

4 February 2015

#### **ASX ANNOUNCEMENT**

#### **CEO Roadshow Presentation Slides**

Medical Developments International Limited (ASX: MVP) will hold a CEO Roadshow in Melbourne and Sydney on the 4<sup>th</sup> and 5<sup>th</sup> February 2015 talking to the attached presentation to interested Fund Managers.

#### **Enquiries:**

David Williams Chairman Medical Developments International Ltd 0414 383 593 John Sharman Chief Executive Officer Medical Developments International Ltd 03 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 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.

# Medical Developments International



## **Vision**

Medical Developments International (MDI) is a leading Emergency Medicine Company.

#### Our aim is to

- 1. Dominate the analgesic trauma and minor surgical procedures market domestically and internationally
- 2. Dominate the Respiratory Medical Devices market domestically and internationally
- 3. Provide unique and innovative products to assist our customers in the management of acute and procedural pain, delivery of respiratory medications, resuscitation and oxygen therapies for human and veterinary patients.



## **Vision**

MDI is working on and delivering two significant business opportunities.

Both opportunities are "company making".

The risk profile of these opportunities is relatively low and well understood.

Penthrox: Our regulatory initiatives if successful will transform the company. Penthrox has the potential to be the market leader in emergency analgesic markets in Europe and elsewhere

Our Respiratory medical devices should generate significant growth



# Two world class opportunities

### **Penthrox**

- Significant competitive advantages to other analgesics.
- Fast, safe, rapid on-set, effective, cost-competitive, self administered.
- No needles, non-opiate, easy to store & transport.
- Building world class regulatory dossier to enable sales of Penthrox in other countries around the world.
- Completed successful phase III trials in Europe.
- Completed other successful clinical trials.
- Positive feedback from European Regulatory Authorities and working towards approval during FY15.
- Working on reducing the cost to compete with other analgesics.



# Two world class opportunities

## Respiratory medical devices

- Leading patented asthma & COPD medicine delivery devices.
- Low resistance, more efficient medicine dosage delivery.
- Won international tenders and major contracts in NZ, Canada, Germany & Australia to supply "Space Chambers".
- Lodged US FDA application.
- Independent testing prove "best delivery of medicine".
- Significant growth in Asthma device sales since 2011.
- Increasing customer base recently established European head office & distributors – recently established North American head office.



# **MDI Corporate Overview**

#### Three business divisions

- Pharmaceutical.
- Medical devices.
- Veterinary.

### We have a widely recognised portfolio of brands such as

- Penthrox;
- Space Chamber;
- Space Chamber Plus;
- OXI-Port;
- OXI-Sok;
- KAB Absorber; and
- OXI-Life.



# **MDI Corporate Overview**

MDI is recognised as a leader in pain relief, emergency medical devices; oxygen therapies and respiratory products. Our products are the first choice of professionals in the hospital, pre-hospital, first aid environments, universities and veterinary institutions.

Medical Developments International (MDI) commenced operations in 1972 and listed as a public company in December 2003.

MDI design, manufacture and distribute innovative healthcare products within Australia and Internationally and is located in Melbourne, Australia.

Our products are used in 11 countries with the list of new country registrations increasing.

Our manufacturing facilities are ISO 13485, GMP compliant.



## **MDI Pharmaceutical**

### **Penthrox**®

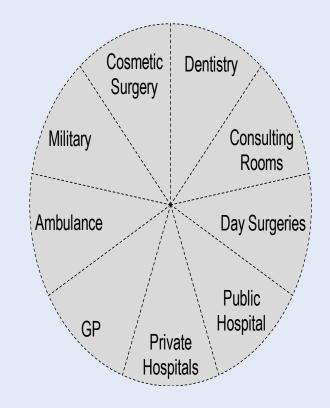
- Inhalational analgesic
- Demonstrated safety and efficacy profile
- Only manufacturer in the world
- Sold in Australia, N.Z, GCC
   South America, Eastern Europe & others
- Manufactured in GMP compliant plant





# Penthrox Clinical application

- Burn injuries
- Breaks, fractures and dislocations
- Abdomen pain
- Chest pain
- Other acute pain



#### Painful procedures

- Cutaneous excisions
- Liquid nitrogen removals of skincancers, warts, etc
- Invasive angiographies
- Dental procedures
- Colonoscopy
- Imaging
- Other non-general anaesthetic painful procedures

Either as an adjunct to or replacement of current forms of pain relief.



