

# September 2018



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10. loss of key executives or other employees; and
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# Vision

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

**Our aim is to:**

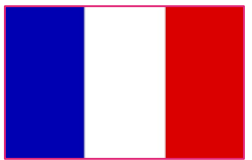
1. Provide unique and innovative products to assist our customers in the management of acute pain, trauma and procedural pain and to be the market leader globally.
2. Provide unique and innovative products to assist our customers in the management and delivery of respiratory medications, resuscitation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

# Penthrox<sup>®</sup>

# Penthrox®

## Penthrox is gaining global acceptance

Penthrox is currently registered in more than 30 countries and is expected to be sold into approximately 70 countries over the coming years.



### Approved in 25 countries in the last 2 years:

- Austria
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- Germany
- Iceland
- Italy
- Latvia
- Lithuania
- Norway
- Poland
- Portugal
- Romania
- Slovenia
- Slovak Republic
- Spain
- Sweden
- Switzerland
- Canada
- Mexico
- Taiwan

### Expected regulatory approvals in FY19 and FY20:

- Luxembourg
- Hong Kong
- Russia
- Qatar
- Saudi Arabia
- Jordan
- Syria
- Namibia
- Zambia
- Zimbabwe
- Morocco
- Oman
- Lebanon
- Bahrain
- Kuwait



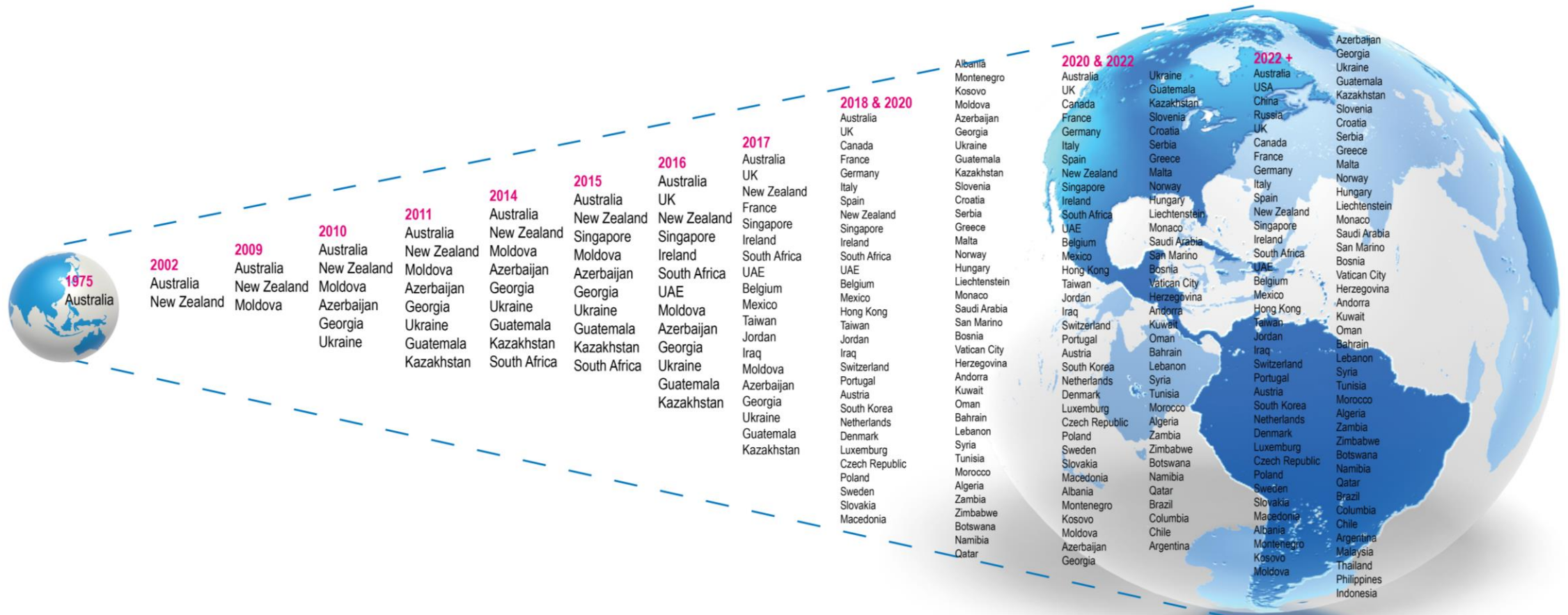
## Roll out in Europe commenced

Sales orders for most remaining countries in Europe expected in FY19.



# Penthrox®

## Regulatory approval for Penthrox in the rest of World





# Penthrox®

## UK and Ireland update

“In market” sales in the UK and Ireland grew 53% in H2FY18 vs H1FY18.

