

# Medical Developments International

## Update

# PENTHROX update

# Penthrox update

## Europe

MVP signed a major distribution deal in Europe with Mundipharma.

This complements our distribution deal already done with Galen for the UK & Northern Ireland.

Collectively we now have full sales & marketing coverage for Europe and extended countries.

# Penthrox update

## Europe - Mundipharma

Mundipharma / (Purdue in the USA) is a top 20 global pharmaceutical company with sales estimated in excess of \$2 billion.

Mundipharma has a presence in 51 countries with more than 7800 employees across the world.

Mundipharma is a world leader in pain medication.

Mundipharma is committed to develop the clinical indications for Penthrox in Europe and has indicated it is willing to make significant financial investments to achieve this.

# Penthrox update

## Europe - Financial details

Upfronts and milestone payments from Galen and Mundipharma are potentially worth more than AUD \$80 million.

Approximately AUD \$10 million is due within the next 10 days from Mundipharma.

We expect another AUD \$15 million will be received during FY17 from Mundipharma.

We expect to receive another AUD \$1 million from Galen upon final Marketing Authorisation approval in the UK.

# Penthrox update

## European sales

We expect peak sales to be in excess of 10,000,000 units per annum for Europe.

Mundipharma is committed to develop the clinical indications for Penthrox in Europe and MVP will be able to participate in clinical trials that develop our markets.

MVP has agreed with Mundipharma that it will target the largest markets in Europe as a priority, including France, Italy, Germany and Spain.

Galen has submitted all its training and marketing materials to the UK authorities and we are waiting on final approval to sell.

# Penthrox update

## Manufacturing

Our new manufacturing process has been assembled and tested.

Commercial scale production runs have been completed.

Product has been placed in stability trials and we expect validation of the process to be completed during FY16. When successful MVP will have achieved:

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

We have secured new premises and will commence building new manufacturing facilities to cope with increased demand during 2016.

# Penthrox update

## Intellectual property

MVP has invested significant resources in developing intellectual property for Penthrox.

As part of the development program, MVP filed 4 International Patents relating to Penthrox and its delivery systems.

This IP will help secure and protect the future of Penthrox globally.



# Penthrox update

## Clinical development

MVP continues to invest in the clinical development of Penthrox.

MVP recently completed a psychomotor function study at Royal Adelaide hospital which showed the use of Penthrox did not alter the patient's ability to function such that:

1. A patient could go back to work after using Penthrox;
2. A patient could use heavy machinery after 20 minutes from use;
3. A patient could drive a car 20 minutes from use.

These results give Penthrox a significant competitive advantage over all other narcotic analgesic products which typically require many hours of observation and rest before returning to work or operating machinery, or driving a car.

# Penthrox update

## Registrations and approvals

We are waiting for the administrative processes and national phases of approvals in Europe to be complete.

We are meeting with regulatory officials in Mexico during October and we are hopeful of an approval within the months following that meeting.

We have received positive feedback from the Singapore regulatory officials indicating we will receive formal approval to sell Penthrox in Singapore in the coming months.

Our business in South Africa continues to grow.

We are in the final stages of appointing advisors for the USA. Initial feedback has been encouraging but we will know more about the pathway to approval in the coming months.

We are working towards approvals in other jurisdictions.

# Penthrox update

## Future

Our ambition is to globalise Penthrox.

We continue to develop and build a “world class” regulatory dossier which we will ultimately use to obtain approval to sell Penthrox in the USA and elsewhere in the world.

MDI has spent almost \$8million on developing its regulatory dossier and we continue to develop this asset.

MVP has funded this investment entirely from cash generated from its operations.

# Financial update

# Financial update

Net Profit After Tax	Total Sales	Earnings Before Interest and Tax	Net Profit After Tax
\$1.529m	24% up on prior period	191% up on prior period	75% up on prior period
Bank Debt *	Cash Flows From Operating Activities		
\$2.46m	159% up on prior period		

