

# March 2018



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9. litigation;
10. loss of key executives or other employees; and
11. adverse publicity and news coverage.

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# Vision

Medical Developments International (MVP) 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 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.

# Penthrox<sup>®</sup>

# Penthrox®

Penthrox is becoming mainstream in the UK and Ireland

Everton's James McCarthy suffered a double leg fracture in Everton's premier league game against West Bromwich



Shown on television show "24 Hours in ED" St George Hospital, UK - 2018





# Penthrox<sup>®</sup>

## Penthrox is becoming mainstream in the UK and Ireland

Ireland centre Robbie Henshaw injured  
against Italy in the 2018 Six Nations



Source: The Times UK. <https://tinyurl.com/yd4c3trv>



Source: Sports Joe <https://tinyurl.com/ydysk74e>

Ireland's Jordi Murphy is carried off the field during the first half of a match  
against New Zealand in Chicago, USA (Nov 2016)



Source: The Irish News <https://tinyurl.com/ydhko94x>

# Penthrox®

## UK and Ireland update

In market sales in the UK and Ireland grew 83% in H1FY18 vs H2FY17.

There are 90 hospital formulary approvals.

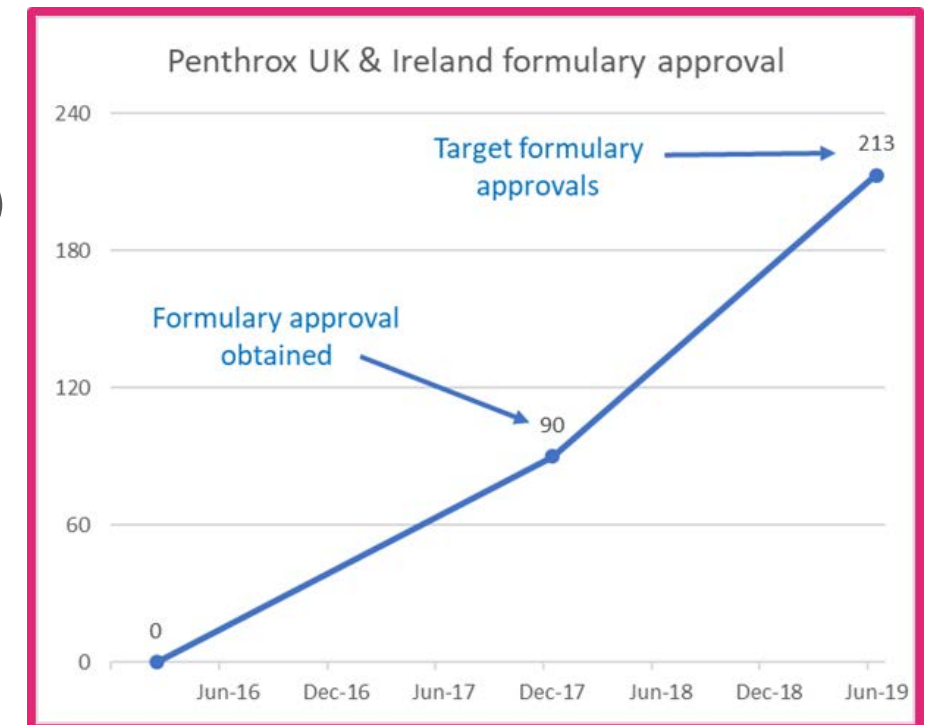
All 90 hospitals are ordering on a regular basis.

Penthrox has been sold into 286 (up from 122 in October) Hospitals, clinics and ambulance services in the UK and Ireland so far.

Many of these first sales are “pre formulary” approvals.

136 of these customers have re-ordered Penthrox.

Penthrox is currently listed in 7 Major Trauma Centres.



