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2. legislative and regulatory developments and economic conditions;
3. delay or inability in obtaining regulatory approvals or bringing products to market;
4. fluctuations in currency exchange rates and general financial market conditions;
5. uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6. increased government pricing pressures;
7. interruptions in production;
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9. litigation;
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.
3. Develop world leading intellectual property using continuous flow technology.

# Penthrox<sup>®</sup>

# Penthrox®

A world class opportunity

## Penthrox®

- Market Leader for trauma pain
- Opiate sparing, fast-acting inhalational analgesic
- 85% of patients reach clinical analgesia within 6-10 breaths<sup>1</sup>
- Is a solution to a significant unmet clinical need
- Demonstrated safety and efficacy profile for 30+ years
- Manufactured in Australia



<sup>1</sup> Coffey (2014)- STOP!: A Randomised, Double-blind, Placebo-controlled Study Of The Efficacy & Safety Of Methoxyflurane For The Treatment Of Acute Pain



# Penthrox®

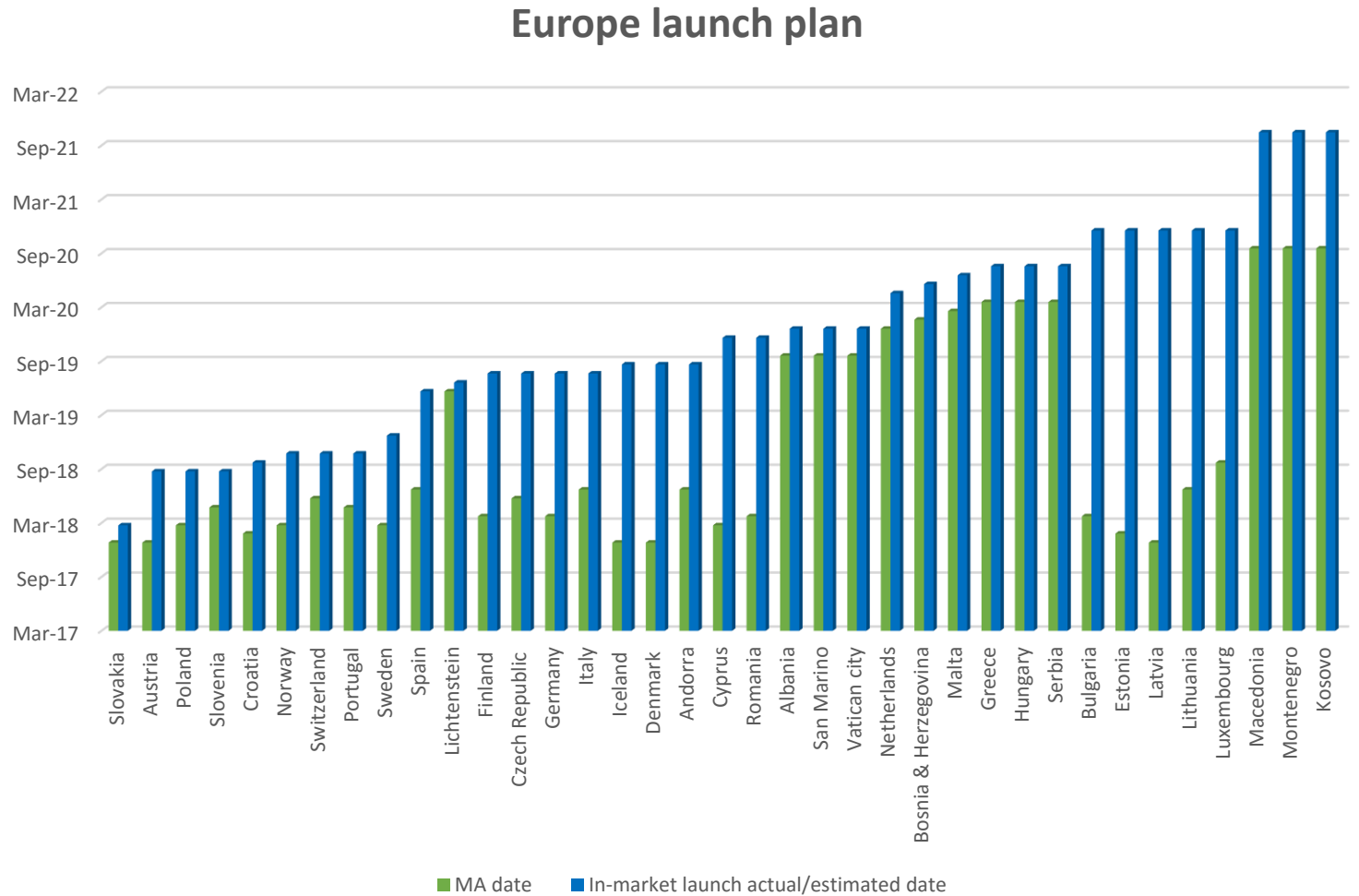
## European Expansion Plans

In addition to the UK, Ireland, France and Belgium, MVP has launched Penthrox in 9 of the 37 countries recently approved (or in the process of approval)

MVP still has another 28 countries to launch Penthrox; including Germany, Italy and Spain.

Regulatory variations have caused the delay in Penthrox launch in the majority of European markets.