\* Net bank debt of nil when combined with closing cash balances

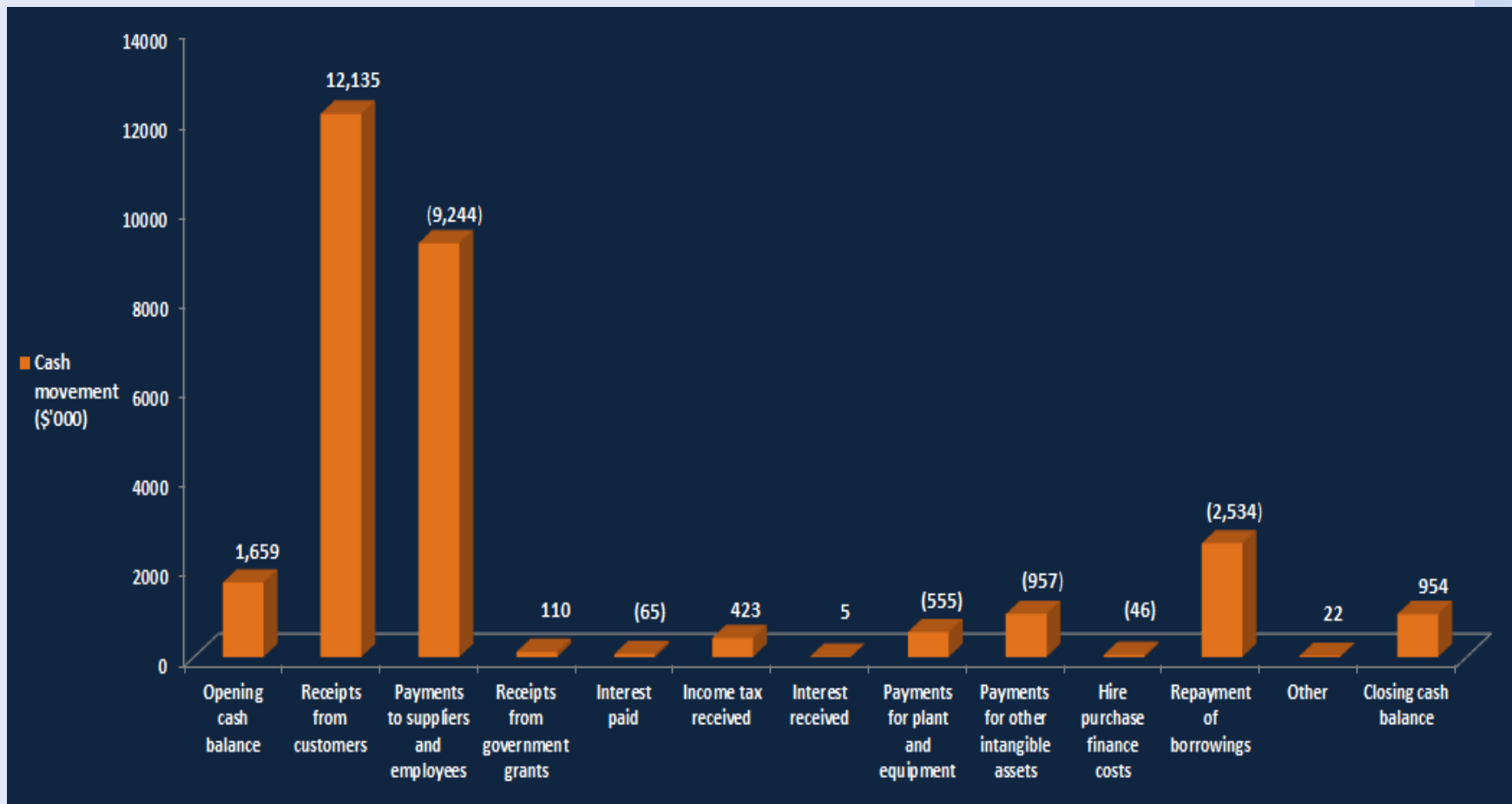
# Financial update

Results	FY15 \$'000	FY14 \$'000	Growth
Sales	11,608	9,365	24%
EBITDA	2,509	976	157%
EBIT	2,251	776	191%
NPAT	1,529	876	75%

# Financial update

Results	FY15 \$'000	FY14 \$'000	Growth
Sales of Pentrox	7,092	5,377	24%
Sales of Medical Devices	4,078	3,503	16%
Operating Expenses as a percentage of sales	48%	57%	(16%)

# Financial update – FY15 Cash Flow





# Medical Device update

# Medical Device update

## Respiratory division

Since 1985 MDI 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.

In 2014 MDI launched its Space Chamber Autoclavable product as well as a range of masks.

In 2014 MDI launched a Portable Nebuliser.

# Medical Device update

## Respiratory division

In 2014 MDI completed the commissioning of its Respiratory Laboratory which it uses to develop and test new products. This Respiratory Laboratory is one of only a few in Australia and around the world.

In 2015 MDI launched its range of antistatic Space Chamber Plus® and the Compact Space Chamber Plus® in the Australian and International markets.

