# Medical Developments International

**Road Show** 





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#### Vision

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

#### Our aim is to:

- 1. Provide unique and innovative products to assist our customers in the management of acute pain, trauma and procedural pain and to be the market leader in these markets globally.
- 2. Provide unique and innovative products to assist our customers in the management of delivery of respiratory medications, resuscitation and oxygen therapies and to be the market leader in Medical Devices for Asthma and COPD markets globally.



# The Business

MDI is delivering two world class "company making" business opportunities.

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

Penthrox: Penthrox has the potential to be the market leader in acute pain markets around the world. Penthrox is not an opiate and delivers time and cost savings. It is the pain solution for acute pain, trauma and minor surgical procedures.

Our Respiratory Medical Devices are amongst the world's best and will generate significant growth.









#### Penthrox®

- First sales of Penthrox® in France and Belgium
- ✓ National reimbursement of Penthrox® in France
- Submitted Regulatory Applications to have Penthrox® approved in 22 countries
- Regulatory approval in the UAE
- Regulatory approval in Taiwan
- ✓ Distribution deal signed with Purdue Pharma in Canada
- Distribution deal signed with BL&H Co Ltd Corporation for Korea
- ▼ Received upfront payments from Korea and Canada
- Submitted two new Global Patent Applications for Penthrox® Inhalers
- Enrolled first patient in Penthrox® Post Authorisation Safety Study in Europe
- Commenced pre-clinical and clinical work for FDA approval
- ✓ Commenced planning pre-clinical and clinical work for Penthrox® indication extensions.



#### **Respiratory Medical Devices**

- ✓ Global sales growth of 142%
- ✓ Signed new distribution deal in USA with McKesson
- ✓ Sales growth of 148% for USA
- First sales into 1,600 pharmacies in the USA. More to follow
- ✓ Sales growth of 192% in Australia
- ▼ Record sales for Breath-A-Tech®
- ✓ Sales growth of 159% in UK and Europe
- ✓ Sales growth of 41% in New Zealand
- ▼ Patent Application for new respiratory devices
- ✓ Launch of six new respiratory products



#### Corporate

- \$5.5 million cash in bank
- ✓ No debt
- ✓ Construction of new manufacturing facility on time and on budget. Due for completion in March 2017
- ✓ Continued investment in new product development
- ▼ PDCO approval of Paediatric Study protocol, first patient expected July 2017
- ✓ MVP has 9 Patent and Patent applications
- ✓ MVP has Trademarks in over 30 countries



# Introducing Penthrox



#### A world class opportunity

#### **Penthrox**®

- Market Leader for trauma pain
- Opiate sparing, fast acting inhalational analgesic
- 85% of patients reach clinical analgesia within 10 breaths
- Is a solution to a significant unmet clinical need
- Demonstrated safety and efficacy profile for 30+ years
- World class regulatory dossier completed and being used to generate regulatory approvals around the world (work commenced in USA)
- Manufactured in Australia













#### A world class opportunity

#### **Penthrox**®

- Sold in 17 countries around the world including Australia, UK, France, Ireland, South Africa, Singapore, Belgium, New Zealand, UAE, Qatar and elsewhere.
- Major distribution deals signed in Europe and elsewhere in 2015.
- \$18.5 million in upfronts and milestones received.
- Sales commenced in UK, Ireland, Singapore, France and Belgium.
- Six patent applications lodged covering new Penthrox delivery devices.
- Patent application lodged covering new Penthrox manufacturing technology.











#### **Penthrox**® History and planned launches 2010 2015 Pre 2000 2021 - 2022 2020 Planned Launch: 2019- 2020 Malaysia Planned Thailand 2017 & 2018 Launch: Philippians Planned Launch: Brazil 2016 Indonesia Canada Columbia Launched: 2014 Germany Chile Ireland Italy Launched: 2011 Argentina Spain UAE South 2009 Launched: Switzerland 2020 2002 UK Africa 2018 & 2019 Launched: Guatemala **Portugal Planned** Launched: Planned Launch: Moldova Austria Slovenia Launch: New South Korea 1975 Croatia USA Zealand Netherlands Launched: Serbia 2017 Denmark Australia Greece 2011 Luxemburg 2020 **Planned** Malta Launched: Czech Planned 2010 Launch: Norway Republic Kazakhstan Launch: Launched: Hungary Poland Russia Liechtenstein Azerbaijan France Sweden Monaco Georgia Belgium • Slovakia Saudi Arabia Ukraine Mexico • Macedonia 2015 San Marino 2021 Albania Taiwan Launched: Bosnia Planned Montenegro Jordan Singapore Vatican City



Launch:

China

Herzegovina

Andorra

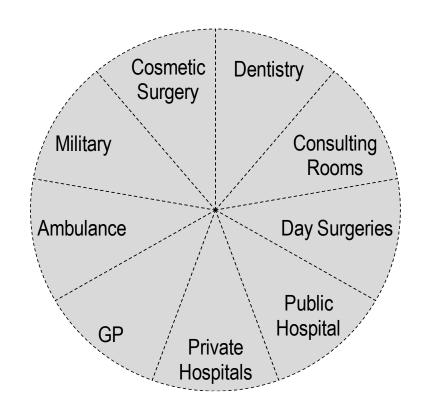
Kosovo

Iraq

# **Penthrox**<sup>®</sup> Clinical application

#### **Painful procedures**

- 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
- Cosmetic procedures

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



#### Benefits to medical professionals

Rapid onset of action

Inhaled self-administration

Improve patient compliance

Portable, easy to use

**Opiate** sparing

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

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

Fastest time to analgesia and effective at calming patients before procedures; makes patients more compliant and cooperative during treatments/procedures. No known drug to drug interaction. Patients can drive themselves home and go back to work after 30 minutes.