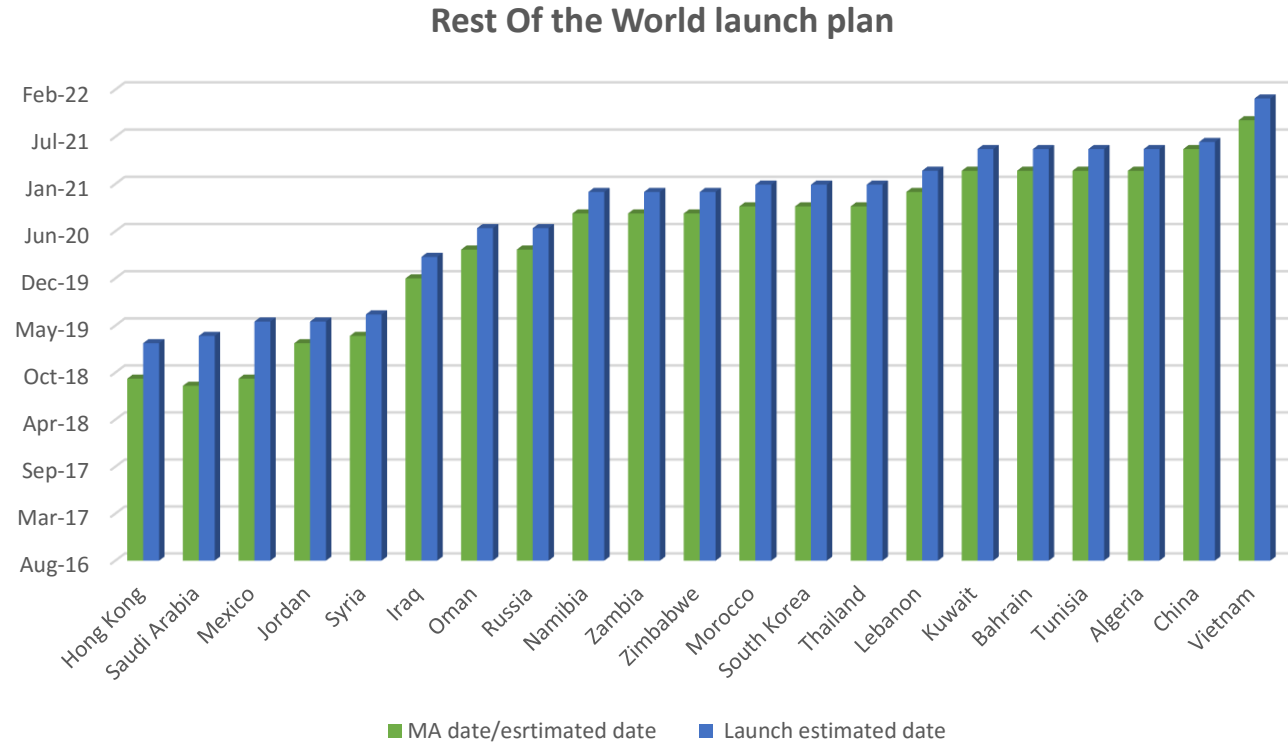
Significant sales growth is expected in FY20 and beyond.



# Penthrox®

## Rest of World Expansion Plans

In addition to the 37 countries in Europe, MVP is working towards approval and to launch Penthrox in another 22 countries including China, Russia and the USA<sub>1</sub>