There are 103 hospital formulary approvals.

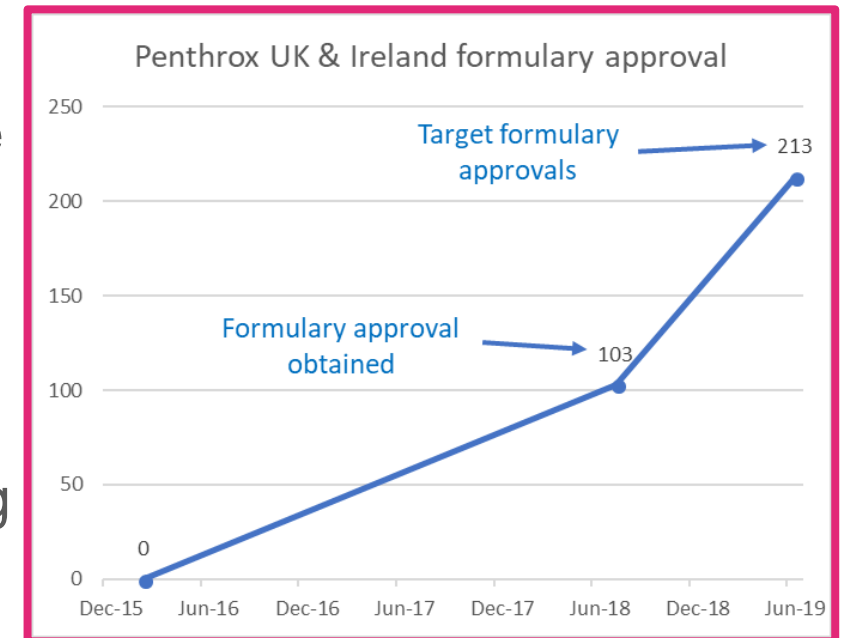
All 103 hospitals are ordering on a regular basis.

Penthrox has been sold into 408 hospitals, clinics, ambulance services and pharmacies in the UK and Ireland so far.

200 of these customers have re-ordered Penthrox.

Penthrox is currently listed in 7 Major Trauma Centres.

There are 6 UK and Ireland Ambulance services using/trialling Penthrox and 3 more committed to start evaluation in the UK.





# Penthrox®

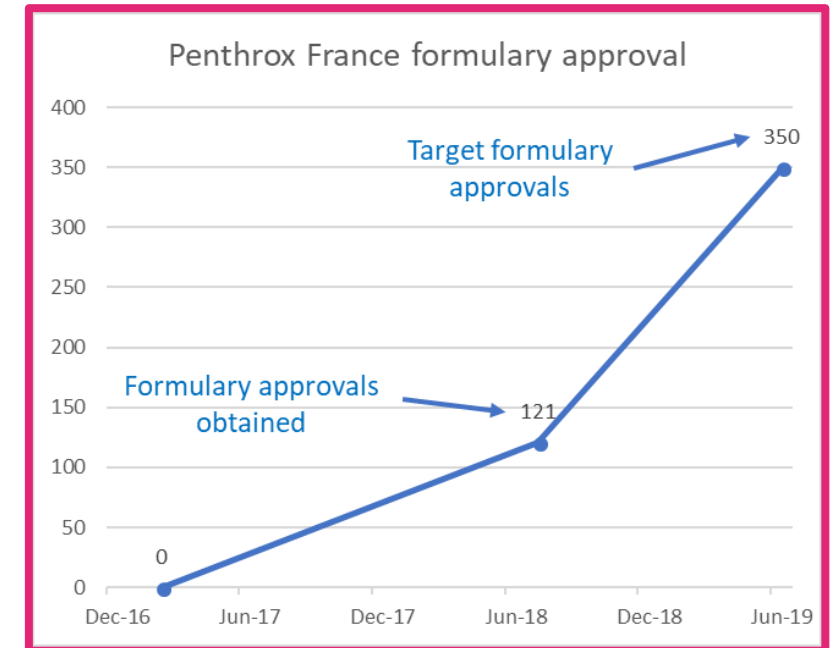
## France update

Our partner is making excellent progress in France.

In market sales in France grew 66% Q3FY18.

In summary:

- 185 formulary applications have been submitted.
- 121 formularies have approved Penthrox in France.
- 64 formulary applications are pending.
- 256 Penthrox customers.
- 15 new clients by month since the launch.



# Penthrox®

## USA Update

MDI submitted an Investigational New Drug (IND) application to the FDA in July 2018.