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

Addiction and the use of narcotics is increasingly problematic. Penthrox is non narcotic and non addictive, making it the better solution for medical professionals.



#### Benefits over Opiates

#### The benefits of using Penthrox® over Morphine include:

- Penthrox does not effect vital signs; no clinical depression of respiration or circulation.
- Penthrox can be used on children, Morphine often cannot.
- Penthrox is not a narcotic, nor is it an 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, improves time to analgesia.
- Penthrox can be used by a wider community of health professionals including first aiders and volunteers.
- Morphine has considerable, expensive and complex administration and monitoring protocols during its use and for a significant time during recovery.
- After using Penthrox there is no long observation period needed before patients can go home (possibly drive themselves home after 30 minutes).
- Penthrox does not require specific storage and use protocols (is not a restricted medicine).
- Penthrox can be disposed of easily and safely.



#### Benefits over Nitrous Oxide

#### The benefits of using Penthrox® over Nitrous Oxide include:

- Penthrox does not effect vital signs; no clinical depression of respiration or circulation.
- Penthrox is self-administered and easy to use.
- Penthrox is compact and can be used in any location or situation.
- Penthrox does not carry any 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.
- Penthrox offset ranges from 3-5 minutes up to 20 minutes.
- Penthrox is easy and stable to store.
- After using Penthrox there is no long observation period needed before patients can go home (possibly drive themselves).



#### Non-narcotic and clinically proven efficacy

#### VAS scores compared, IV morphine vs IN fentanyl vs Penthrox

Summary of mean VAS Pain Scores										
Time	0	5 minutes	10 minutes	15 minutes	20 minutes	30 minutes				
Morphine	67	42	41	-	35	33				
Fentanyl	68	55	46	-	37	37				
Penthrox®	65	43	37	31	30	-				

#### **Summary of mean reduction in VAS Pain Scores**

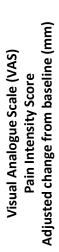
Time	0	5 minutes	10 minutes	15 minutes	20 minutes	30 minutes
Morphine	0	25	26	-	32	34
Fentanyl	0	13	22	-	31	31
Penthrox®	0	22	28	34	35	-

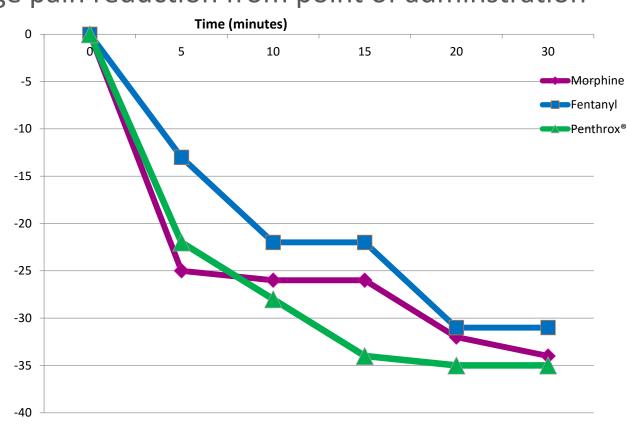
The criteria for the cross study comparison were a similar study design and endpoint as the Penthrox® study, MEOF-001. Borland et al (2007) has a similar study design and endpoints as those of MEOF-001 (Table 2). Borland et al (2007) compared two active drugs, IV morphine against IN fentanyl. The VAS scores observed for the three drugs at Baseline, 5, 10, 20 and 30 minutes are compared in Table 1. The results demonstrate that Penthrox® is as effective as the alternate opioid analgesic agents that are currently used in A&E but has a significantly better safety profile. Treatment with Penthrox® does not result in respiratory depression as demonstrated in clinical trials of the development programme - MEOF-001, 06/61, MEOF-003. The retrospective observational study Vital Signs Report (see Vital Signs Report) showed no deleterious effects on pulse rate, systolic BP, or respiratory rate. Methoxyflurane has negligible effects on the cardiovascular system and can be safely administered to patients in shock. In fact, a stabilising action of methoxyflurane on cardiorespiratory function has been reported (Virengue et al. 1975)



## Provides rapid pain relief

#### Average pain reduction from point of adminstration<sup>1-2</sup>





<sup>1</sup> COFFEY, Frank, et al., 2014. STOP!: A Randomised, Double-Blind, Placebo-Controlled Study Of The Efficacy And Safety Of Methoxyflurane For The Treatment Of Acute Pain; Emergecny Medicine Journal.

<sup>2</sup> BOLAND, Meredith, et al., 2007. A Randomized Controlled Trial Comparing Intranasal Fentanyl to Intravenous Morphine For Managing Acute Pain In Children In The Emergency Department; Emergency Medicine Journal.