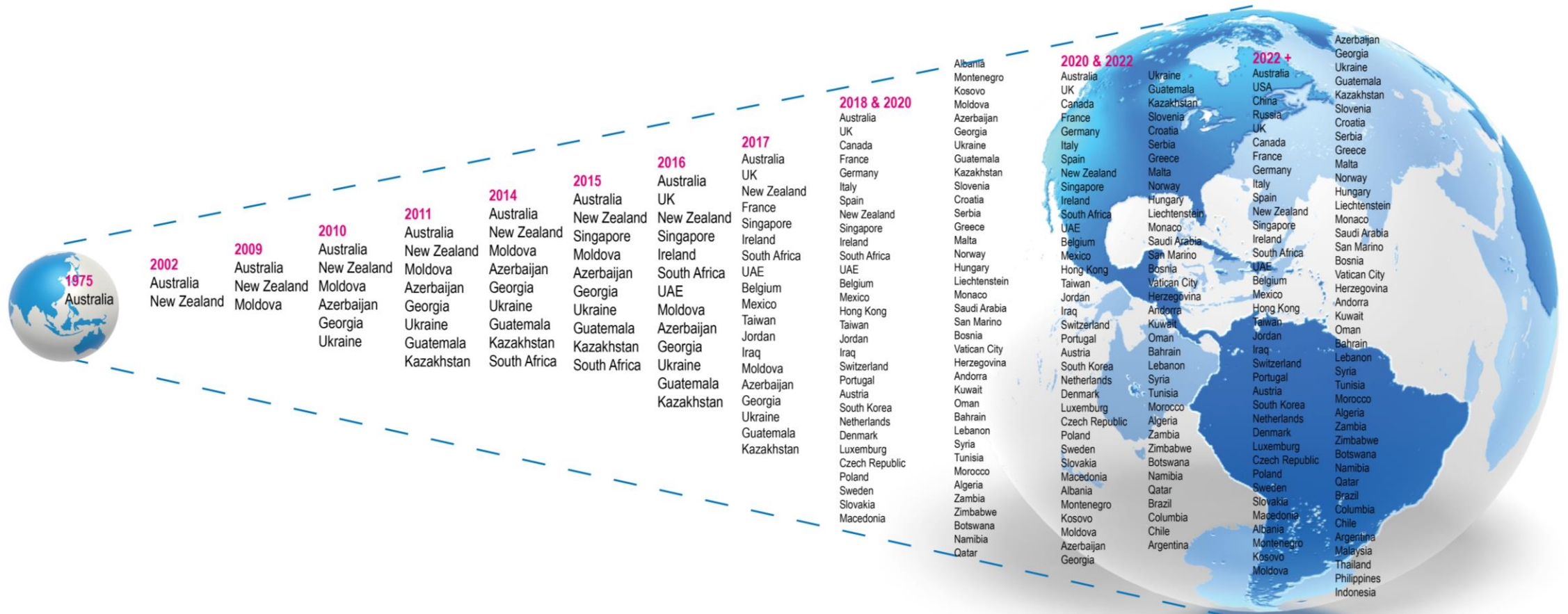


1: Subject to each country's Regulatory Agencies approval



# Penthrox<sup>®</sup>

## Penthrox global expansion plans



# Penthrox®

## UK and Ireland update

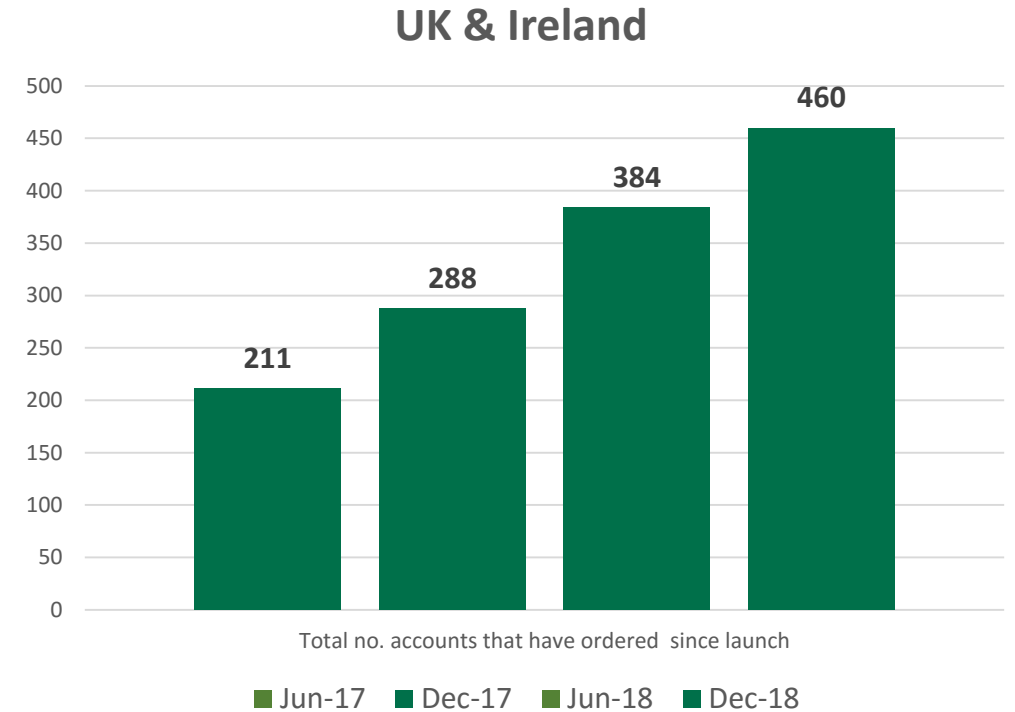
“In market” sales in the UK grew 96% in the current half year compared to the first half of 2018.

“In market” sales in Ireland grew 30% in H2 of 2018 vs H1 of 2018.

Focus has shifted from developing Hospital Formulary approvals to new customers and sales.

Penthrox has been sold into 460 hospitals, clinics, ambulance services and pharmacies in the UK and Ireland so far.

Penthrox is currently listed in 7 Major Trauma Centres.



# Penthrox<sup>®</sup>

## UK and Ireland Ambulance Service Updates

Ambulance Service Updates	Status	Expected Launch
National Ireland Ambulance Service	Approved (using)	✓
East of England Ambulance Service	Approved	Q4FY19
Scottish Ambulance Service	Approved (selective use)	✓
Yorkshire Ambulance Service	Evaluation	H1FY20
East Midlands Ambulance Services (EMAs)	Evaluation (1000 patient trial)	H1FY20
North West Ambulance Services	Evaluation/Waiting on results of EMAs	FY20
Welsh Ambulance Services	Evaluation	H1FY20
South East Coast Ambulance Service	Evaluation	H1FY20
London Ambulance Service	Discussion	FY20
North East Ambulance Service	Discussion	FY20
Dublin Fire Brigade (Ire)	Approved (using)	✓

# Penthrox<sup>®</sup>

## Europe

Our partner is making excellent progress in Europe.