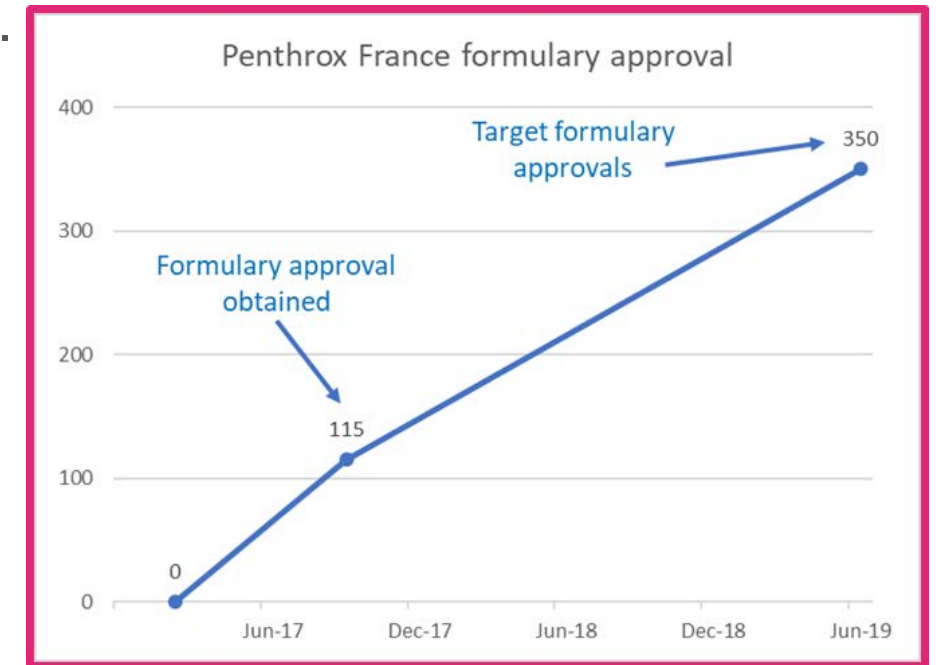
# Penthrox®

## France update

Our partner is making excellent progress in France.

In market sales in France are growing. In summary:

- The target is 350 hospitals to approve Penthrox in France.
- 250 formulary applications have already been submitted.
- 115 formularies have approved Penthrox in France.
- 16 formulary applications rejected.
- 208 Penthrox customers, 115 customers with at least 2 orders.
- 55% of customers who have ordered Penthrox have already re-ordered.





# Penthrox®

## Regulatory approval for Penthrox in the rest of Europe

In addition to France, Belgium, UK, and Ireland we have 6 new European countries approved to sell Penthrox.

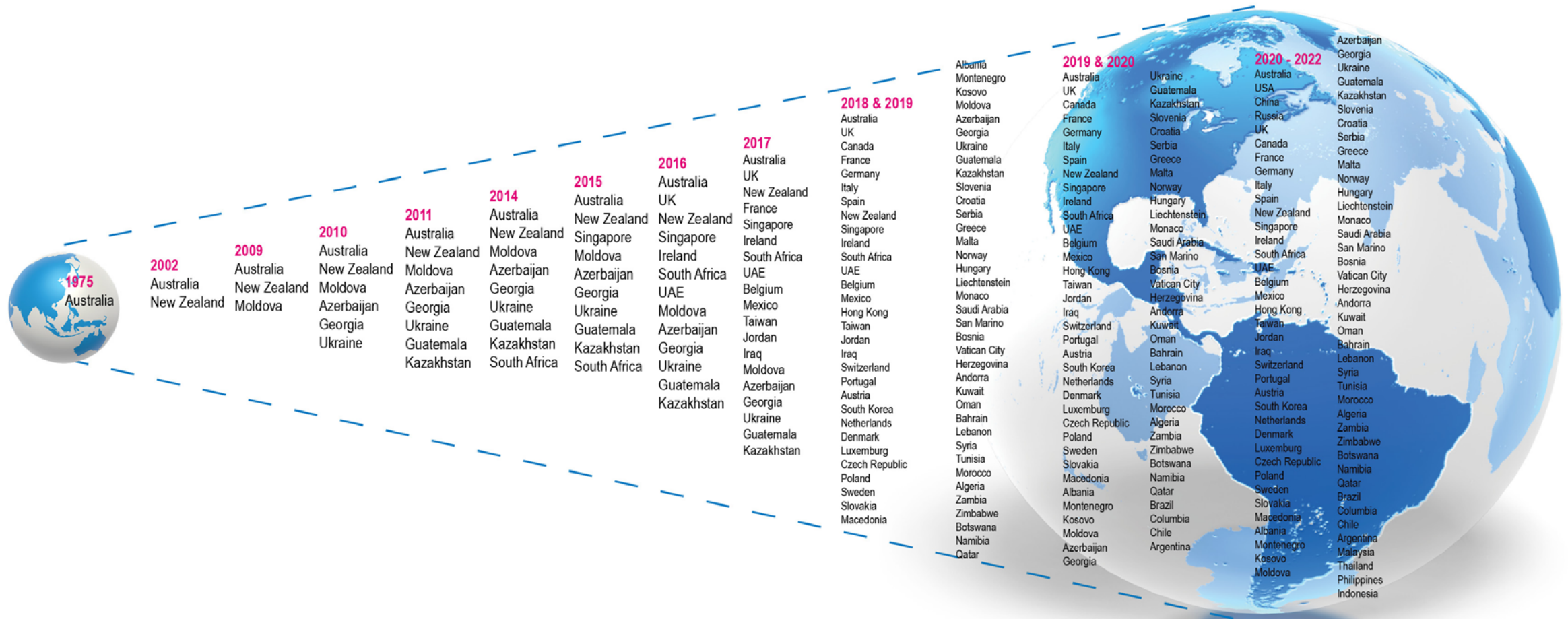
We expect Regulatory Approvals for an additional 16 countries during 2018 – Bulgaria, Germany, Italy, Spain, Norway, Sweden, Finland, Poland, Czech Republic, Slovenia, Portugal, Cyprus, Lithuania, Luxembourg, Romania and Croatia.