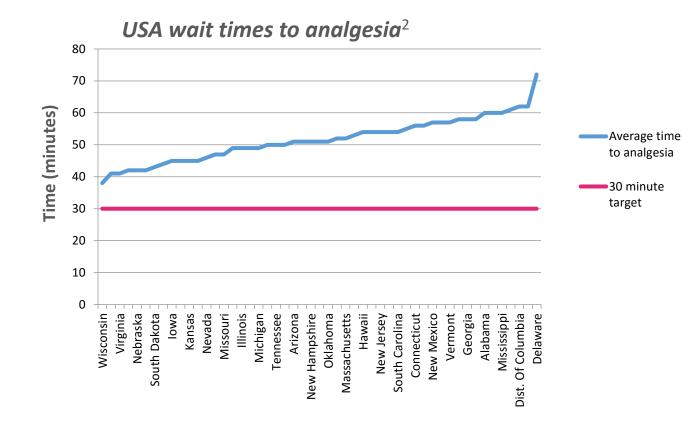


#### Can reduce patient waiting times to analgesia



#### Penthrox® assists by being:

- ✓ Self administered
- ✓ Easy to use
- ✓ Not a restricted drug (in Australia)
- ✓ Providing rapid non-opioid pain relief
- ✓ Able to drive home after treatment¹
- ✓ Less observation time
- ✓ Earlier discharge



GROEGER, Lena, et al., 2017. ER Wait Watcher- State-by-state Waiting Times; ProPublica. https://projects.propublica.org/emergency/



<sup>&</sup>lt;sup>1</sup> NGUYEN, Nam, 2016. Psychomotor And Cognitive Effects Of 15-Minute Inhalation Of Methoxyflurane In Healthy Volunteers: Implication For Post-Colonoscopy Care; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5110336/

#### Can reduce resources used in pain management

Penthrox® provides rapid pain relief and is a cost effective option to increase patient flow & throughput

> Pain is the most common presentation in the ED

Up to 78% of Emergency Department visits experience pain1

Penthrox® requires minimal supervision and is simple, portable, patient administered

Most common treatment for moderate to severe pain is IV opioids

The use of IV opioids is often the only reason ● Bed/Room an IV was administered

Inhalation of Penthrox® is non-invasive and does not require IV access or ongoing patient monitoring



Resources required for IV administration

Equipment

Time

- Nurses/Doctors
- 2 staff to access the opioids

Common use of IV opioids

30 year record in Australia of treating a wide range of painful conditions



#### Results of high resource use

Decreased patient flow Cost to patient and hospital<sup>2</sup> Takes staff away from other patients IV resources required Common use of IV opioids

TODD, Knox, 2010. Chronic Or Recurrent Pain In The Emergency Department: National Telephone Survey Of Patient Experience; Western Journal of Emergency Medicine. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3027428/ PALMER, Pamela et al., 2016. Cost Of Delivering Intraveneous Opioid Analgesia In Emergency Departments In The United States; AcelRx



## Can reduce overcrowding in EDs

#### PENTHROX® IN THE ED

Penthrox® has the ability to improve an ED's medical care as it can:

#### Leads to:

- Treatment of patients outside designated zones
- Decreased patient satisfaction
- Longer delays in evaluation and treatment
- Increased cost to the hospital
- Increased ambulance diversion time
- A lower quality of medical care and compromising patient safety

Increase patient satisfaction levels

Reduce the time to analgesia

- Reduce the costs to hospitals
  - Administered anywhere without the additional risk
     to patients
    - Reduce observation time and accelerate time to discharge

#### OVERCROWDING IN THE ED

Overcrowding impact is recognized by the American College of Emergency Physicians (ACEP)

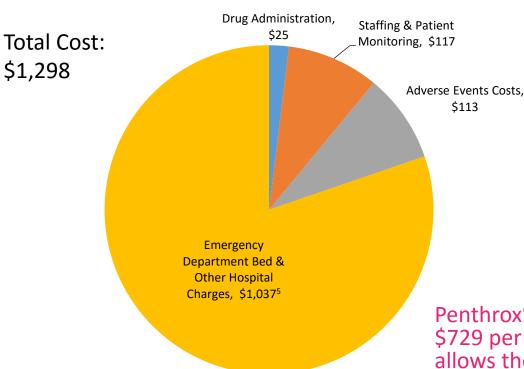
American College of Emergency Physicians (ACEP), 2016. Clinical & Practice Guidelines- Crowding; ACEP. https://www.acep.org/clinical---practice-management/crowding/

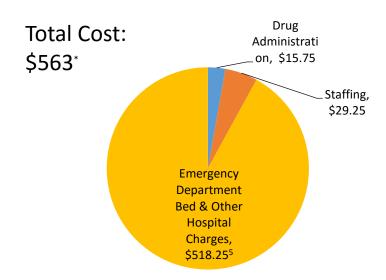


#### Can reduce the cost of analgesia

#### Average costs of an IV Opioid treatment

#### Average costs of a Penthrox® treatment\*





Penthrox® could help to reduce the cost of analgesia by approximately \$729 per patient, as it is non-invasive, requires less observation time and allows the patient to receive medical attention and be discharged earlier.