In 2015 MDI launched a Pulse Oximeter.

MDI continues to invest heavily in developing new and innovative products which are world leaders in their field.

# Medical Device update

## Respiratory division

MDI offers a range of innovative world leading devices that 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
- Portable Nebuliser
- EZ-fit face masks
- Pulse Oximeter
- KDK oxygen regulators



# Medical Device update

## Respiratory division

MDI continues to develop its global footprint and expand its respiratory business. Sales are growing strongly. Currently we have business and are making sales in:

Australia

Hong Kong

Belgium

Ireland

Spain

New Zealand

Switzerland

UK

Canada

Germany

Greece

USA

UAE

China

Singapore

Malaysia

Netherlands

Italy

Denmark

Austria

Luxembourg

# **Medical Developments Global Strategy**

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



# MDI Global Strategy

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



Product innovation  
(worlds best delivery  
devices and significant IP)

# MDI Global Strategy



# MDI Global Strategy

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



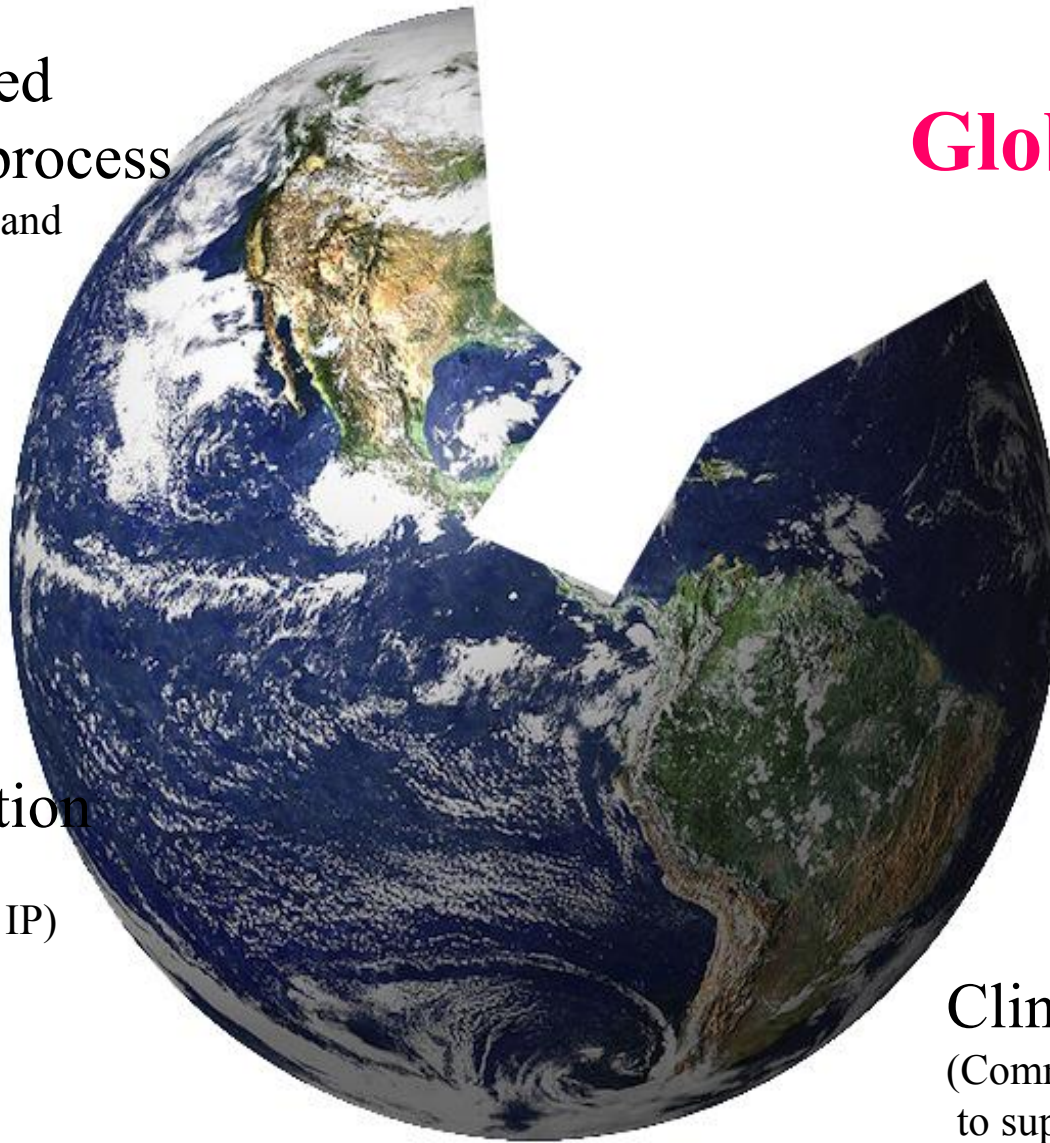
Product innovation  
(worlds best delivery  
devices and significant IP)