Sales are expected to commence during H2FY18.



# Penthrox®

## Regulatory approval for Penthrox in the rest of World



# Penthrox®

## USA

Work on getting Penthrox approved in the USA is progressing well.

We are on track to submit our IND in the next few months.

After discussions with the FDA we will request Penthrox be granted “fast track” status.

We believe the aggressive negative bias against opioids for analgesia in the USA make Penthrox a compelling alternative.

### The Washington Times

Trump directs administration to treat opioid crisis as a ‘national emergency’

### The New York Times

#### Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis

The opioid epidemic killed more than 33,000 people in 2015. What follows are stories of a national affliction that has swept the country, from cities on the West Coast to bedroom communities in the Northeast.

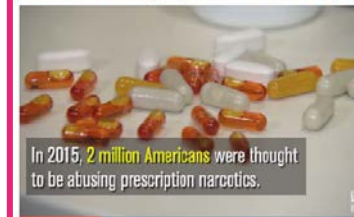
JAN. 6, 2017

### The Washington Post

Trump says opioid crisis is a national emergency, pledges more money and attention

### Los Angeles Times

The U.S. should rethink its entire approach to painkillers and the people addicted to them, panel urges



In 2015, 2 million Americans were thought to be abusing prescription narcotics.

Thousands of people who are dependent on painkillers will have to attend drug court in California next month (July 14, 2017)

### The New York Times

#### Drug Deaths in America Are Rising Faster Than Ever

By JOSH KATZ JUNE 5, 2017

New data compiled from hundreds of health agencies reveals the extent of the drug overdose epidemic last year.

AKRON, Ohio — Drug overdose deaths in 2016 most likely exceeded 59,000, the largest annual jump ever recorded in the United States, according to preliminary data compiled by The New York Times.

# Penthrox®

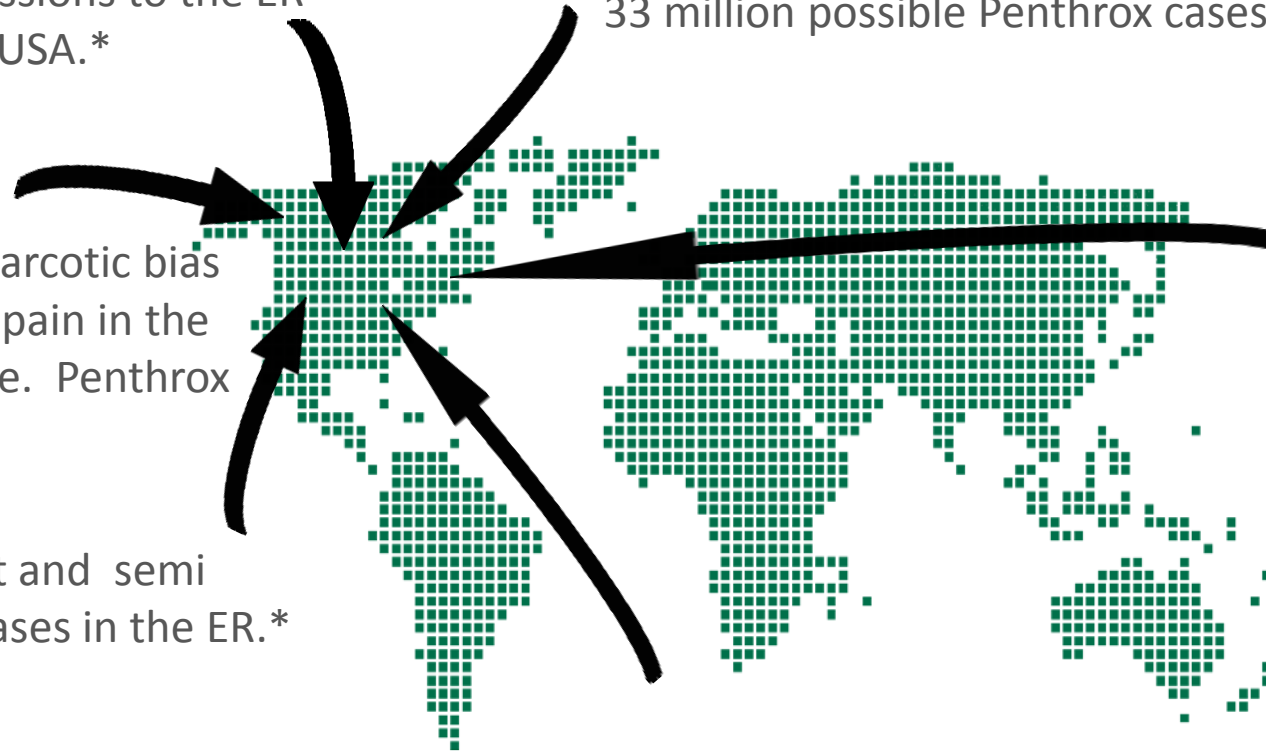
## A billion dollar opportunity in the USA