\$113

\*Based on company estimates



ntravenous Administration of Morphine In The Emergency Room Inflicts A Substantial Economic Burden In The EUS. Available from: http://www.acelrx.com/technology/publications/arx-04/Poster%20PSY45\_060CT2016.pc

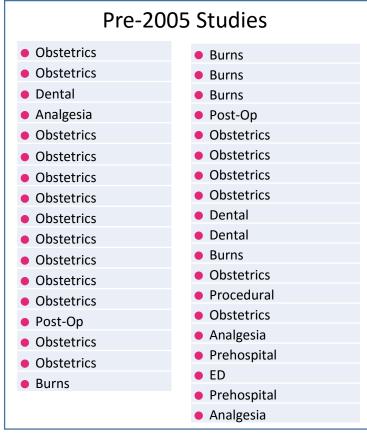
mela et al., 2016. Cost Of Delivering Intraveneous Opioid Analgesia In Emergency Departments In The United States; AcelRx http://www.acelrx.com/technology/publications/arx-04/ISPOR%202016%20ER%20IV%20MS%20Poster%205%209%2016.pdf

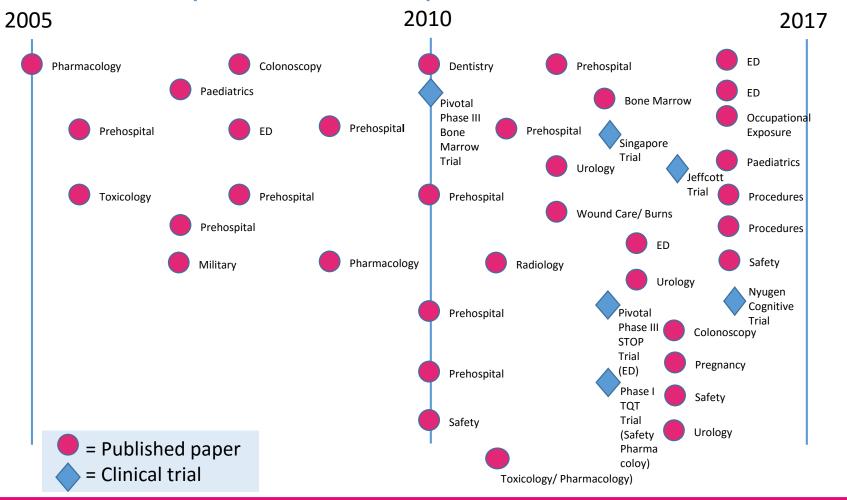
<sup>3</sup> FOLEY, Mathew, et al., 2008. Financial Impact of Emergency Department Crowding. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3099606, 4 Cleveland Clinic, 2016. Patient Price Information List; http://my.clevelandclinic.org/ccf/media/files/Patients/cleveland-clinic-main-charges.pdf

<sup>5</sup> Based on company estimates of 4-6 hours observation post IV administration compared with 2 hours of observation pre discharge when using Penthro

# **History of Penthrox**

#### Clinical studies & publications to present







# **History of Penthrox**

Clinical studies & publications to present

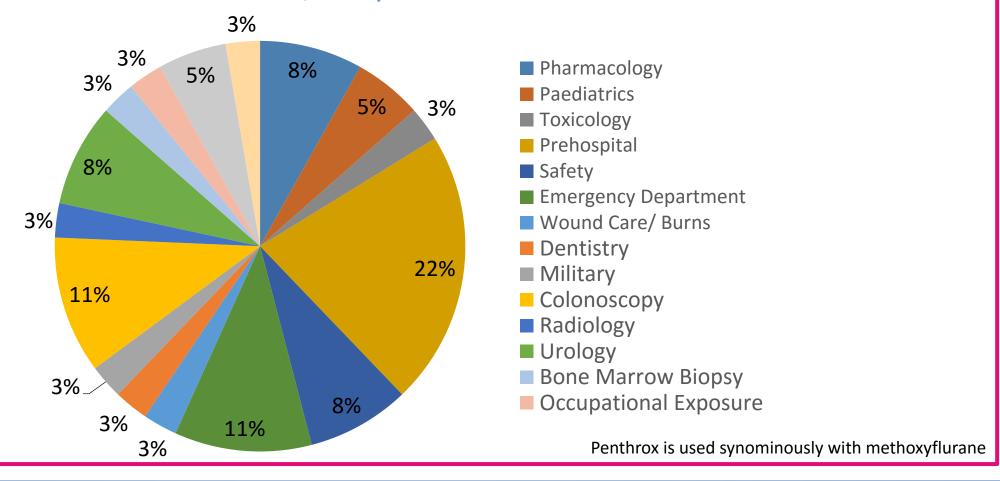
# 235,861 patients have been studied in more than 75 clinical trials over 30 years