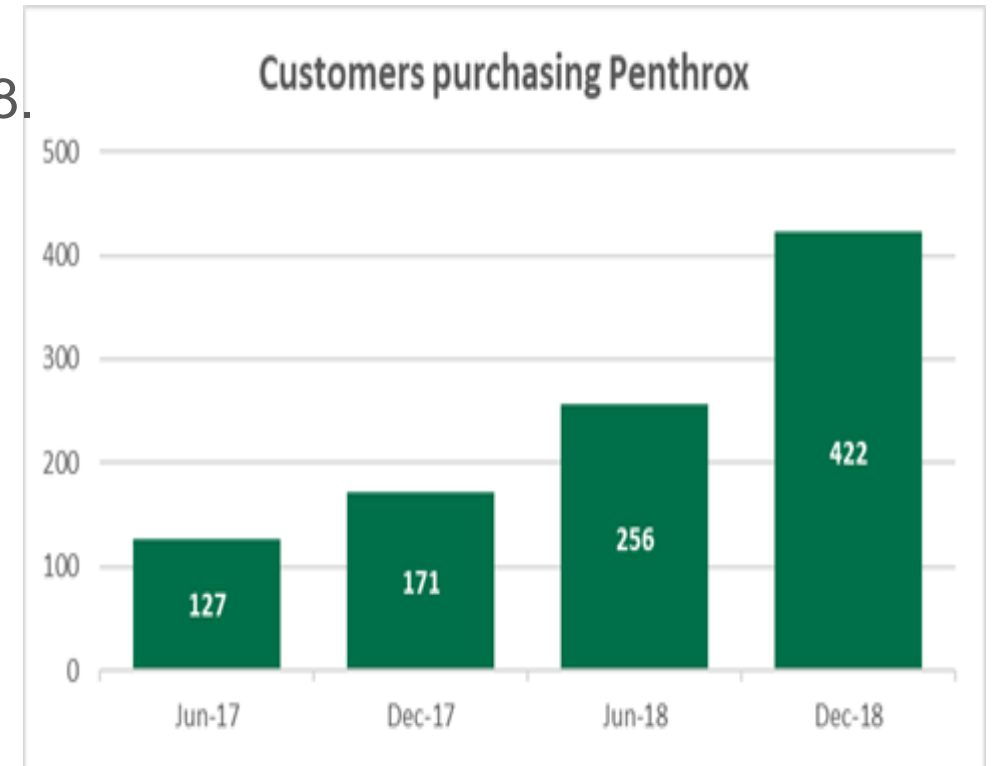
In market sales in France grew 108% H1FY19 v H1FY18.

Including UK, Ireland, France and Belgium, sales have been made into 13 of the 41 countries in Europe.

Launch activities are planned for the remaining 28 countries including the main markets of Germany, Italy and Spain.

Sales have been made to 422 customers.

Strong growth is expected.



# Penthrox<sup>®</sup>

## St Mary's Major Trauma Centre, London

Penthrox v. Standard of Care (120 patients). The study has been completed and should be published by the end of the year.

In November 2018, an interim analysis of 35 patients was conducted. The interim analysis showed

- A reduction in total time of patient stay in the hospital of over an hour (+/-)
- A reduction of time to analgesia of approximately an hour and a half (+/-)
- A significant reduction in pain score
- A good safety profile

Note: Final publication of results may vary materially from preliminary “observed” data.

# Penthrox®

## China Update

MVP concluded a significant transaction with Daiichi Sankyo for the China, Thailand and Vietnamese markets.

MVP received an upfront payment of circa \$21m for the commercialisation rights.

There is an additional USD \$17.5m to be paid subject to performance milestone and registrations being achieved.

The process of registration of Penthrox in China has begun.

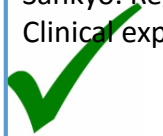
- MVP's Regulatory Dossier is being translated into Mandarin. This will take two more months.
- We expect to submit our IND to the Chinese Food and Drug Administration (CFDA) during June or July of 2019.
- First sale of Penthrox in China is planned for H1FY22.

# Penthrox<sup>®</sup>

## Penthrox<sup>®</sup> clinical program for China

2018

Received \$22m from Daiichi Sankyo. Regulatory and Clinical experts appointed



2019

Regulatory Dossier preparation, review and translation

IND submission to Chinese FDA

2020

Phase I Dose ranging  
Healthy Volunteer Study in China

Phase III to support existing Phase III studies and data. Can be run in parallel with Phase 1 Study

2021

File NDA with Chinese FDA

CFDA Approval

2022

Penthrox Launch In China

# Penthrox®

## USA Update

MVP expect to submit a Type A meeting request to the FDA during Q4FY19. MVP expect to meet with the FDA during Q4FY19.

The purpose of that meeting will be to discuss MVP's Clinical and Non-Clinical response to the FDA "Clinical Hold" issued in August 2018.