141 million admissions to the ER each year in the USA.\*

33 million possible Penthrox cases pa.\*

Significant non narcotic bias for treatment of pain in the ER and elsewhere. Penthrox is a solution.

79 million urgent and semi urgent trauma cases in the ER.\*



Additional Future Indications include:

- Minor surgical procedures
- Breakthrough pain (cancer and post operative)
- Dentistry procedures
- Cosmetics procedures

(Total estimated market \$3 billion)

Peak sales in USA (trauma) could be \$1 billion per annum.\*\*

\*National Hospital Ambulatory Medical Care Survey 2014

\*\*Bases on company estimates relating to selling price and market penetration

# Penthrox®

## Why Penthrox in the USA?

Non-narcotic trauma relief, non-addictive, safe.<sup>1</sup> Not a restricted or controlled medicine.

You can drive home and go back to work after Penthrox.<sup>2</sup>

The average time spent in the ER if you have a narcotic is 6 hours. Penthrox may be able to reduce that by more than 50%.<sup>3</sup>

Penthrox can materially improve the throughput of patients<sup>7,8</sup> in the ER because it enables better time to analgesia and less medical care and observation compared to narcotics.

Penthrox improved time to analgesia.<sup>5,6</sup>

In 2008 the average cost for an ER bed for a category 4 trauma was USD\$1298<sup>4</sup> (without medical care or medication costs).

1. Penthrox Summary of Product Characteristics (SPC), 2015

2. Nguyen et al., Journal of Gastroenterology and Hepatology, 30 (Suppl. 3): 55, 2015

3. Company estimate

4. US Agency for Healthcare Research and Quality. Emergency Room Services-Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment: 2008. Medical Expenditure Panel Survey Household Component Data.

5. Sokoloff et al. BMJ Open 2014; 4:e004288. doi:10.1136/bmjopen-2013-004288

6. Ng et al. Clinical Evaluation of Penthrox® (Methoxyflurane) and Tramadol for the Singapore Emergency Ambulance Service. SEMS. 27 Feb 2016.

7. Spruyt et al., BMJ Supportive & Palliative Care, 4(4):342-8. 2014

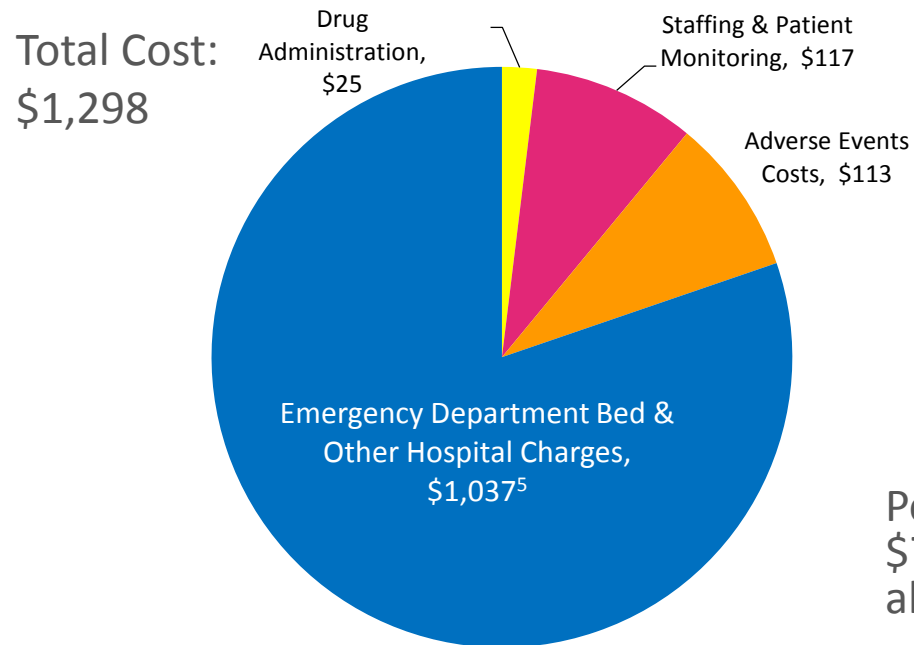
8. Nguyen et al. Endosc Int Open. 3(5): E487-93. 2015.