The FDA response was to ask for a Clinical Hold until the following 7 questions were answered. In summary MVP is required to:

1. Identify an appropriate patient population for its suggested Phase 1 Study for whom the risk/benefit of Penthrox would be reasonable.
2. Provide additional information and justification for the rare occurrence of idiosyncratic hepatotoxicity.
3. Provide clarification around a chloroform impurity which is a process element in the manufacturing of methoxyflurane.
4. Provide clarification and validation re the “Instructions For Use” material for the Penthrox device (whistle).
5. Provide additional information about the variability of concentrations of the administration of methoxyflurane from closing the dilutor hole in the whistle.
6. Provide additional testing to demonstrate the absorption capacity of the AC Chamber.
7. Provide additional information about the performance characteristics of the valve system contained within the Penthrox device (whistle).

We are currently consulting with our scientific team, USA and EU advisors on the development program needed to satisfy the FDA's requests. These issues are required to be answered in full at which time the Phase 1 study in the USA may be granted approval to proceed.

# Penthrox®

## USA Update

In addition, the FDA has advised of other issues which do not form part of its “Clinical Hold” Statement. The issues to be addressed include: -

1. The inadvertent exposure of methoxyflurane to healthcare professionals.
2. Minor amendments to the labelling suggested in our application.
3. Additional analytical tests for the characterisation of methoxyflurane delivered from the whistle, which can be used for both release and stability control testing.
4. Amendments to acceptance criteria of impurities in the finished product of methoxyflurane.
5. Additional biocompatibility testing for the whistle itself.

# Penthrox®

## USA Update

MVP believes it can satisfactorily answer all the FDA queries.

- We are currently completing a Phase 1 study in Europe which includes 56 patients across 7 cohorts. This is a bigger and wider study than the one proposed for the FDA.
- We are currently completing a Post Authorisation Study in Europe which includes 2000 patients and forms an important safety data base.
- We have completed a Post Authorisation Survey in Europe on our “Instruction For Use Material” of 500 Healthcare Professionals and patients.
- We will have safety data available from our Paediatric trial in Europe.
- Our partner has recently completed a Phase III Minor Surgical Colonoscopy study in Europe.
- We have years of safety data covering millions of patients.

# 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

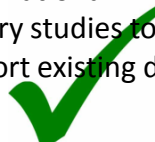


FDA meeting



### Safety Pharmacology:

- General functional Observational Battery studies to support existing data



2018

### IND Metabolism:

- General In Vitro studies to support existing data



Ongoing discussions

Phase I Dose ranging  
Healthy Volunteer Study

Phase I IND  
submission to  
FDA

End of Phase II  
FDA meeting

2019

Additional Phase III to  
support existing Phase III  
studies and data

Phase III IND  
Amendment  
submission  
to FDA



Paediatric  
Submission  
to FDA

Pre NDA  
meeting  
with FDA

2020

NDA submission  
to FDA

FDA Approval

Launch In USA

# Penthrox®

## Clinical Program

MVP continues to invest heavily in developing the clinical profile and indications for use of Penthrox.

Plans have begun for “prescription take home” and “repeat use” studies.

The purpose of our clinical program is to accelerate the adoption of Penthrox globally.

Our FY19 investment is expected to be almost \$12 million (\$7 million allocated to USA).

The following slide is a summary of the clinical programs underway, completed or planned.

# Penthrox<sup>®</sup>

## Clinical Trial Pipeline





# 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:

- sell Penthrox in 37 countries. We expect to make first sales during FY19 for most, if not all, of these new countries. However, we expect more material sales growth to commence during late FY19 and FY20 and beyond as the various approvals at hospital level are obtained and the use of Penthrox becomes “mainstream”;
- conclude additional distribution partnership for China;
- conclude additional distribution partnerships for new countries; including USA and 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

## FY18

Sales of Respiratory Devices in the USA grew year on year.

