

29 October 2018

ASX ANNOUNCEMENT

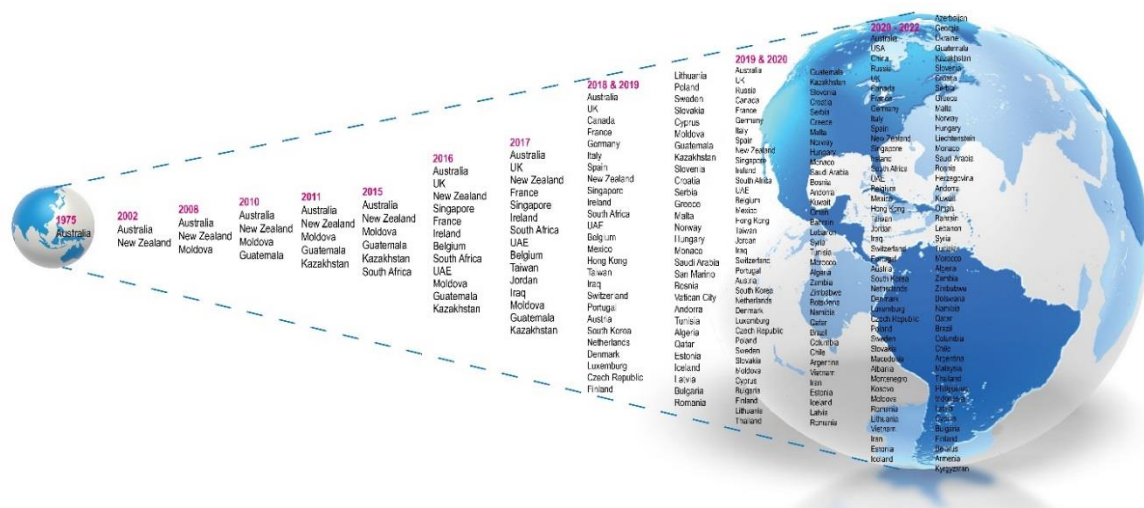
Chairman's and CEO's Address to Shareholders

Address by Chairman – Mr. David Williams

Last year I mentioned that Medical Developments International Limited had reached a sweet spot in terms of its global expansion ambitions.

At the start of FY16 Pentrox was approved in 6 countries, but selling into only two main markets, and Australia represented 81% of our global Pentrox revenue. Presently we have approvals in 38 countries. By the end of Calendar 2020, we plan to be approved and selling into 77 countries including Russia, and possibly China, and by the end of Calendar 2022 our target is to have approval to sell Pentrox in 89 countries, including the United States of America.

Since the beginning of Calendar 2018, we received regulatory approval from twenty-six additional countries to sell Pentrox. We have product launches underway in all 26 countries and have received first orders to deliver Pentrox in 12 European countries during FY19 (countries like Germany, Sweden and Poland). We expect another 14 countries to begin selling Pentrox during FY19 and FY20.



In relation to the USA, MVP submitted our Investigational New Drug application (IND) to the United States FDA in June of this year. In response to our submission the FDA asked a series of questions and put our IND on 'clinical hold' until we provide a full response. We are confident that we can answer the questions and respond appropriately to the FDA.

The FDA questions have delayed our US development timetable by up to 12 months; but these things happen in drug development, and particularly with a drug like ours.



Earlier this month we announced one of the biggest deals in the company's history which resulted in Daiichi Sankyo (a large Japanese pharmaceutical company) paying us \$21million upfront for the rights to China, Thailand and Vietnam. There will be more milestone payments to follow once the product gets approved and sales commence.