# **Penthrox Benefits to medical professionals**

Rapid onset of action

Minimal waiting time before a painful procedure can be performed (3 minutes) and rapid pain relief when a patient is treated for burns, trauma, etc.

Inhaled selfadministration Medical professionals can perform a procedure/attend to an injury whilst the patient is self-administering with minimal supervision needed.

Improve patient compliance

Effective at calming patients before procedures; makes patients more compliant and cooperative during treatments/procedures.

Portable, easy to use

Easy to store in a range of clinical settings (doctor's bag, ambulance, GP/specialist consulting rooms, hospital departments, military unit, etc.)



# **Penthrox Benefits over Nitrous Oxide**

Penthrox® does not effect vital signs; no clinical depression of respiration or circulation at low analgesic dosing.

Self-administration, easy to use and administer.

Compact and can be used in any location or situation.

No risk of overdose.

Single use device ensures no cleaning or cross contamination.

Medical professionals can perform a procedure / attend to an injury almost immediately whilst the patient is self-administering with minimal supervision.

Offset ranges from 3-5 minutes up to 20 minutes.

Easy and stable to store.

Patients can drive themselves home.



# Penthrox Benefits over Morphine

The benefits of using Penthrox® over Morphine are the same as detailed for Nitrous. In addition there are a number of specific benefits Penthrox has over Morphine which include:

Penthrox can be used on children, Morphine often cannot

Penthrox is not a narcotic; opioid or drug of addiction

Penthrox has less severe side effects

Penthrox is non invasive – no needles

Penthrox has a quicker onset to pain relief

Penthrox can be used by a wider community of health professionals including first aiders and volunteers

Morphine has considerable and complex administration and monitoring protocols during its use and for a significant time during recovery.

Penthrox does not require specific storage and use protocols



MDI has signed a deal with CSIRO to develop a new manufacturing technique for Penthrox

If successful this will provide MDI with:

- 1. World leading intellectual property
- 2. Very significant increased production capacity
- 3. Very significant reduction in cost to manufacture
- 4. Very significant competitive advantage



Our aim is to create a world class regulatory dossier capable of gaining approval to sell Penthrox anywhere in the world.

MDI has spent more than \$7 million on developing a regulatory dossier capable of getting Penthrox approved for sale in other countries.

Our Marketing Application was submitted to European authorities during 2013. We have received positive feedback from the authorities indicating that Penthrox is "approvable" subject to completing a number of tasks.

We are working towards achieving formal approval in the coming months.



MDI is working on regulatory approvals to expand into new countries in Europe, Central America, Canada, Asia, Africa, Russia, Israel, Saudi Arabia. The following numbers are MDI estimates of the market potential for Penthrox in Europe:

		AUD million
EUROPE	Penthrox potential sales	\$422

		AUD million
UK	Penthrox potential sales	\$40
France	Penthrox potential sales	\$37
Germany	Penthrox potential sales	\$38
Italy	Penthrox potential sales	\$36
Spain	Penthrox potential sales	\$28
Rest of Europe	Penthrox potential sales	\$243





Our plan is to use the Regulatory dossier to improve the positioning and obtain approvals to sell Penthrox around the world.

We are developing new Penthrox products which could deliver IP protection.

We are developing a new manufacturing methodology to make Penthrox.

If successful it may be possible to sell millions of units of Penthrox per year.