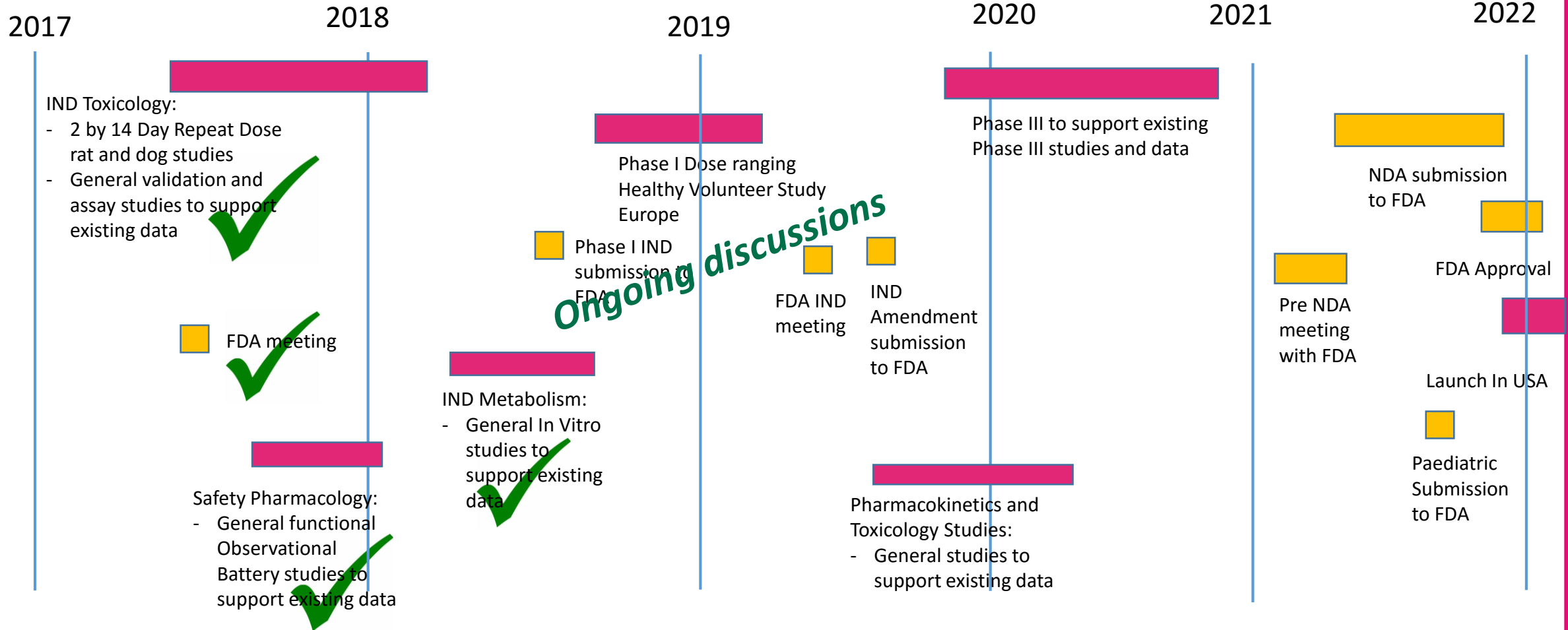
MVP has the following additional information to discuss with the FDA:-

- MVP and its partner recently completed a Phase 1 Pharmacokinetic Study in Europe which includes 56 patients across 7 cohorts. The final reports are expected in Q4FY19.
- We are currently completing a Post Authorisation Study in Europe which includes 3200 patients and forms an important safety data base. An interim analysis has been conducted on 500 Penthrox patients (circa 1,000 patients in total). Interim report due Q4FY19.
- We have completed a Post Authorisation Survey in Europe on our "Educational Material" of 500 Healthcare Professionals and patients.
- We have years of safety data covering millions of patients.



# Penthrox<sup>®</sup>

## USA Update



# Penthrox®

## Clinical Program

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

The purpose of our clinical program is to expand the indications for Penthrox and accelerate the adoption of Penthrox globally.

Our FY19 investment was expected to be almost \$12 million. We now expect:-

AUD \$m	FY19	FY20	Total
USA	1.0	7.0	8.0
China	2.6	4.0	6.6
Other	<u>5.8</u>	<u>1.8</u>	<u>7.6</u>
Total	<u>9.4</u>	<u>12.8</u>	<u>22.2</u>

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

# Penthrox®

## Clinical Trial Pipeline



Start up   Ongoing   Completed   \* Partner study

# Penthrox<sup>®</sup>

## Outlook

MVP's ambition is to globalise Penthrox, and in doing so, make it the mainstream analgesic of choice around the world. This process has begun.

Over the next 12 months+ we expect to:-

- begin selling Penthrox into another 31 countries;
- 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 China, and extend the ‘indications for use’ for Penthrox.

# Respiratory and Medical Devices

# Respiratory Division

## H1FY19

The first half of FY19 delivered the following results:-

- Overall respiratory device sales were up 6%
- Sales into the USA grew 136%
- Sales into Asia grew 297%
- Sales of Breath-A-Tech in Australia grew 11%
- Sales into the UK fell 61%. We believe this is a timing issue and will reverse during 2019.

# Respiratory Devices

## USA

We have access to over 17,000 pharmacies in the USA.

There are approximately 65,000 pharmacies in the USA.