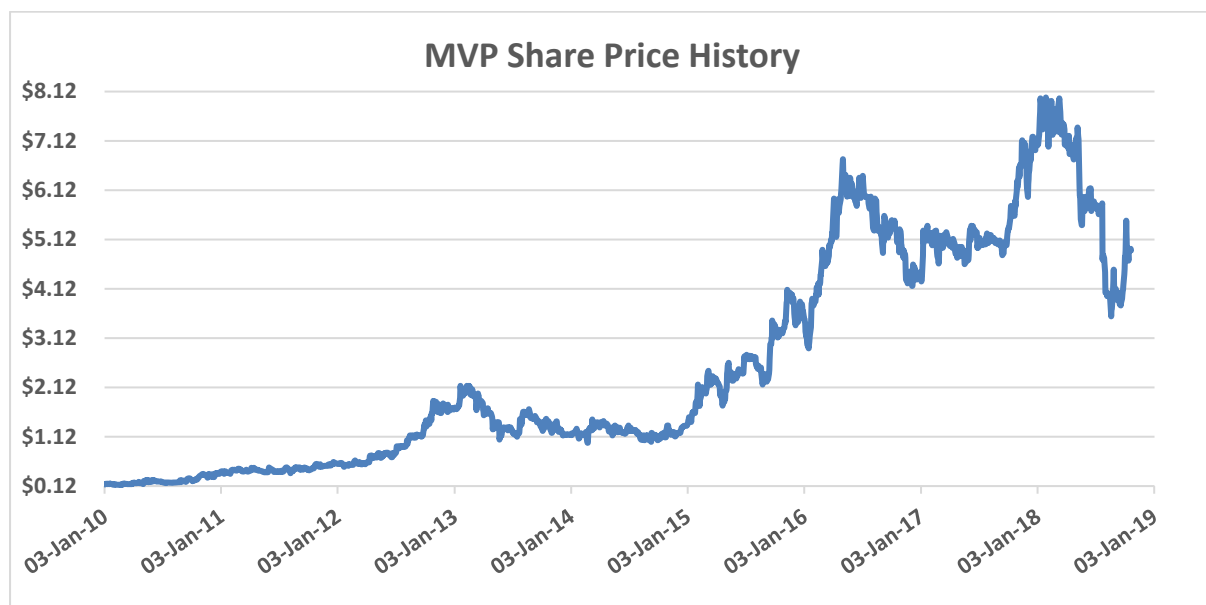
Pentrox is entering an exciting phase. Much of the ground work has been done in terms of geographic global expansion. We have quality partners in place whom are developing and rolling out Pentrox into new markets. We have several additional clinical and regulatory programs underway to expand the use of Pentrox into minor surgical procedures throughout Europe and elsewhere.

While we watch the global expansion of Pentrox, our respiratory device business continues to develop, and we are confident that business will continue to deliver good returns to shareholders. At present we are in approximately 15,000 pharmacies in the US, 4,500 pharmacies in Australia and the prospects in Europe are good.

While we build Pentrox and devices, we have a new business which is born out of the CSIRO technology used to manufacture Pentrox. Almost 8 years ago Medical Developments partnered with the CSIRO in a Research and Development Program to improve the way our drug, Methoxyflurane, was made. That development program delivered a new continuous flow manufacturing technology. As a result of this success, MVP entered into a multi-million dollar, multi-year contract with the CSIRO last year to develop new continuous flow manufacturing technologies. We are excited about the future of this technology, but I will let our CEO tell you more about this.

Our recent capital raise was well received by the market and heavily oversubscribed; as was the Shareholder Share Purchase Plan. Collectively MVP raised \$24.5million.

Share price gains over the last 8 years have been impressive despite the recent retreat.



The company has never been in a better position than it is today and we look forward to reporting on its future successes.



Address by CEO – Mr. John Sharman

I would like to thank our Chairman, the Board of Directors, our business partners and especially our staff who continue to work tirelessly to improve the performance of our Company. We are looking forward to a very exciting FY19 and beyond.

Our ambition is to make MVP a world-class international pharmaceutical and medical device company. In doing so, we intend to make Pentrox the leading acute pain medication in markets around the world and our respiratory devices first choice to consumers and health care professionals.

We also have an incredible opportunity in terms of our new technology to manufacture pharmaceutical products.

MVP invested heavily in FY18 in our people, our clinical development programs, our CSIRO continuous flow manufacturing technology and our manufacturing facility. Pentrox is well positioned to provide an alternative to opioid medicines in the multi-billion-dollar pain market and was approved for sale in another 26 countries so far in 2018. Pentrox is now approved for sale in thirty-eight (38) countries and we expect another fifty-one (51) countries to approve the sale of Pentrox in the coming years, including China, Russia and the USA.

Our ambition is to expand the use of Pentrox globally and to extend its use into acute pain applications, including surgical procedures, breakthrough pain, and ultimately, home use.

Our program with the CSIRO could potentially change the way some pharmaceutical products are made, and our respiratory device business is performing well in FY19.

Pentrox

Since the beginning of FY16 we have achieved 33 new country approvals for Pentrox and sales have, or will, commence in all those markets over the course of the next 12 months.