Since 1985 Medical Developments International has invested significant R&D resources to improving the delivery of Asthma and COPD medication.

In 2011 MDI launched the Space Chamber Plus® and the Compact Space Chamber Plus® in the Australian and International markets.

Both these spacers include MDI's Cross Valve Technology TM, a patented system of drug delivery which ensures very low resistance during inhalation and exhalation, while maximizing the dose of medication available.

MDI products are world leaders in their field.



MDI offers a range of innovative world leading devices that can be used to help patients manage and take control of their asthma and COPD.

- Space Chamber Plus® aerosol spacer
- Space Chamber® re-usable
- Compact Spacer Chamber Plus®
- Breath-Alert® peak flow meter
- EZ-fit face masks
- KDK oxygen regulators











### **MDI Space Chamber Plus ®**

- Recently approved by the FDA for sale in the USA.
- Recently registered by MHRA for full reimbursement.
- Won an international tender in New Zealand to supply MDI's range of asthma products exclusively for three years.
  - ✓ Defeated more than 10 international bidders.
- German distributor replaced its entire range of competitors products with MDI's Space Chambers.
- Won a tender to supply Canadian Hospitals with MDI's Space Chamber for 5 years.



### **MDI Space Chamber Plus ®**

- New patent cross valve technology
- Universal end suitable for all Metered Dose Inhalers
- Compact design
- Provides very low resistance for both inhalation and exhalation
- Enables unrestricted and continuous breathing
- Performance equivalent to worlds best practice for inhalers
- Transparent design to allow you to see medication delivery
- Superior looks
- Can be used with any international standard facemask
- Best value



The MDI Space Chamber Plus®is worlds best practice for delivering Asthma medications

— Elivatida	125	μg/actuation;	Conjeter	Dotob	numberer	A NIO 1 E O	/Eva ADD	0/421
± Flixoude,	123	µg/actuation,	Camster	Daten	numbers.	ANJIJO	(EXP APR	V 13)

		. Weight of drug per actuation (μg)		% drug per actuation		
Device		Exiting Spacer	Particles	Exiting Spacer	Particles	
SpaceChamber plus (n=6)	Mean	58.7	47.6	52.6	42.7	
	SD	4.9	4.5	3.0	3.1	
	cv	8.3	9.6	5.7	7.4	
AeroChamber plus (n=6)	Mean	46.6	39.5	41.3	35.0	
	SD	6.4	4.7	4.9	3.9	
	cv	13.7	12.0	11.9	11.0	
Breath-A-Tec (n=6)	Mean	43.3	37.7	38.3	33.4	
	SD	7.5	6.6	6.7	6.1	
	cv	17.2	17.4	17.5	18.4	



#### References

- 1. Laboratory Usage of respiratory spacers and the delivered Fluticasone (Flixotide) dose of commonly used spacers available in Australia and New Zealand.
- 2. Output of Fluticasone (Flixotide) pressurized metered dose inhaler (pMDI) delivered via Space Chamber Plus, the Aerochamber and the Breath a Tech Spacer device. Data on file at MDI

# Respiratory division Future

Since 2012 we have obtained approval and signed distribution deals to sell our Space Chamber Plus' and other medical devices including

USA

UK

**UAE** 

Denmark

**Netherlands** 

Austria

Singapore

Switzerland

Germany

Canada

Italy

Greece

**Finland** 

Hong Kong

Malaysia



# Respiratory division Future

We now have business and are making sales in

Australia

Hong Kong

Belgium

Asia

Spain

New Zealand

Switzerland

UK

Canada

Germany

Greece

USA

UAE

Singapore

Malaysia

Netherlands

Italy

Denmark

Austria



# Respiratory division Future

MDI is investing heavily in developing new and innovative products

- Anti static spacers
- Anti static mask (1<sup>st</sup> of its kind)
- Electronic peak flow
- Smart phone asthma & COPD applications



# MDI Medical Rescue and resuscitation

Our emergency medical equipment business has grown significantly since FY2011.