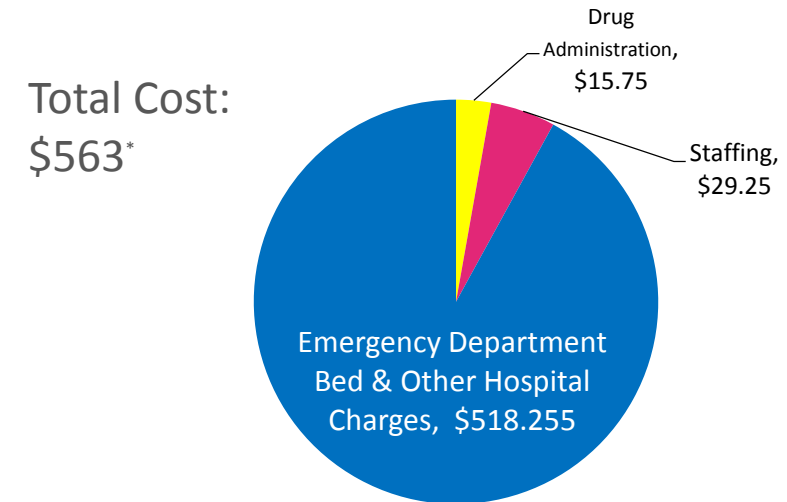
# Penthrox®

## Potential cost analysis for USA

### Estimated costs of IV Opioid treatments for acute pain



### Estimated costs of a Penthrox® treatment for acute pain\*



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.

<sup>1</sup> DIDONATO, K, et al, 2016. Intravenous Administration of Morphine In The Emergency Room Inflicts A Substantial Economic Burden In The EU5. Available from: [http://www.acerx.com/technology/publications/arx-04/Poster%20PSY45\\_06OCT2016.pdf](http://www.acerx.com/technology/publications/arx-04/Poster%20PSY45_06OCT2016.pdf)  
<sup>2</sup> PALMER, Pamela et al., 2016. Cost Of Delivering Intravenous Opioid Analgesia In Emergency Departments In The United States; AcerRx <http://www.acerx.com/technology/publications/arx-04/SPOR%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/>  
<sup>4</sup> 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 Penthrox

\*Based on company estimates

# Penthrox®

## Penthrox® clinical program for USA

2017

### IND Toxicology:

- 2 by 14 Day Repeat Dose rat and dog studies
- General validation and assay studies to support existing data

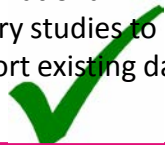


FDA meeting



### Safety Pharmacology:

- General functional Observational Battery studies to support existing data



2018

### IND Metabolism:

- General In Vitro studies to support existing data

2019

Phase I Dose ranging  
Healthy Volunteer Study



Phase I IND  
submission to  
FDA



End of Phase II  
FDA meeting



Phase III IND  
Amendment  
submission  
to FDA



Paediatric  
Submission  
to FDA

2020

Additional Phase III to  
support existing Phase III  
studies and data



NDA submission  
to FDA



Pre NDA  
meeting  
with FDA



FDA Approval



Launch In USA

# Penthrox®

## New manufacturing technology

Construction of MVP's new manufacturing facility was completed on time and on budget.

The TGA issued the "Licence to Manufacture Pharmaceuticals" in February 2018.

We expect GMP certificate and global regulatory approvals during H2FY18.

The new facility will deliver a quantum shift in the manufacturing of Penthrox in terms of cost, quality, consistency and capacity.



# Future of MVP

## New manufacturing technology

Our ambition is to develop new patentable manufacturing technologies that will deliver cost saving, improved quality, consistency and safety standards for existing and new pharmaceutical products.

We have successfully completed the Stage II small scale production run for Lidocaine.

We estimate the global sales market for Lidocaine is USD \$3.5billion.

We will continue work to develop and innovate manufacturing technologies to make pharmaceutical products and create intellectual property.

We have a number of other drug products we are working on.