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



# 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.

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 potential 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

## Future API technologies

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

Progress is being made on:-

- **LIDOCAINE (USP):**

We have begun the process of looking for a commercial partner for this technology. The global market for Lidocaine is estimated at USD \$3.5 billion in sales

- **DICHLORFENAC:**

Estimated USD \$6.0 billion global sales

- **SALBUTAMOL:**

Estimated USD \$6.0 billion global sales

- **CANNABIDIOL:**

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



# 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/early 2021.

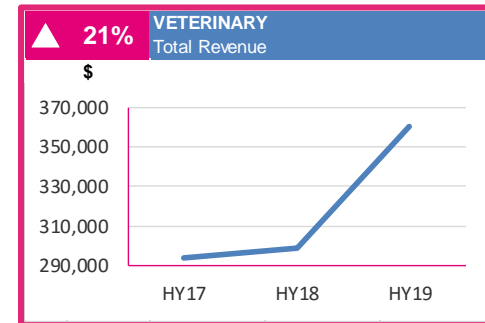
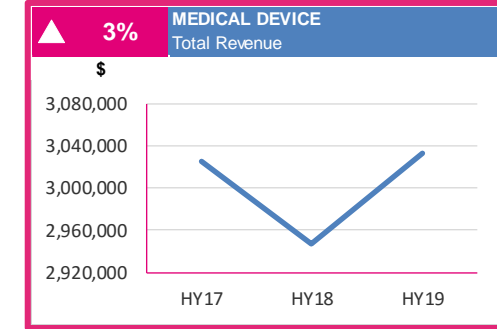
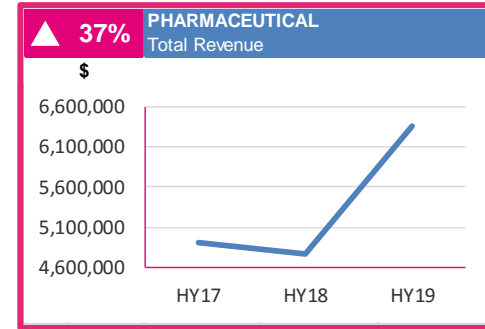
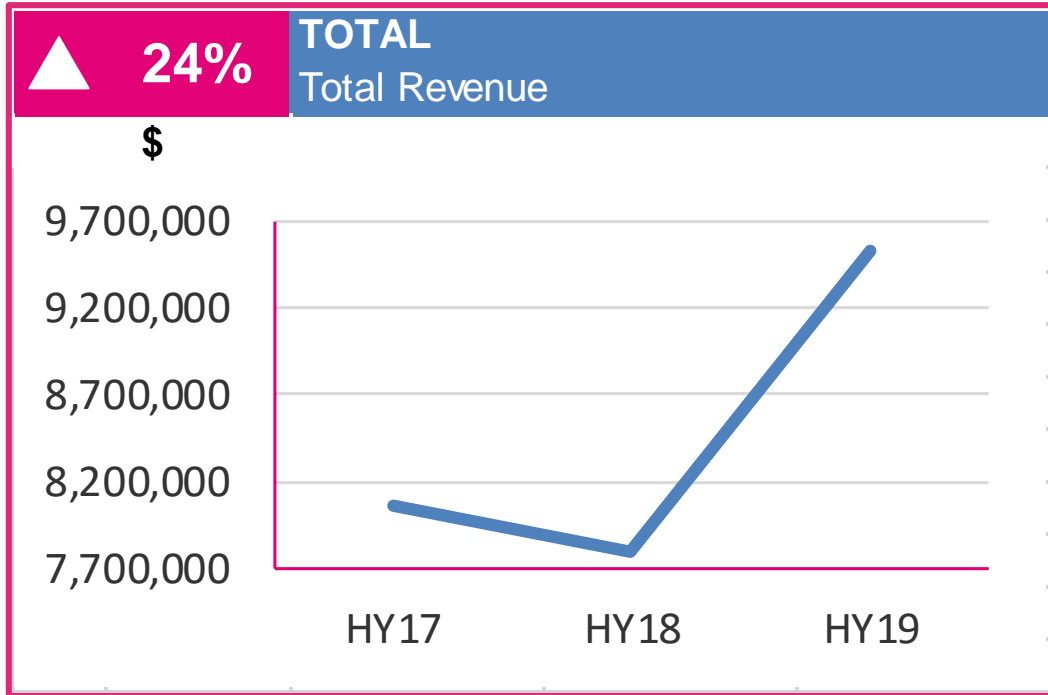
MVP plans to invest up to \$5m in plant, equipment and production facilities to cater and promote the global expansion of Penthrox.