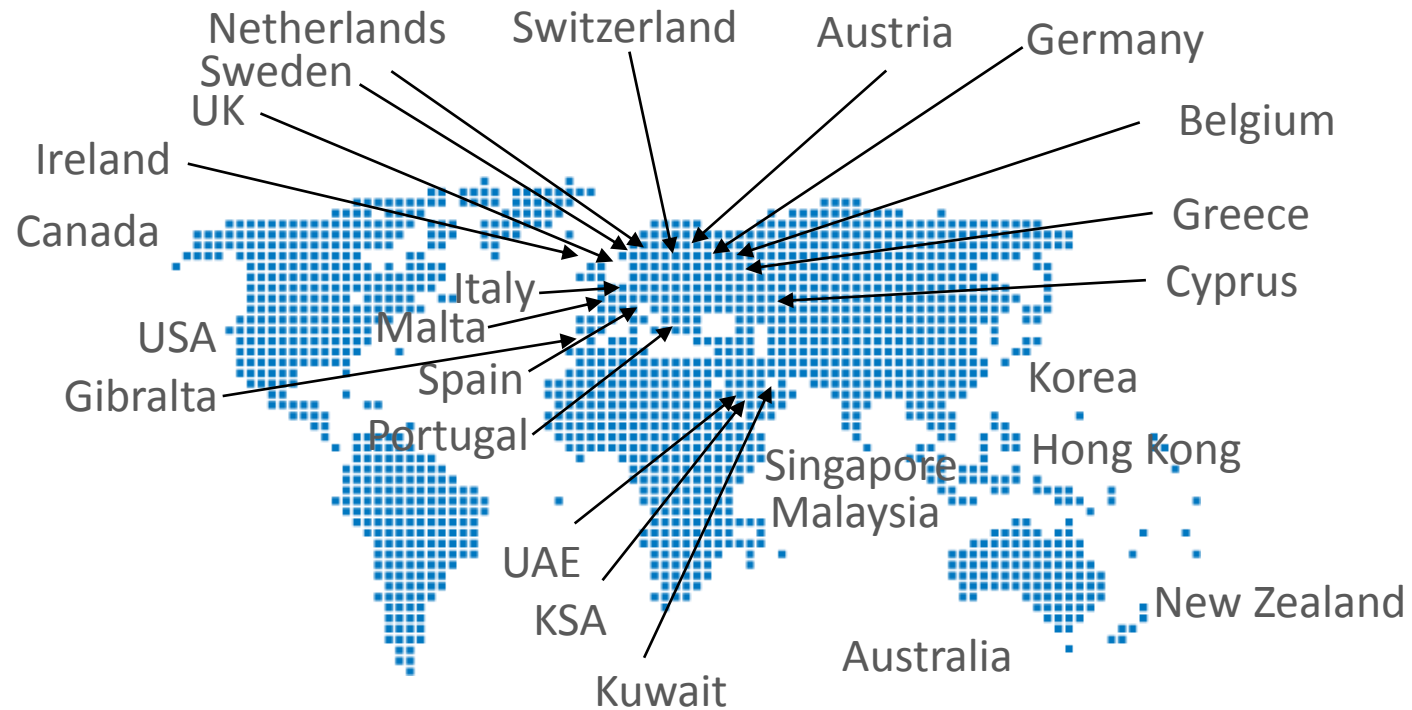
Underlying sales “off the shelf” grew strongly.

Sales of Respiratory Devices in the UK and Europe grew 35%.

Sales of Breath-A-Tech in Australia declined on a comparative basis because there were no new product launches in FY18 and stock cycling work in market work through.

# Respiratory Devices

Sold in 26 countries



# Respiratory Devices

## USA

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

We have completed ranging deals with national groups; Walgreens, Walmart, Sam's Club, Costco and Kmart plus many regional groups.

There are approximately over 65,000 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 the institutional channel; IDNs and GPOs.

We expect continued sales growth from the USA business.



# 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 26 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.

# 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.

MVP maintains a number of valuable Trade Secrets.

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



# Continuous Flow

A new way to manufacture API



# Global breakthrough in API manufacturing technology

Medical Developments International (MDI) has worked with Australia's Commonwealth Scientific & Industrial Research Organisation "CSIRO" for almost 10 years on this project.

CSIRO is a world leading scientific academy backed by the Australian governments with approximately 5000 scientists.

Together with MDI, CSIRO has a team of dedicated scientists working to develop global technology to manufacture small molecule pharmaceuticals.

In 2018 we achieved a number of global technology breakthroughs.

We intend for our Continuous Flow "CF" process API manufacturing technologies to be covered by Patents (applications and pending) or kept as Trade Secrets depending on the market.

# Technology

Our CF technology delivers:-

- Increased yields
- Increased purity
- Better control over process
- Increased productivity
- Lower cost of production
- Lower capex
- Less manpower
- Smaller footprint

CF has the capacity to reduce the cost of API manufacturing by more than 50% compared to batch processing. In some cases, the savings will be significantly greater.