Regulatory Approval  
and new markets

**MDI**

# Global Strategy

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



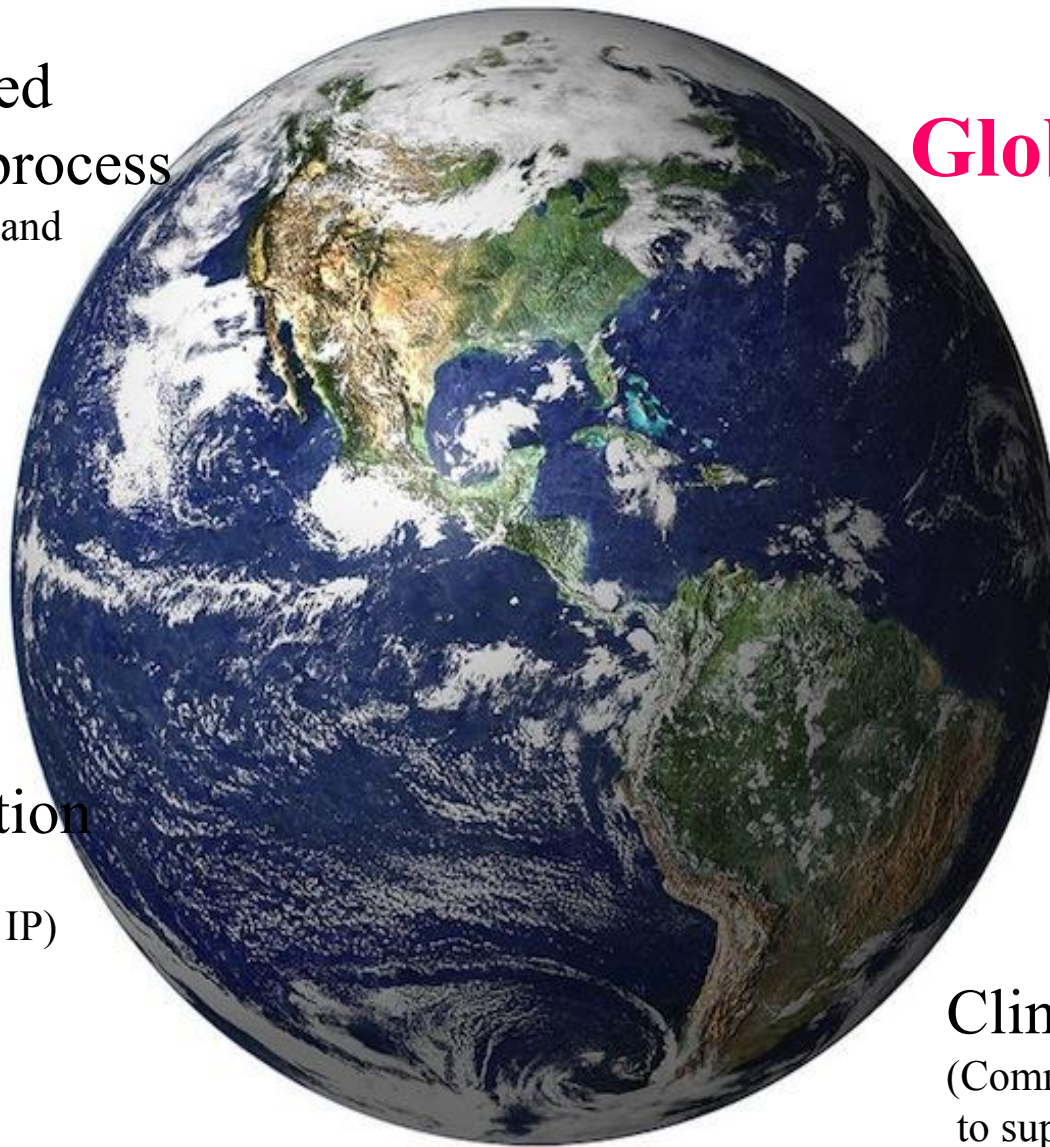
Product innovation  
(worlds best delivery  
devices and significant IP)

Clinical trials  
(Commercial clinical studies  
to support marketing and  
product development)

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)

Clinical trials  
(Commercial clinical studies  
to support marketing and  
product development)

Regulatory Approval  
and new markets

# Contact details

## HEAD OFFICE

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

Tel: +61 3 9547 1888

Fax: +61 3 9547 0262

Web: [www.medicaldev.com](http://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.