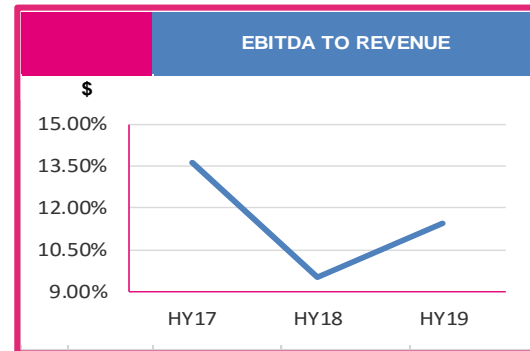
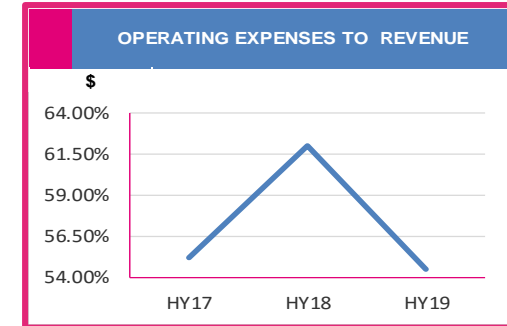
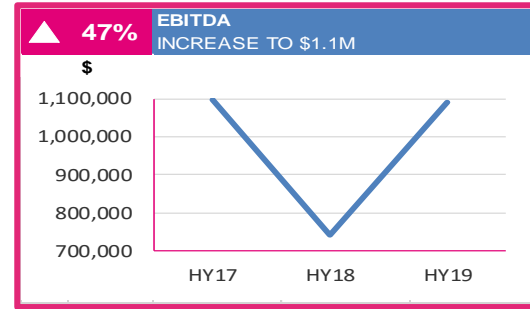
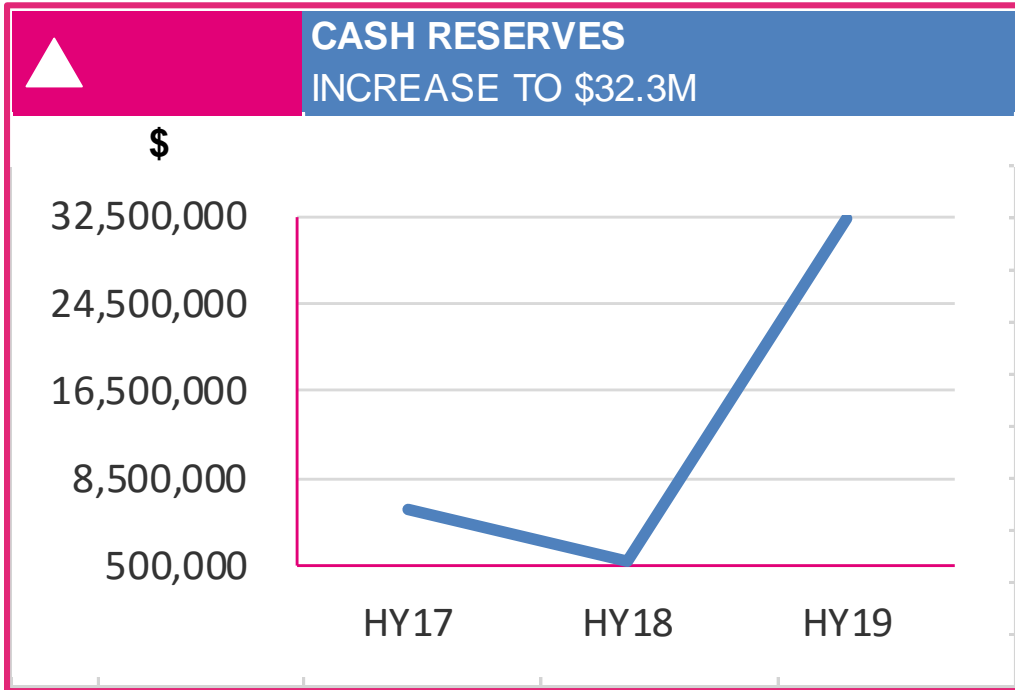
# MVP Corporate