# Future of Pentrox®

## Clinical development program

Additional clinical trials and studies are planned for FY18 (and beyond) which will broaden the indications for use of Pentrox®. Our longer term ambition is to extend the use of Pentrox® into:

- Acute Pain / Minor Surgical Procedures (market size estimate \$2billion);
- Acute Anxiety – replacement therapy for SSRI's or Benzo's;
- Breakthrough Pain / Repeat Use (market size estimate \$6billion); and ultimately
- Home Use / First aid box.



# Penthrox®

## Outlook

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

- obtain approval to sell Penthrox in 37 countries throughout Europe and in a number of countries outside the EU. We expect to make first sales during H2FY18 into a few of these new countries. However, we expect more material sales growth to commence during FY19 and beyond as the various approvals at hospital level are obtained and the use of Penthrox becomes “mainstream”;
- conclude additional distribution partnership for new countries, including USA, China, Asia; 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.

# Respiratory and Medical Devices

# Respiratory Division

## H1FY18

Sales of Respiratory Devices in the USA grew 115%.

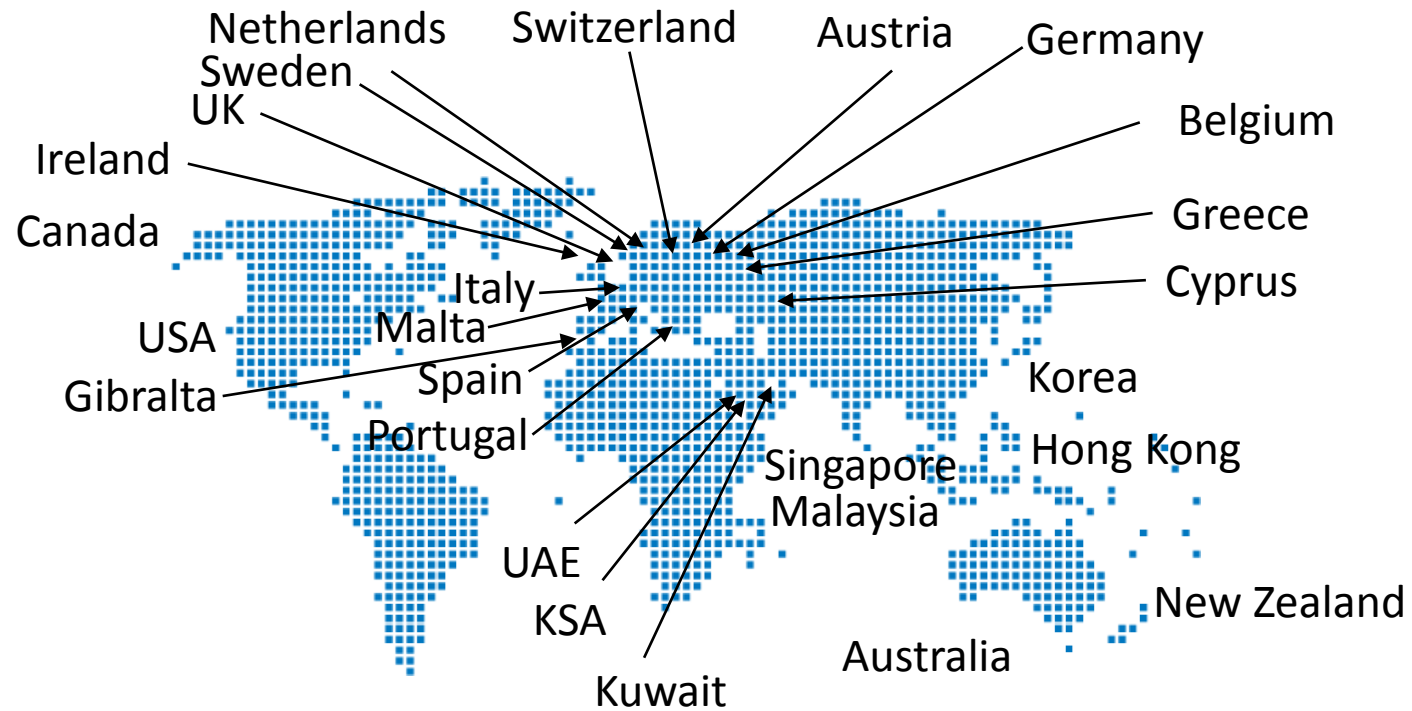
We now have almost 13,000 pharmacies available to sell our product across the USA.

Sales of Respiratory Devices in the UK and Europe grew 21%.

Sales of Breath-A-Tech in Australia declined on a comparative basis because there were no new product launches in H1FY18.