# Technology

## Our own API - Methoxyflurane

### Benefits of methoxyflurane manufacture under Continuous Flow vs Batch Process

1. Better overall process control
  - 40% better reaction conversion
  - 90% better overall yield conversion
  - Significantly reduced impurity profile
2. Fast scale-up capability
  - Increase output up x10+ on same footprint
3. Safer Environment
  - Reduced manual handling
  - Controlled energetic process (exotherm)

# Technology

## Our own API - Methoxyflurane

### Batch Process

2000L/pa at existing site (single shift)

4000L/pa at existing site (double shifts + CapEx)

>4000L/pa = new manufacturing site + significant CapEx

### Continuous Flow Process

10,000L/pa at existing site (300 mL CF reactor - single shift)

20,000L/pa at existing site (600 ml CF reactor – single shift)

40,000L/pa at existing site (1.2 Ltr CF reactor – single shift)

# Technology

## Future API technologies

MDI is developing its core flow technology into several generic APIs currently manufactured under standard batch processing.

Examples of this are:

- **LIDOCAINE (USP):**

Estimated USD \$3.5 billion global sales

- **DICHLUFENAC:**

Estimated USD \$6.0 billion global sales

- **SALBUTAMOL:**

Estimated USD \$6.0 billion global sales

# Technology

## Future API technologies

- **ISO-/DES-/SEVOFLURANE**

Significant improvements in handling highly toxic & corrosive Fluoride intermediates under safe flow conditions. Estimated USA \$3 billion global sales market

- **CANNABIDIOL**

Early stage development in producing CBD in high purity (>98%)



# Product Development

## Update



# Penthrox<sup>®</sup> Inhaler Developments

## *Selfie Inhaler*

The Penthrox<sup>®</sup> Selfie inhaler is the next generation of inhalers under development at MDI.

It is a fully integrated pain relief system which delivers 3ml of Penthrox<sup>®</sup> to patients in a quick and easy manner.

The Selfie inhaler will be suitable for patients in emergency, clinical, military and may lead to further development of home use devices.

The Selfie system is undergoing initial trials and production is planned for launch in 2020.

MVP plan to invest up to \$5m in plant, equipment and production facilities to cater and promote the global expansion of Penthrox.



# Penthrox<sup>®</sup> Inhaler Developments

## *Selfie Inhaler*

When pain relief is required the Health Care Professional:

- removes the lock out tab then
- pushes down the plunger to activate the inhaler
- patient then breathes through the mouthpiece

Initial testing indicates the methoxyflurane delivery from the Selfie inhaler is comparable to the current Green Whistle which will make global registration easier.



# MVP Corporate

# Financial Summary

## Summary of Capital Raise

In August 2018 MVP raised \$17 million in a placement to institutional investors at \$4.00 per share.

- 69% went to overseas institutions.
- 41% of the issue went to new shareholders.

The Shareholder Purchase Plan to issue a maximum of 1,250,000 shares at \$4.00 closes on 11 September. It may have to be scaled back depending on demand.

During the year MVP declared two fully franked dividends of \$0.02 cents per share and issued 196,916 shares as part of the DRP.

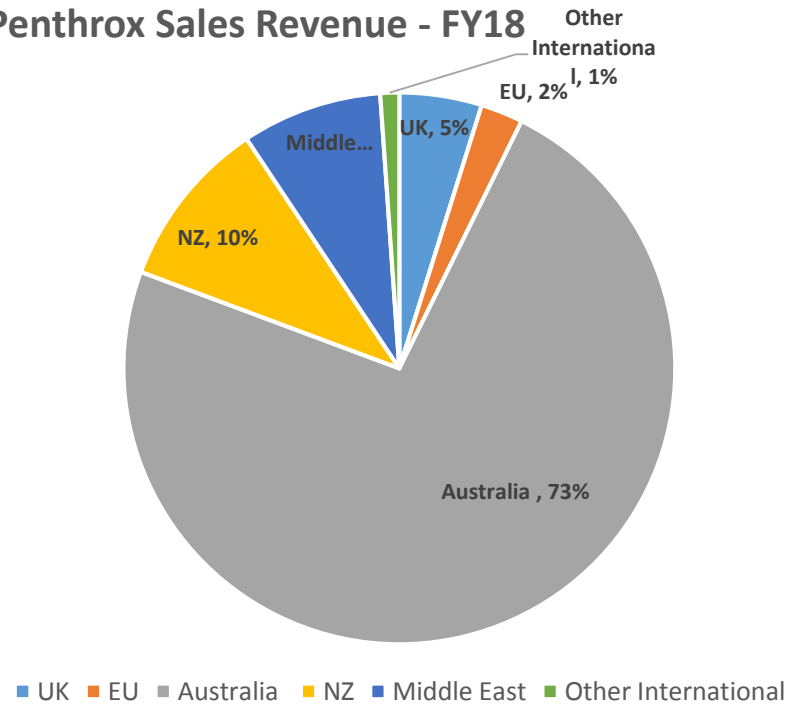
There is strong global support of MVP and Penthrox.