# Financial



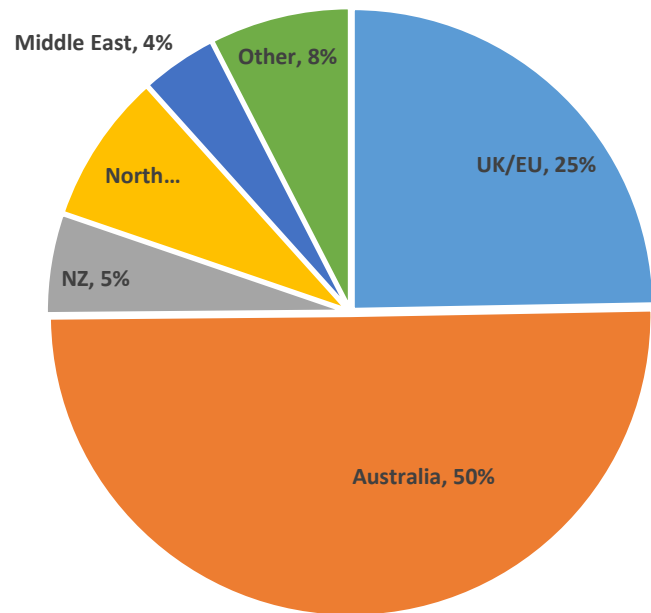
# Financial



# Financial Summary

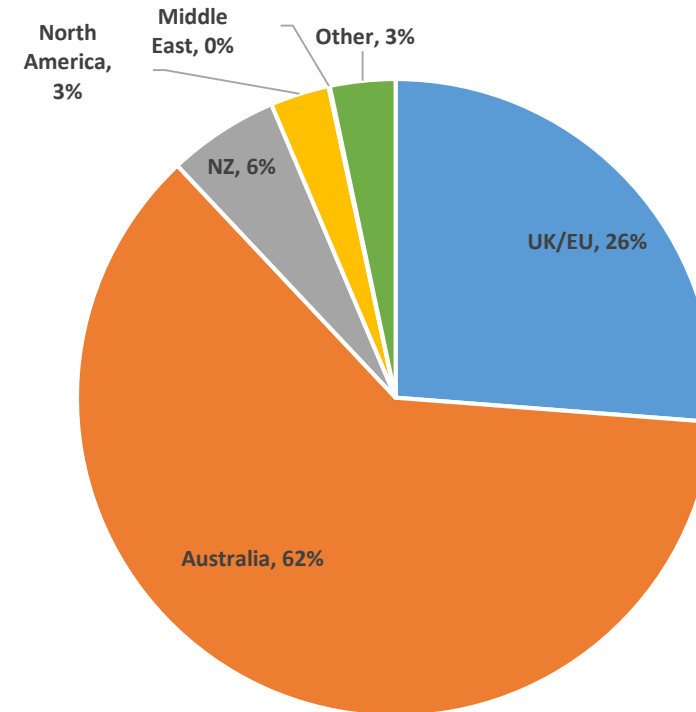
## Breakdown of sales revenue

### Geographical Sales Revenue - FY19



■ UK/EU ■ Australia ■ NZ ■ North America ■ Middle East ■ Other

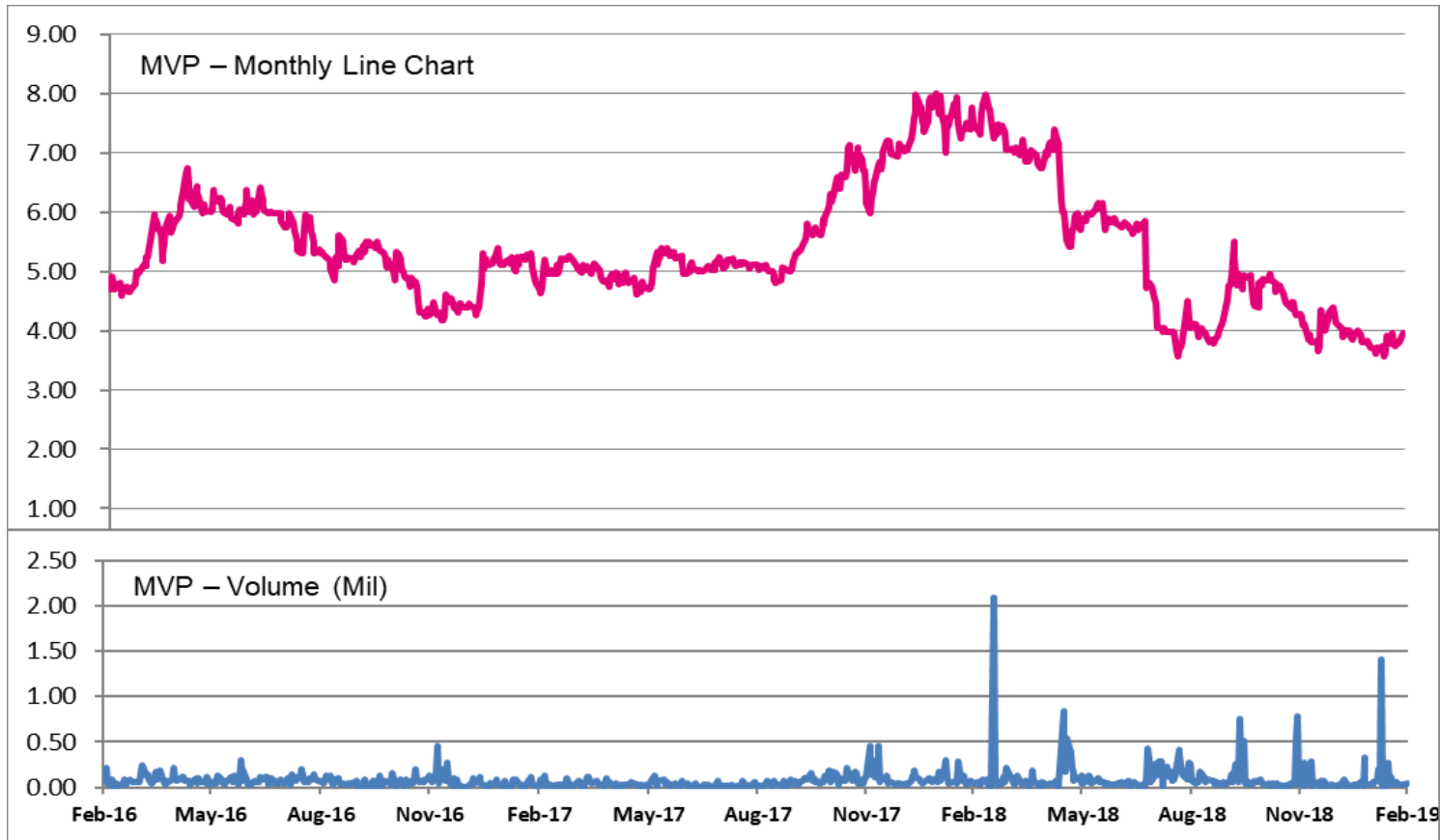
### Geographical Sales Revenue - FY18



■ UK/EU ■ Australia ■ NZ ■ North America ■ Middle East ■ Other

# MDI Investor Dashboard (ASX: MVP)

## Historical Stock Chart (3yr)



## Current Stock Price

**4.16** ▲ 0.020 (5.051%)  
27 Feb, 2:52pm

Day High 4.390

Day Low 4.100

Open 4.100

Prev. Close 3.960

Avg. Volume 90,002

52 Wk. High 8.000 (13 Mar 2018)

52 Wk. Low 3.480 (15 Feb 2019)

Mkt. Cap 258.99 (Mil)

# MVP Corporate Overview

David Williams



**Non-Executive  
Chairman**

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

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.

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**

Matthew Golden



**Business Unit Manager  
– Pentrox**

Thomas Materia



**Business Unit Manager  
– Medical Devices**

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