Penthrox is used synominously with methoxyflurane



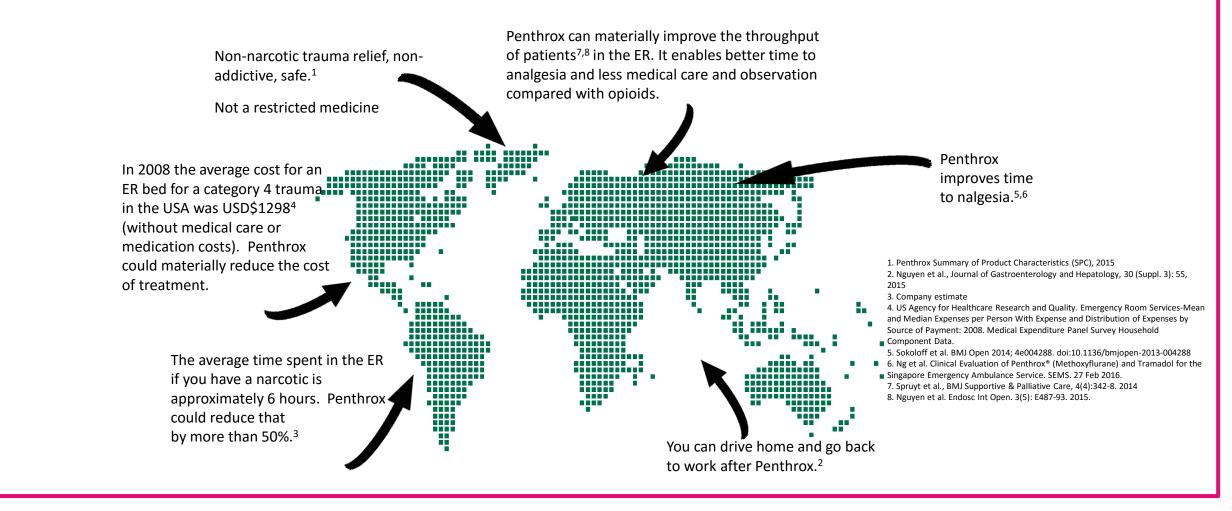
# **History of Penthrox**

Clinical studies & publications to present 235,861 patients



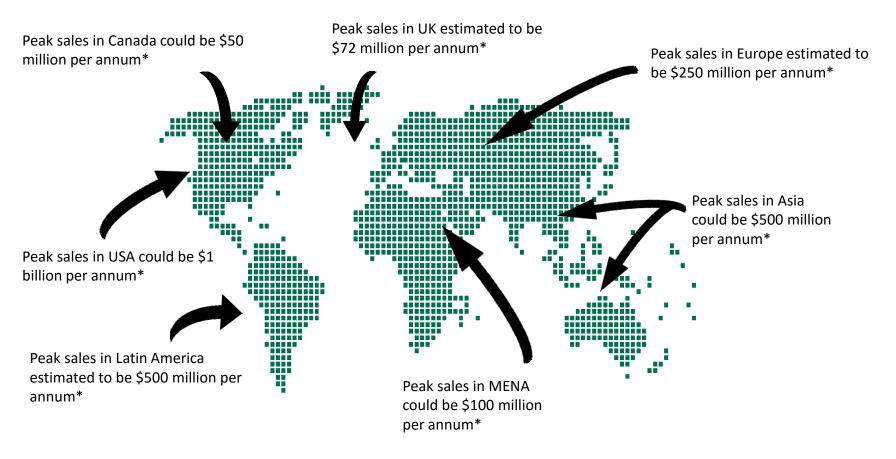


#### Value Proposition





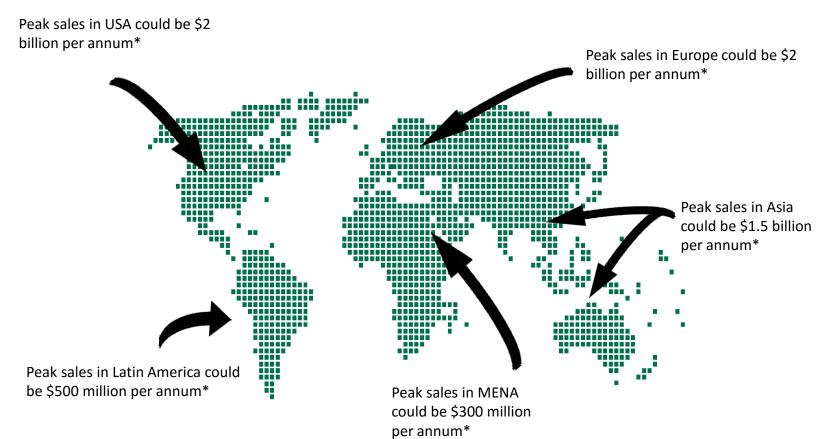
#### Potential global sales for Acute Trauma pain \$2 billion+



\*Bases on company estimates including assumptions around market penetration and reimbursement levels



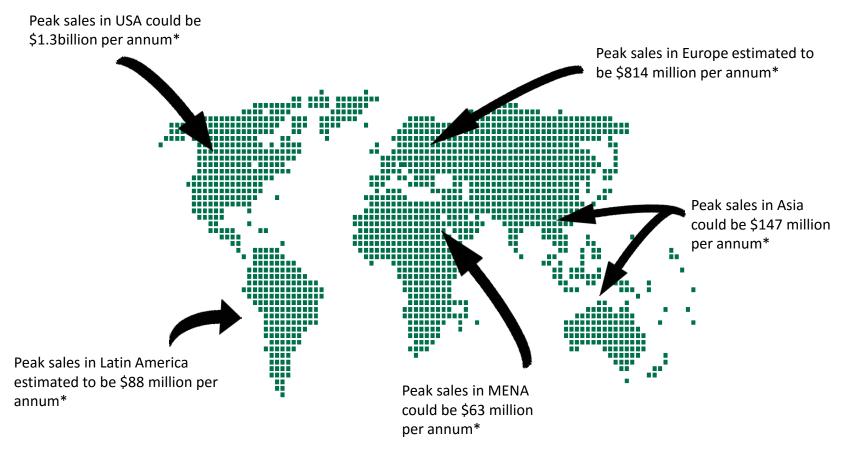
## Potential global sales for Breakthrough pain \$6 billion+