# Financial Summary

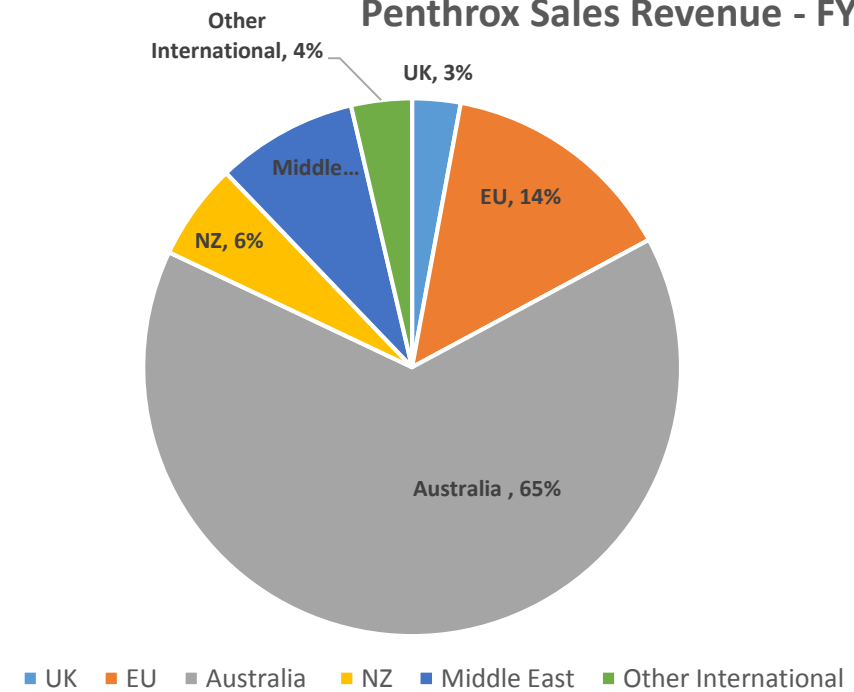
## Breakdown of sales revenue

MVP is still deriving most of its revenue from Australia. That will change beginning FY19.

Pentrox Sales Revenue - FY18



Pentrox Sales Revenue - FY17

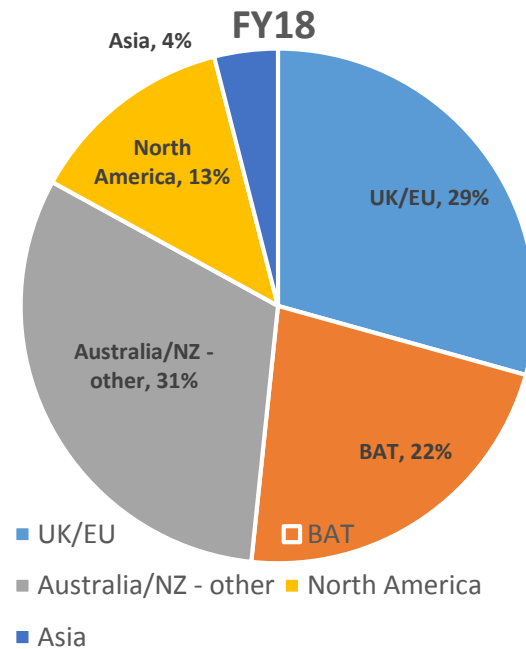


# Financial Summary

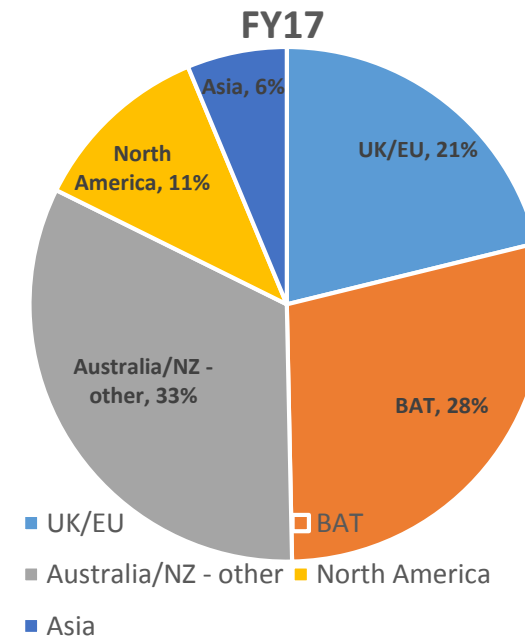
## Breakdown of sales revenue

We expect revenue generated from North America and Europe will become a significant driver for growth.