During 2018 approval was granted in 26 new countries including Austria, Denmark, Estonia, Iceland, Latvia, Slovak Republic, Croatia, Poland, Sweden, Norway, Germany, Cyprus, Bulgaria, Finland, Romania, Slovenia, Portugal, Switzerland, Czech Republic, Italy, Spain, Lithuania, Saudi Arabia, Canada, Hong Kong and Mexico.

Additional regulatory approvals are underway or planned for another 51 countries including China, Russia, Netherlands, Greece, Hungary, Albania, South Korea, Iraq, Iran, Jordan, and of course, the United States of America.

During the year, MVP incurred several regulatory delays. Some of these regulatory delays were caused by factors beyond our control, including the exit of the United Kingdom from Europe which slowed various country approvals as well as the processing of relatively simple administrative variations. Most



of these delays are now behind us and product launches are underway for the remainder of FY19. Accordingly, MVP expect to receive the next set of milestone payments from Mundipharma (\$7m) during FY19.

UK, Ireland, France and Belgium

In terms of our progress in the UK and Ireland, our partners are now selling to 436 customers including 125 hospitals (compared to 191 customers a year ago). In France we are selling to 272 customers (compared to 166 customers a year ago).

In the UK and Ireland the rapid improvement in customer numbers is due to the take up of Pentrox outside of hospital formularies and includes medical day clinics, ambulance services and other emergency healthcare providers.

USA

In the USA, the FDA put our IND on “clinical hold” until we provide a full response to seven (7) questions. We are making progress on our responses and we already have some of the information the FDA asked for. We continue to work with our advisors and experts on gathering whatever additional data we need, and at this stage, we expect our USA program to be delayed by up to 12 months. We will have more information about our development program and timelines once we have our next face to face meeting with the FDA, which is expected during Q3FY19.

China

We recently closed on one of the biggest and most important deals in the company’s history. Daiichi Sankyo, one of Japan’s biggest and most profitable pharmaceutical companies, agreed to pay just over \$21million upfront with additional milestone payments of \$25million for the distribution rights for Pentrox in China, Thailand and Vietnam. We have commenced the regulatory work to get Pentrox approved in these countries and are planning to be selling into China during FY21.

CSIRO

Our development program with the CSIRO is now more than a year old. Progress has been good. We have a number of target molecules in development, with Lidocaine the most advanced. We have manufactured 5kg of pure Lidocaine sulphate using our continuous flow technology and have begun communicating with several parties around the world, which may be interested in our technology.

Other than Lidocaine, our most advanced product is Salbutamol which is an asthma drug with global sales of more than \$6billion. We are planning to have completed a small-scale production run using continuous flow to manufacture Salbutamol during H2FY19.

Clinical program

We continue to invest heavily in our clinical programs which are focused to:

- extend the indications for use of Pentrox into minor surgical procedures (Europe and elsewhere); repeat use, breakthrough cancer pain and ultimately home use;
- gather the data required to respond to the FDA questions; and
- get Pentrox approved in China

Medical Devices

Sales in our medical device business has made a strong start to FY19. Compared to the same period last year (Q1FY18) sales into our USA business are up 94% and sales into Europe have been strong. The Australian business is up 6% and we delivered a large order into New Zealand.

Importantly, we continue to expand our reach across the USA and now have access to almost 15,000 pharmacies which are selling our product. We continue to work on closing distribution deals with some of the larger pharmacy chains in the USA.

Trading update

MVP has made a good start to FY19. At the completion of Q1FY19 (compared to Q1FY18):

- Overall sales are up 56%;
- Pentrox revenue is up 57%;
- Respiratory device revenue is up 58%;
- Gross Margin is up 32%; and
- MVP will have cash of \$35m (after receiving \$21m from Daiichi Sankyo, due next week).

Conclusion

MVP is in the strongest position it has ever been in terms of delivering on its global potential. We will have \$35m of cash in the bank, a global pipe line for sales growth for Pentrox and our Respiratory Devices, and a development portfolio of value creating opportunities within those businesses. We expect to deliver new partnership deals, expand our product offering and grow sales significantly.

Clinical programs and indication extensions will expand the use of Pentrox globally and our manufacturing technology development program could deliver a global change to how some pharmaceuticals are made.

We look forward to reporting our progress and successes.