally, as Chairman and major shareholder, I can see the globalisation of our company is real and happening. I am excited by the very substantial opportunities we have both in hand, as a result of contracts with existing marketing partners, but more importantly, into the future with new indications and further expansions of global markets.

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

#### **Address by CEO – Mr. John Sharman**

#### **The Globalisation of Medical Developments**

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 FY17 and beyond.

Our ambition is to globalise Pentrox and make it the mainstream acute pain medication of choice in markets around the world, and make MVP a world-class international pharmaceutical and medical device company.

Our achievements to date demonstrate we are well on the way to delivering this ambition. We have attracted global, world class partners into both our Respiratory and Pharma businesses. In terms of Pentrox we have sales and marketing partners covering 59 countries (excluding the USA) with more to come. Some of the world's best companies including Mundipharma, Purdue Pharma, Galen Pharma, Link Pharma, Douglas Pharma, Pharma Solutions, Besin's and others have all signed up to promote Pentrox. In addition we have relationships with Cardinal Health, AmerisourceBergin, Mint, Carestream, Cegla, Henley's, Pheonix Medical, Accuramed, OAPL, Airflow, Symbion/Allersearch, Overpharma and others, who have all signed up to promote our range of Respiratory devices across 23 countries.

We are very excited by our progress and we are well positioned to grow our company into the future.

### **Penthrox – The Future**

As we continue to invest in our Regulatory Dossier and begin new clinical programs, both independently and with our global marketing partners, the opportunity to expand Pentrox's use and clinical indications beyond simply an Acute Trauma Pain drug is becoming a reality.

For instance, we are embarking on a clinical program to expand the indication for use of Pentrox to Minor Surgical Procedures. This involves a Phase III clinical study (in addition to the Phase III we successfully completed at the Peter MacCallum Cancer Institute in 2013). The successful outcome of this trial should result in a new clinical indication for Pentrox in Europe. Pentrox is already approved for use in Minor Surgical Procedures in Australia where it is used in procedures in dentistry, cosmetic surgery, endoscopy, colonoscopy and gynaecology, as well as many other specialty areas. The benefit of this extension will be available to both our partners in Europe and, more importantly, it will provide essential clinical data to have the market opportunity for Pentrox extended in jurisdictions all over the world. We estimate the market for Minor Surgical Procedures to be more than \$2 billion p.a. globally.

In addition to the extension to Minor Surgical Procedures, we have begun to develop clinical and non-clinical programs so that in the future we can broaden Pentrox indications into 'Repeat Use' and 'Breakthrough Pain' including breakthrough cancer pain; where Pentrox is the perfect alternative for

short acute pain episodes for patients who are currently treated with narcotics and opiates. The market for this indication is estimated to be more than \$6 billion p.a. globally.

Our vision is to have Pentrox used in the battlefields for the military where the alternative use of narcotics and opioids are problematic. We can see a time where Pentrox is used by First Aiders all over the world, where the alternative to using narcotics for short-term procedures is inappropriate and difficult to administer, store and handle. We can see a time when people take Pentrox home (via prescription) and keep it in their First Aid Kits for those rare occasions when they suffer trauma injuries in or near the home. Pentrox can be used to relieve their acute pain whilst on their way to seeking medical assistance in Emergency Departments all over the world.

We are very excited by the future prospects for Pentrox. Whilst we have partnered with leading global pharmaceutical companies for the sales and distribution of Pentrox in Europe, the UK and Ireland, we have also signed deals in Canada, Singapore, Hong Kong, South Africa, Korea, New Zealand, Saudi Arabia, Iran, Iraq, Jordan, Qatar and the UAE; in addition to existing distribution relationships we have in certain countries in Eastern Europe.

As our global footprint continues to expand we expect to add additional marketing partners and to obtain a number of product approvals over the coming twelve months.

### **New Manufacturing Technology**

As noted by the Chairman, construction of our new manufacturing site in Scoresby began in September 2016. The new facility will house our new manufacturing technology, which is a generational shift in the manufacturing of pharmaceuticals. We have submitted a “patent application” over the manufacturing process and will decide sometime in the future whether we publish this truly innovative technology or whether we keep it to ourselves as a trade secret.