Medical Devices Sales Revenue -



Medical Devices Sales Revenue -

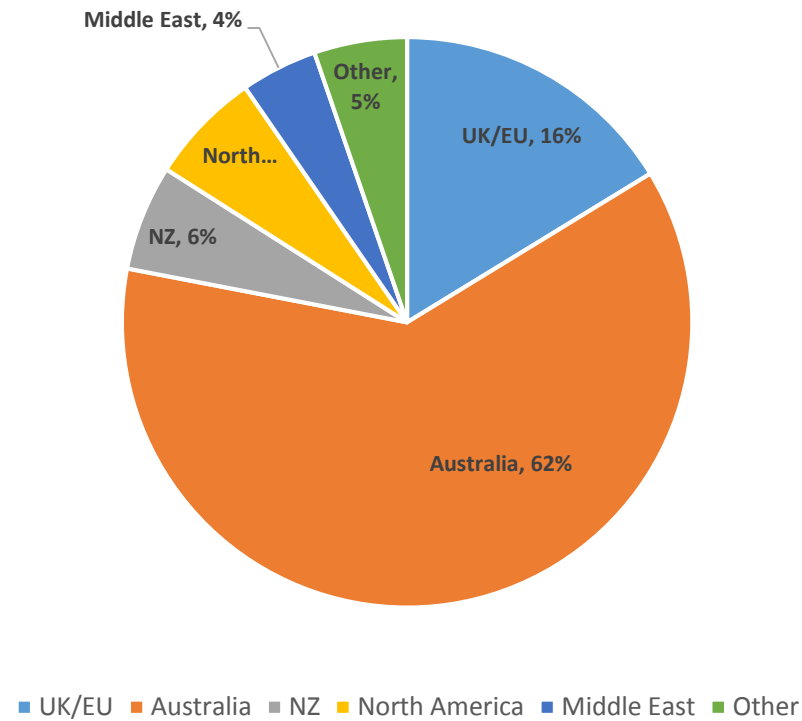




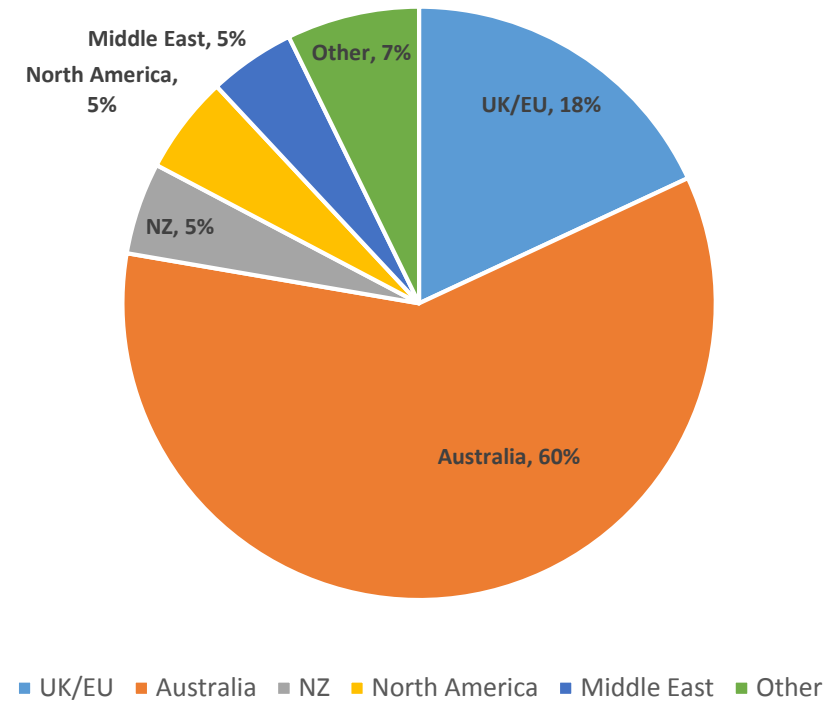
# Financial Summary

## Breakdown of sales revenue

Geographical Sales Revenue - FY18



Geographical Sales Revenue - FY17



# Financial Summary

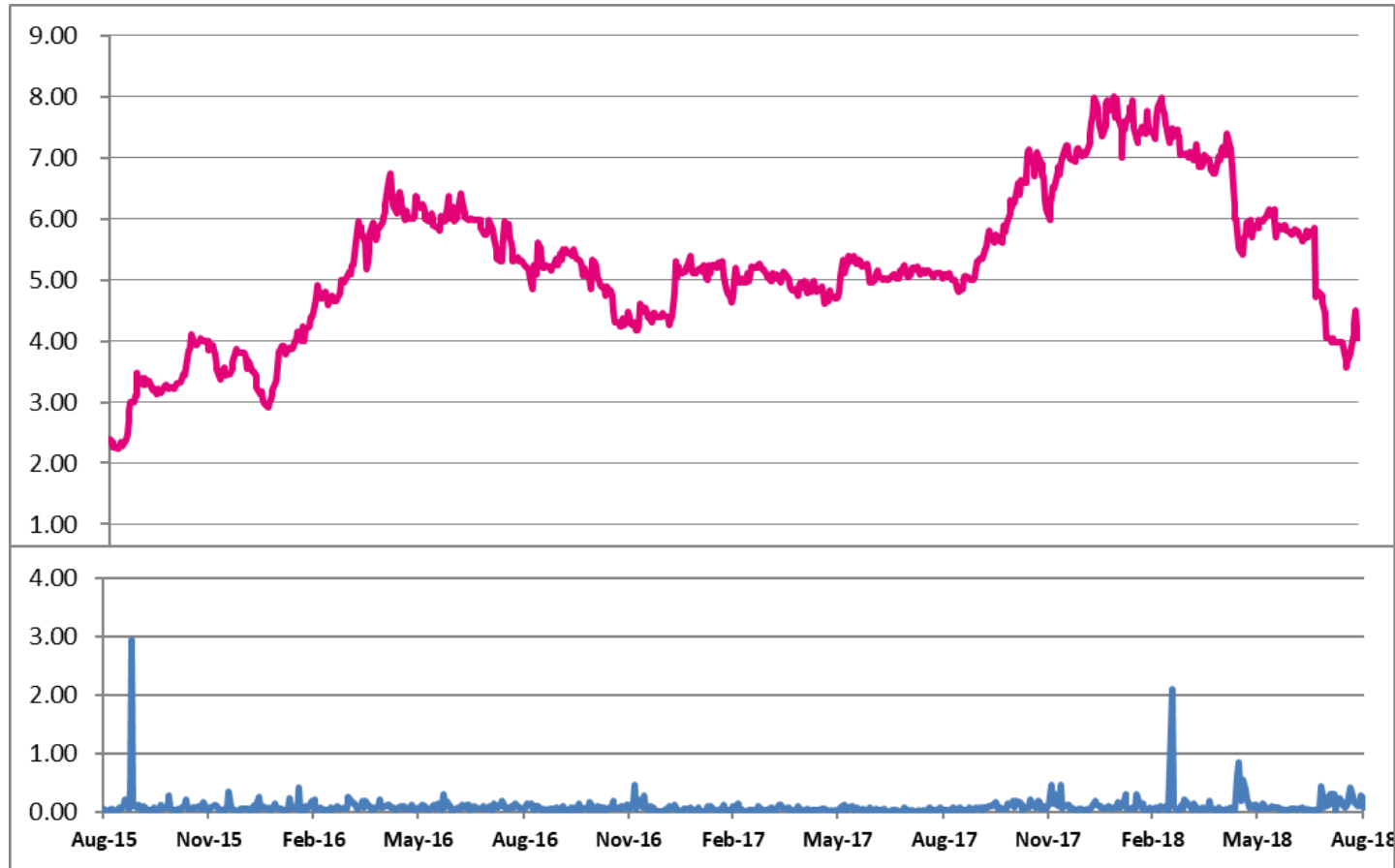
## Cash

For the FY18 Year, MVP made the following cash investments:

- \$3.7m into USA regulatory program;
- \$2.5m into other clinical trials and Pentrox regulatory approvals;
- \$0.9m in a European Phase I PK Study with our partner;
- \$2.0m into equipment for the Scoresby Manufacturing facility;
- \$0.8 into the CSIRO project; and
- \$1.3m in dividends (net of DRP).

# MDI Investor Dashboard (ASX: MVP)

## Historical Stock Chart (3yr)



## Current Stock Price

**4.15** ▲ 0.110 (2.723%)  
3 Sep, 3:16pm

Day High 4.190

Day Low 4.070

Open 4.070

Prev. Close 4.040

Avg. Volume 131,929

52 Wk. High 8.070 (12 Jan 2018)

52 Wk. Low 3.560 (21 Aug 2018)

Mkt. Cap 256.23 (Mil)

# MVP 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**



**Chief Financial Officer & Company Secretary**

**Scott Courtney**



**Director of Research & Operations**

**Michelle Bradney**



**Head of Medical Affairs**

**Chi Wai Ng**



**Head of Regulatory Affairs**

**Jake Golding**



**Quality Assurance & Validation Manager**

**Matthew Golden**



**Business Unit Manager – Penthrox**

**Thomas Materia**



**Business Unit Manager – Medical Devices**

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