# More about Penthrox

# Penthrox

## Penthrox®

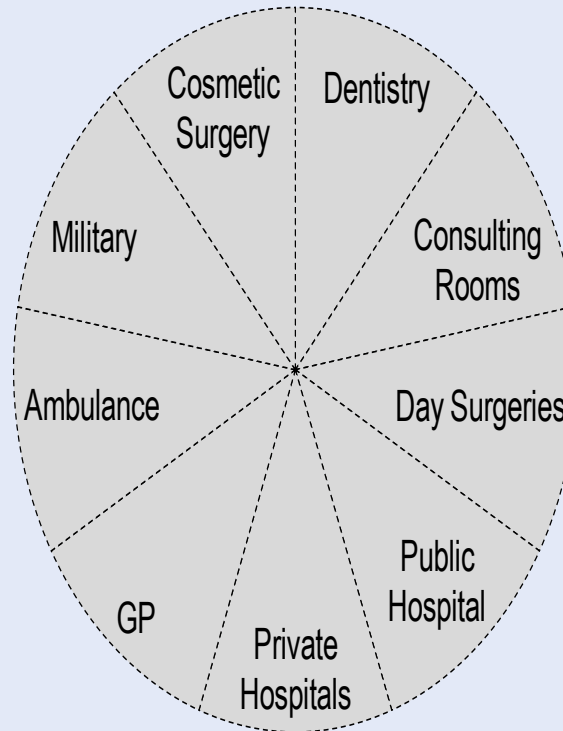
- Inhalational analgesic
- Demonstrated safety and efficacy profile
- Only manufacturer in the world
- Sold in Australia, N.Z, GCC  
South America, Eastern Europe & others
- Manufactured in GMP compliant plant



# Penthrox

## Clinical application

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



### Painful procedures

- Cutaneous excisions
- Liquid nitrogen removals of skin-cancers, 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 self-administration

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<sup>®</sup> 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.

# More about 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:** We are well on the way to achieving the globalisation of Penthrox. We recently signed significant distribution deals with Mundipharma and Galen Ltd. to distribute Penthrox across Europe and the UK. We are working on expanding into the USA.

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 Canada, Germany and Australia to supply “Space Chambers”.
- Range of products approved in USA. Additional product approvals expected in the coming months.
- Independent testing proves “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.

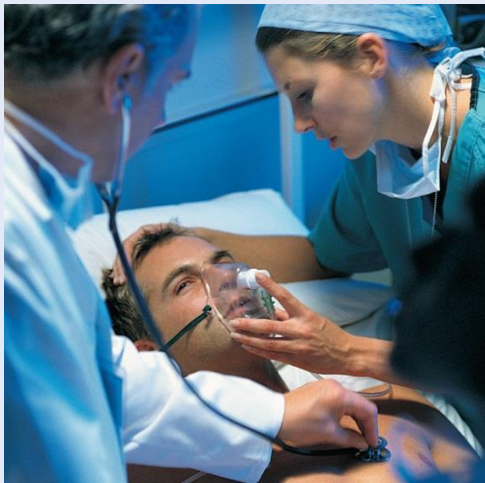


# MDI Medical

## 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
- CO<sub>2</sub> absorbers
- Ventilators



# MDI Veterinary

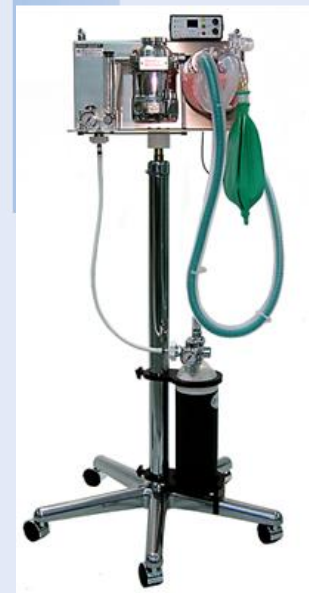
Design, assemble and test a wide range of veterinary devices.

Focus on anaesthesia and surgical consumables.



## Anaesthesia

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



**END**