The new facility will be state-of-the-art. It will, when fully commissioned, have the capability to produce 25 million units of Pentrox per annum. We envisage this demand will be sufficient to satisfy the European markets, as well as the markets we have contracts for at the current time.

In the future, we plan to ship Pentrox from Australia and use 3<sup>rd</sup> party packaging operations to package and distribute the other components of Pentrox to various locations around the world.

This new manufacturing process will revolutionise our manufacturing of Pentrox and transform the capacity and cost base of our company.

The construction of the facility is on-time and on-budget and we expect it to be fully commissioned in Q3FY17 and operational by June 2017.

### **Innovation, Research & Product Development**

In addition to the initiatives noted earlier, we have begun a program to expand the technological manufacturing base that we possess into new products. Our exploration includes looking at the benefits of extending our technological expertise and intellectual property into areas such as the manufacture of anaesthetic gasses and other pharmaceutical compounds which readily lend themselves to being manufactured by our technology.

Whilst this program is in its infancy, these markets are multi-billion dollar markets and we believe this technology gives us the opportunity to become a world-class player.

We expect the first stage of this innovation program to take up to 24 months before we can progress to commercial scale validation.

We look forward to reporting our future success in this regard.

### **Regulatory Update**

We expect approval to sell Pentrox in more than 25 additional countries in Europe to be obtained within the next 12 months or so, and from there, we expect the scale-up for sales of Pentrox into Europe and elsewhere to be many multiples greater than our current existing global sales.

We are also expecting approvals and first sales into Mexico, Taiwan and possibly Iran during FY17.

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## **Trading Update**

Our results in FY16 were the beginning of what we see as significant sales growth for our company. Earlier in FY17 we received our first order to deliver product for the French market. That order was the single biggest order our company has ever received.

Revenue overall is growing strongly and is forecast as at the end of October 2016 to be 50% above the same period last year.

Revenue from Pentrox is 37% greater than this time last year (October 2015) and we expect H1FY17 sales to show strong growth.

Our respiratory business continues to show strong growth. Global sales are 137% up on the same time last year. Our European business is showing excellent growth (sales up 269%) and we continue to build our infrastructure in North America, which should make a strong contribution in H2FY17.

## **USA**

In July, we received feedback from the FDA about our development program to have Pentrox approved for sale in the USA. That development program is now complete and includes a number of clinical and non-clinical studies, as well as an additional Phase III Pivotal Trial. The clinical and non-clinical work in several cases repeats work done years ago and we are confident all the data collected will reconfirm what we already know. In terms of a Phase III Trial, we are confident the results will replicate what we have already proven in the two Phase III studies completed, and used for the successful registration of Pentrox in Europe and elsewhere.

We estimate the work needed to submit a New Drug Application (NDA) in the USA will be completed within two and a half years, at a cost of \$USD15 million.

## **Conclusion**

Our respiratory device business is well placed to provide long term sales growth for our company. Our expansion into the North American market is progressing well and the recent acquisition of Breath-A-Tech is providing better than expected returns so far.

Penthrox is a category leading drug in Australia and we expect it can dominate many of the acute pain trauma and minor surgical procedure markets around the world. Recent developments in terms of additional indications available for the use of Penthrox are very exciting and we look forward to exploring and exploiting those opportunities in the future.

Recent initiatives in terms of our manufacturing technology and the opportunities to enter billion dollar global markets as a manufacturer of generic pharmaceuticals is something we intend to pursue in the coming months. As we set out on this journey we are confident that our technology will be applicable to other molecules and that returns to shareholders will be significant.

Many of the plans we put in place several years ago are coming to fruition. We have new manufacturing technology and we recently submitted patent applications covering new delivery devices for Penthrox which give us a strong competitive advantage. We have new business partners in respiratory markets around the world, including the USA and we are attracting significant Licensing and Distribution partnership opportunities in both our pharmaceutical and respiratory device businesses globally.

We are excited by the prospects of pursuing approval for the use of Penthrox in the USA.

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

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**About Pentrox**

'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 in excess of 6.0 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 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.