\*Bases on company estimates including assumptions around pricing, market penetration and reimbursement levels



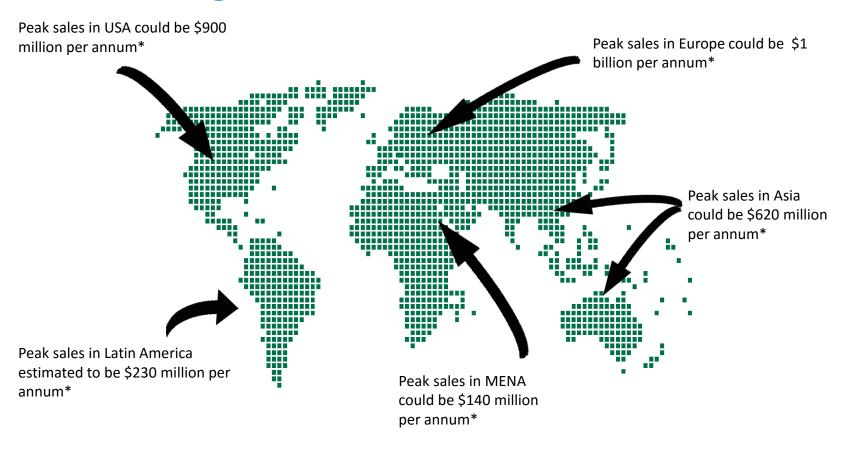
#### Potential global sales for Minor Surgical Procedures \$2.3 billion+



\*Based on company estimates including assumptions around pricing, market penetration and reimbursement levels



#### Potential global sales for Home Use \$3 billion+



<sup>\*</sup>Bases on company estimates including assumptions around pricing, market penetration and reimbursement levels



MVP submitted a detailed regulatory package to the FDA in January 2016. We received a written response from the FDA detailing it's opinion on the strengths of our regulatory package and by inference the work required to get Penthrox approved for sale in the United States of America.

Amongst those requirements is the need to perform a Pivotal Phase III Clinical Trial (in addition to the STOP study and Bone Marrow Biopsy Phase III studies which MVP has successfully completed).

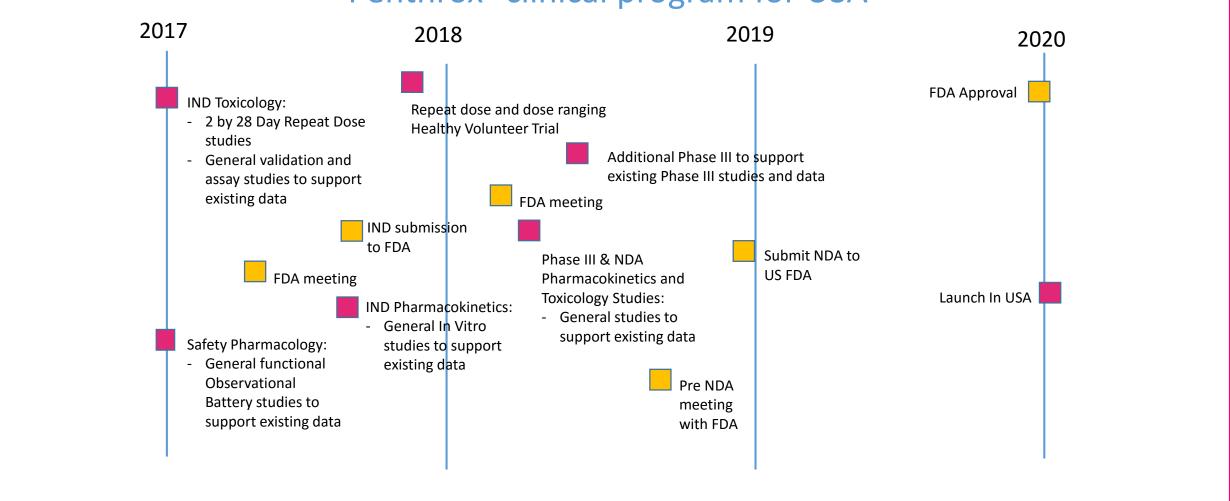
MVP has commenced the clinical work required and estimate it will take 2+ years and circa \$15 million to complete.

MVP has a track record of successfully completing clinical programs, including Phase III studies on time and budget.



# **Future Of Penthrox**<sup>®</sup>

# Penthrox® clinical program for USA





#### Clinical development program

Additional clinical trials and studies are planned for FY17 (and beyond) which will broaden the indications for use of Penthrox® including:

We are developing a program of work to support additional indications for Penthrox worldwide. Our longer term ambition is to extend the use of Penthrox into:

- Acute Pain / Minor Surgical Procedures;
- Breakthrough Pain / Repeat Use; and ultimately; and
- Home Use.