# Respiratory Devices

## Sold in more than 20 countries



# Respiratory Devices

## USA

We have access to 13,000 pharmacies in the USA.

We are core range for Walgreens, Walmart, Sam's, Kmart and others.

There are 67,000 pharmacies in the USA.

The response to our product offering in the USA has been excellent.

We are working on additional pharmacy chain deals.

We are now adding focus to GPO Hospital contracts.

We expect sales growth from the USA business.

The Walgreens logo, featuring the word "Walgreens" in a red, cursive script font.The Walmart logo, featuring the word "Walmart" in blue, the yellow six-pointed star icon, and the tagline "Save money. Live better." in blue.The Costco logo, featuring the word "COSTCO" in red, bold, sans-serif capital letters with three horizontal blue lines underneath.The Kmart logo, featuring a large red "K" above the word "kmart." in red, lowercase letters.The Price Chopper Pharmacy logo, featuring a red shopping cart icon above the words "Price Chopper" in blue, with "FULL SERVICE PHARMACY" in red and blue below.The Sam's Club logo, featuring a blue diamond shape with a green and yellow stylized "S" inside, and the words "Sam's CLUB" in white.The Independent Pharmacy Cooperative logo, featuring a green and blue stylized "IPC" icon next to the words "INDEPENDENT PHARMACY COOPERATIVE" in green and blue.



# 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 20 countries.

Over the next 12 months we expect to:

- obtain additional partnership deals in the USA and deliver sales growth;
- obtain additional partnership deals in other countries around the world;
- consolidate our position as the largest supplier of Respiratory Devices in Australia;
- introduce new products; and
- continue to drive down costs and increase the range and quality of our products.

# MVP Corporate

# Penthrox®

## H1FY 18

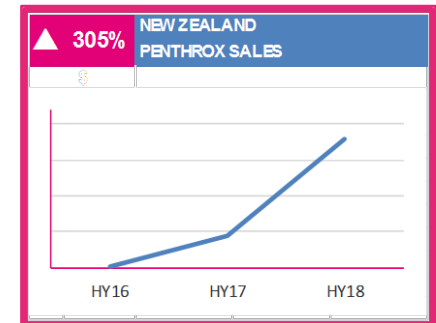
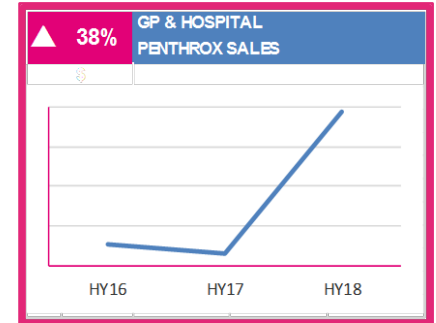
Sales of Penthrox to Ambulance in Australia remain strong.

Sales of Penthrox to Hospitals and GP grew 38%.

Sales of Penthrox to NZ Ambulance grew 305% as a result of all NZ Ambulances adopting Penthrox as first line sole analgesia.

Delivered repeat order for UK and Belgium.

No orders from France or Qatar.



# Financial Summary

During H1 MVP:

- Delivered gross revenue of \$8.0m down 3%
- Sales of Respiratory Devices across the world fell 3% (mainly timing related).
- Strong Gross Margins - increasing from 69% to 72%.
- Moderate expense increases attributed to:
  - increased pharmacovigilance costs as the geographical footprint for Pentrox is expanded;
  - staff increases within Quality, Regulatory and Production; and
  - marketing fee increases due to strong growth in Pentrox sales to New Zealand and also within Australian GP's and Hospitals.
- Delivered Net Profit after tax of \$0.13m.