MDI is the preferred supplier in a number of markets including –



Ambulance, Non-emergency transport and Emergency First Aid

Various public and private health sectors (GP clinics, hospitals, aged care facilities) via wholesale and distribution channels



## **MDI Medical**

Design, assemble and test a wide range of medical devices

ISO 13485 & GMP compliant assembly facilities

Over 30 devices in product portfolio

Focus on respiratory system and oxygen delivery

- >Asthma management
- ➤ Oxygen delivery and equipment
- CO₂ absorbers
- ➤ Ventilators





# **MDI Veterinary**

Design, assemble and test a wide range of veterinary devices

Focus on anaesthesia and surgical consumables

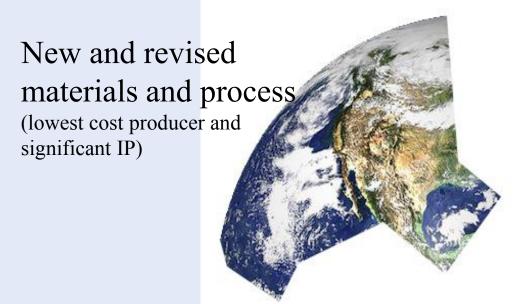


#### **Anaesthesia**

- Anaesthetic machines (closed circuit system)
- Breathing circuits
  - Vaporisers







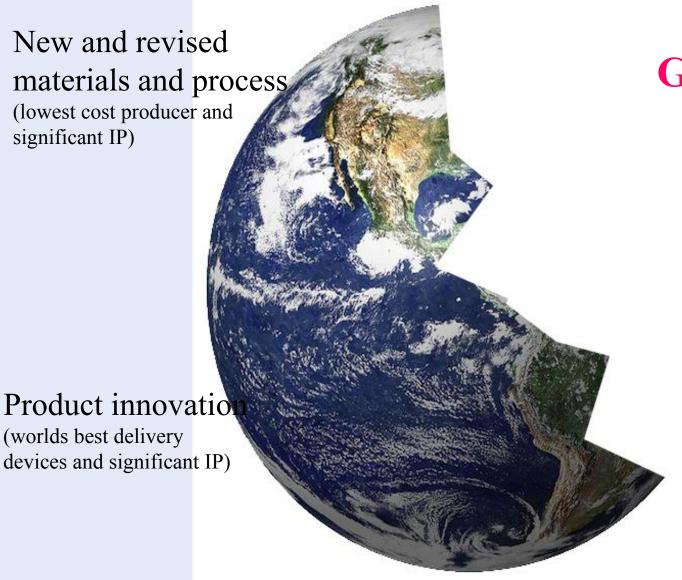
# MDI Global Strategy





# MDI Global Strategy





MDI Global Strategy

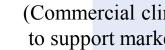


Regulatory Approval and new markets



Product innovation

(worlds best delivery devices and significant IP)



Clinical trials

(Commercial clinical studies to support marketing and product development)

**MDI** 

**Global Strategy** 



Regulatory Approval and new markets

New and revised materials and process (lowest cost producer and significant IP)

**MDI** 

Global Strategy

New Business Partners

Product innovation

(worlds best delivery devices and significant IP)



(Commercial clinical studies to support marketing and product development)



Regulatory Approval and new markets

## **Contact details**

#### **HEAD OFFICE**

Factory 6 / 56 Smith RoadPO Box 21 Springvale, VIC. 3171 Sandown Village, VIC. Australia

Tel: +61 3 9547 1888

Fax: +61 3 9547 0262

Web: www.medicaldev.com



# Forward looking statements

This document contains certain forward looking statements relating to Medical Development International's business, which can be identified by the use of forward looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track" or similar expressions or by express or implied discussion regarding potential filings or marketing approvals, or potential future sales of product. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy any health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Medical Development International Limited is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