#### **Acute Pain & Minor Surgical Procedures**

Penthrox is already approved for use in Minor Surgical Procedures in Australia and elsewhere.

MVP is working with its partners to develop a clinical program to extend the indication of use in markets around the world. We hope to achieve this extension in Europe within the next 2+ years.

We estimate the market for Minor Surgical Procedures globally could be \$3 billion.



#### Clinical development program

#### **Breakthrough Pain / Repeat Use**

MVP has begun the clinical program to get Penthrox approved for sale in the USA. As part of that program, several pre-clinical trials will be concluded. These trials will also be used towards the work program required to have the indication for Penthrox extended to Repeat Use and Breakthrough Pain where Penthrox could be the ideal alternative to high potency and dangerous opioids currently used in the vast majority of cases.

We estimate the market for Breakthrough Pain could be \$6 billion.

#### **Home Use**

Ultimately, we hope the clinical programs we undertake will allow Penthrox to be approved for home use via prescription.

Our vision is that households all over the world will have a Penthrox device for use during those rare occasions when trauma grade, non-opioid analgesia is required.



#### **Intellectual Property**

MDI is protecting its future by generating intellectual property from its manufacturing technology and delivery devices.

MDI has filed and is managing the following patents and trademarks:

- 6 Penthrox Inhaler patents;
- 1 manufacturing patent; and
- Numerous trademark filings to mirror global growth.

MDI is also generating significant "Data Exclusivity" rights from its successful regulatory approvals around the world.

Note: "Data Exclusivity" works like a patent and protects the product in market from competition but usually for a shorter period of time.



#### Manufacturing

MDI has invested millions of dollars developing new manufacturing technology, techniques and methods.

#### MDI has:

- 1. Intellectual property.
- 2. Global production capacity.
- 3. Lowest cost to manufacture.
- 4. Significant competitive advantage.



## Penthrox Outlook

MVP's ambition is to globalise Penthrox and in doing so make it the main stream analgesic of choice around the world. That process has begun. Over the next 12 months we expect to:

- 1. Obtain approval to sell Penthrox in more than 20 countries throughout Europe and in a number of courtiers outside the EU;
- 2. Conclude additional distribution partnership for new countries;
- 3. Commence and progress work on gathering the clinical data needed to submit a "New Drug Application" to the Food & Drug Administration in the USA, and extend the 'indications for use' for Penthrox;
- 4. Commence work to develop new manufacturing process for Analgesic and Anaesthetic products and create significant the intellectual property; and
- 5. Complete our manufacturing facility which will have special purpose Research and Development laboratories dedicated to improving the way we manufacture Penthrox.



## **Introducing Respiratory Devices**



## **MDI** Medical

## Respiratory division

MDI has a long history of investing R&D resources to design and improve respiratory devices used to deliver Asthma and COPD medication.

In 2011 MDI launched a new range of products using MDI's Cross Valve Technology™, a patented system of drug delivery which ensures very low resistance during inhalation and exhalation, while maximising the dose of medication available.

In 2015 MDI invested in developing its own particle size distribution testing and design laboratory.

2016 MDI received FDA approval to sell its range of Anti Static Space Chamber devices in the USA and elsewhere.



## **MDI** Medical

## Respiratory division

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

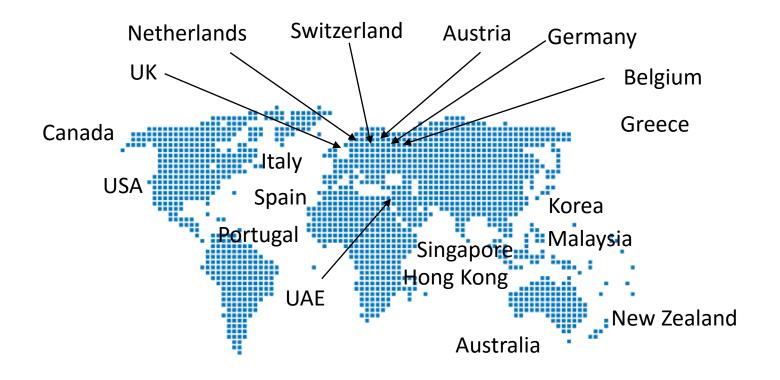
- Space Chamber Plus<sup>TM</sup> anti-static range
- Space Chamber Plus<sup>TM</sup> aerosol spacer
- Space Chamber<sup>™</sup> re-usable
- Compact Spacer Chamber Plus<sup>TM</sup>
- Breath-A-Tech<sup>TM</sup> spacer range
- Breath-Alert® peak flow meter
- EZ-fit face masks
- KDK oxygen regulators





## **Respiratory Devices**

## Existing distribution network





## **Respiratory Division**

#### **Future**

#### MDI respiratory products:

- now sell in 20 countries
- are ranged in 1600 pharmacies across the USA
- have achieved full reimbursement in the USA
- are Australia's leading brand
- are delivering strong growth around the world



## **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)
- Collapsible spacer
- Economical spacer
- Additional patentable devices and technology

Two new products are expected to be launched during 2017.



## **Respiratory Devices**

## **Intellectual Property**

MDI is protecting its future by generating intellectual property from its new range of respiratory devices.

MDI has filed a number of global patents.