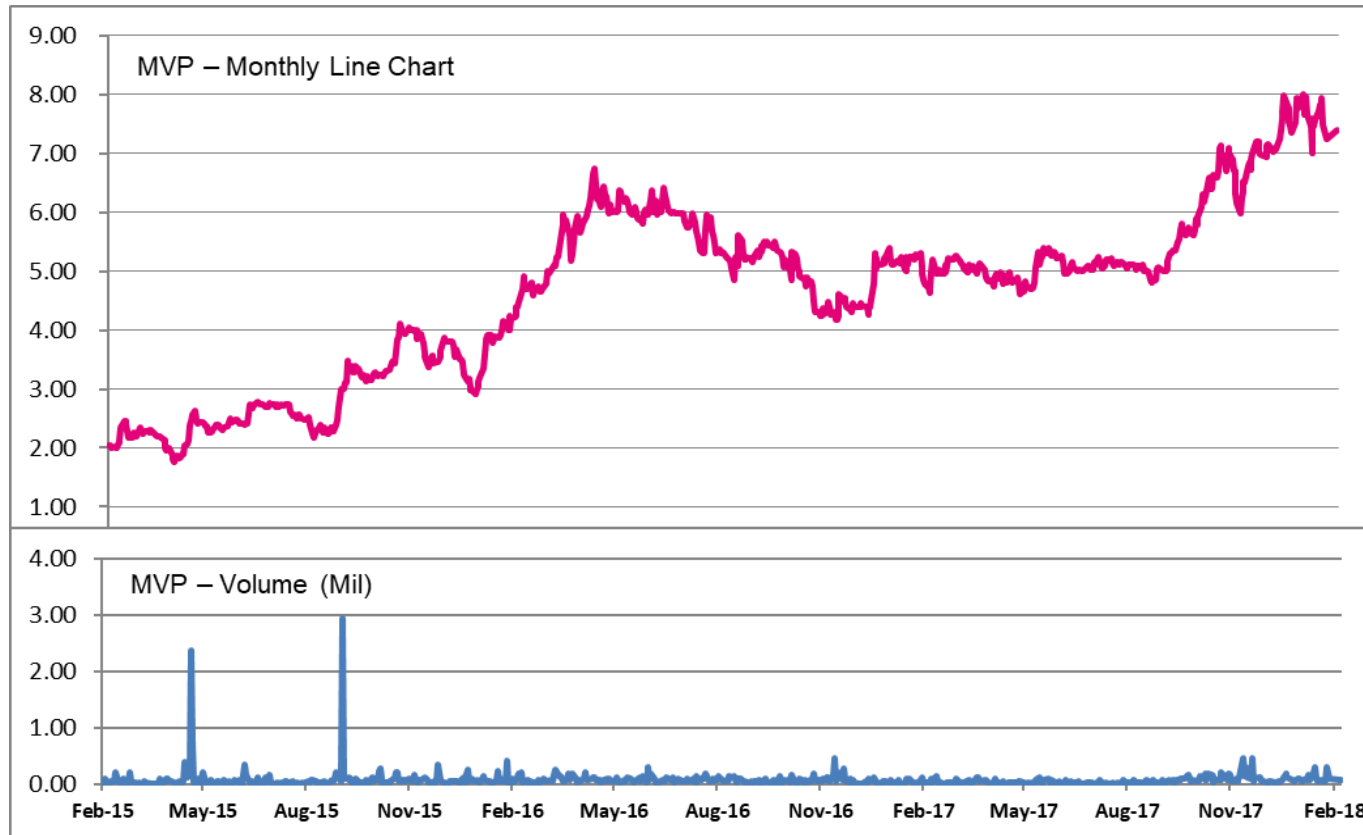
# Financial Summary

During H1FY18 MVP:

- Declared a 2 cent fully franked dividend (DRP with a 5% discount again offered).
- Drew down \$3.5m of the \$11m Debt Funding facility.
- Invested:
  - \$2.1m into USA regulatory program;
  - a further \$1.2m into other clinical trials and Pentrox regulatory approvals;
  - \$1.3m into equipment for the Scoresby Manufacturing facility;
  - \$0.3m into the CSIRO project; and
  - \$0.6m in dividends (net of DRP).

# MDI Investor Dashboard (ASX: MVP)

## Historical Stock Chart (3yr)



## Current Stock Price

**7.50** ▲ 0.110 (1.49%)  
21 Feb, 10:18am

Day High 7.500

Day Low 7.420

Open 7.420

Prev. Close 7.390

Avg. Volume 106,566

52 Wk. High 8.070 (12 Jan 2018)

52 Wk. Low 4.590 (1 Mar 2017)

Mkt. Cap 443.23 (Mil)



# Intellectual Property

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

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

- 7 Pentrox Inhaler patents;
- 5 Respiratory patents;
- 1 manufacturing patent; and
- numerous trademark filings to mirror global growth.

MVP 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.

# MVP Corporate Overview

**David Williams**



**Non-Executive Chairman**

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

**Dr Harry Oxe**



**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 Ereno 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**



**Chief Financial Officer & Company Secretary**

**Glenn Gilbert**



**Head, Sales & Marketing**

**Scott Courtney**



**Director of Operations & Research**

**Chi Wai Ng**



**Associate Director – Regulatory Affairs**

**Sue Anne Yee**



**Associate Director – Medical Affairs**

**Jake Golding**



**Quality Assurance & Validation Manager**

# Contact Details

## HEAD OFFICE

4 Caribbean Drive

Scoresby, Victoria, Australia, 3179

Tel: +61 3 9547 1888

Fax: +61 3 9547 0262

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