MDI has filed international Trade Marks and Registered Designs in more than 20 countries.



## **Respiratory Devices**

#### Outlook

MVP's ambition is to globalise the sales of its Respiratory Devices. That process has begun. We already have partners and make sales in more than 18 countries.

Over the next 12 months we expect to:

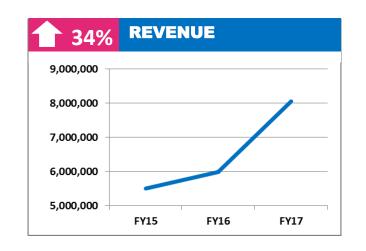
- 1. Obtain additional partnership deals in the USA and deliver sales growth;
- 2. Obtain additional partnership deals in other countries around the world;
- 3. Consolidate our position as the largest supplier of Respiratory Devices in Australia;
- 4. Introduce new products; and
- 5. Continue to drive down costs and increase the range and quality of our products.

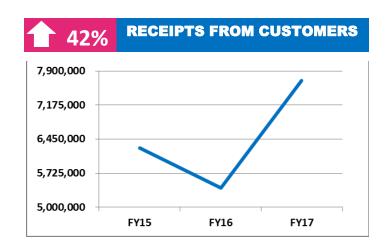


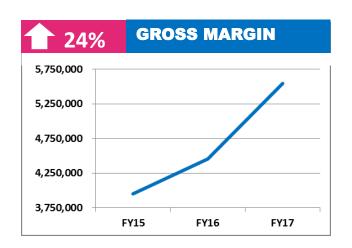
# **Introducing MVP Corporate**

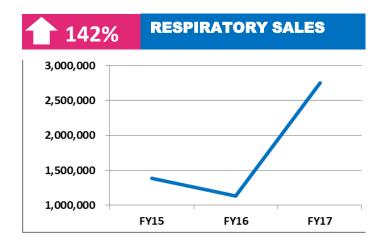


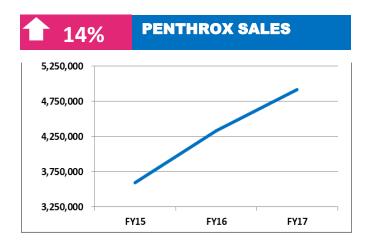
## **Financial Summary of H1FY17**













## **Financial Summary of H1FY17**



34% growth in revenue to a record \$8.05m



74% growth in Net Profit after Tax to \$410,000



24% growth in Gross Margin



51% growth in EBITDA



82% growth in Profit before Tax



14% growth in Penthrox® revenue



108% growth in International Penthrox® revenue



## **Financial Summary of H1FY17**



142% growth in Global Respiratory Device sales



192% growth in Australian Respiratory Device sales



159% growth in European Respiratory Device sales



148% growth in USA Respiratory Device sales



42% increase in Cash Receipts from customers



## **Financial Summary**

MDI has been profitable every year since listing on the ASX in 2003 and used those profits for registration and additional clinical studies and:

- has generated a positive cash flow every year;
- pays tax and has paid fully franked dividends;
- has received almost \$18.5 million in upfronts and milestones in the last 15 months; and
- expects a further \$7 million in milestone payments to be received over the next 18 months.



## **MDI Investor Dashboard (ASX: MVP)**

#### **Historical Stock Chart (3yr)**



#### **Current Stock Price**

5.00

**1** 0.280 (5.93%)

2 Mar, 12:00pm

Day High 5.080 Day Low 4.810

Open 4.810 Prev. Close 4.720 Avg. Volume 63,642

52 Wk. High 6.850 (3 May 2016) 52 Wk. Low 4.120 (6 Dec 2016)

Mkt. Cap 294.34 (Mil)



## **MDI Corporate Overview**

#### **David Williams**



Non-Executive Chairman

The Managing Director of Kidder Williams Ltd, with 32 years experience in investment banking.

#### Dr Harry Oxer



Non-Executive Director

A Medical Consultant to MVP and St John Ambulance in Western Australia.

#### **Leon Hoare**



Non-Executive Director

Recent Managing Director of Smith & Nephew in Australia and New Zealand.

#### **Max Johnston**



Non-Executive Director

Recent MD of J&J Asia Pacific. A Non-Executive Director of Enero Group Ltd, Polynovo Limited and Chairman of Probiotec Limited.

#### Allan McCallum



Non-Executive Director

Over 15 years public companies experience including an ASX 50 company.

#### **Phillip Powell**



Non-Executive Director

A Chartered Accountant and has an extensive finance background.

#### John Sharman



Chief Executive Officer

#### **Mark Edwards**



Group Financial Controller & Company Secretary

#### **Glenn Gilbert**



Associate Director, Commercial

#### **Scott Courtney**



Director of Operations & Research

#### Maggie Oh



Director of Scientific Affairs

#### Keith Jeffs



General Manager, Sales & Marketing

#### Jake Golding



Quality Assurance & Validation Manager



## **MDI Global Strategy**

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New and revised materials and process

(lowest cost producer and significant IP)

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New Business Partners

#### **Product innovation**

(worlds best manufacturing processes and delivery devices resulting in significant IP)

Regulatory
Approval and
new markets

#### Clinical trials

(Commercial clinical studies to support marketing and product development)



## **Contact Details**

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# Medical Developments International