

October 2019



Key Achievements for FY19

Penthrox®

- Sales in Europe grew 401%
- Sales into the UK grew 68%
- Global sales grew 47%
- Sales to Australian Ambulance grew 38%
- Regulatory approval in a total of 27 European countries
- Regulatory approval and launches in Hong Kong and Saudi Arabia
- Regulatory approval in Jordan
- Almost 400 new customers in Europe and 1,058 customers in total
- 359 customers in France (FY18: 248)
- 159 new customers in the rest of Europe
- 540 customers in the UK and Ireland (FY18: 385)
- Signed exclusive Penthrox® deal for China and received A\$20.8m upfront cash payment
- IND submitted in China
- Regulatory submissions and preparations ongoing in USA, Iran, Iraq, South Korea and Russia
- Progressed the Paediatric Study in the UK and Ireland (nearing 60% recruitment)
- Completed recruitment for the Post Authorisation Safety Study in the UK
- Completed a Phase 1 Pharmacokinetic Study in Europe

Key Achievements for FY19

Respiratory Medical Devices

- Sales into the USA grew 62%
- Sales in Asia up 111%
- Australian Breath-A-Tech sales up 9%
- UK/EU sales down 53%

Key Achievements for FY19

Other

- Raised \$24.5m via Institutional Placement and Share Purchase Plan
- Received R&D Tax Incentive concession of \$488,000
- CSIRO development project for new manufacturing technologies progressing
- Repayment of all bank debt
- Continued investment in clinical development programs and trials

Penthrox®

- Market Leader for trauma pain and minor surgical procedures
- Opiate sparing, fast acting inhalational analgesic
- 85% of patients reach clinical analgesia within 6-10 breaths¹
- A solution to a significant unmet clinical need and clinical evidence proving superior to IV morphine and other opioid analgesics
- Recommended as “First line” analgesic in European guidelines
- Demonstrated safety and efficacy profile for 30+ years
- World class regulatory dossier completed and being used to generate regulatory approvals around the world
- Manufactured in Australia



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

Future for Penthrox®

1975
Australia

2002
Australia
New Zealand

2009
Australia
New Zealand
Moldova

2010
Australia
New Zealand
Moldova
Azerbaijan
Georgia
Ukraine

2011
Australia
New Zealand
Moldova
Azerbaijan
Georgia
Ukraine
Guatemala
Kazakhstan

2014
Australia
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Azerbaijan
Georgia
Ukraine
Guatemala
Kazakhstan
South Africa

2015
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Singapore
Ireland
South Africa
UAE
Belgium
Mexico
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2018 & 2020
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2022 +
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Bosnia
Vatican City
Herzegovina
Andorra
Kuwait
Oman
Bahrain
Lebanon
Syria
Tunisia
Morocco
Algeria
Zambia
Zimbabwe
Botswana
Namibia
Qatar
Brazil
Colombia
Chile
Argentina
Malaysia
Thailand
Philippines
Indonesia

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Saudi Arabia
San Marino
Bosnia
Vatican City
Herzegovina
Andorra
Kuwait
Oman
Bahrain
Lebanon
Syria
Tunisia
Morocco
Algeria
Zambia
Zimbabwe
Botswana
Namibia
Qatar
Brazil
Colombia
Chile
Argentina
Malaysia
Thailand
Philippines
Indonesia

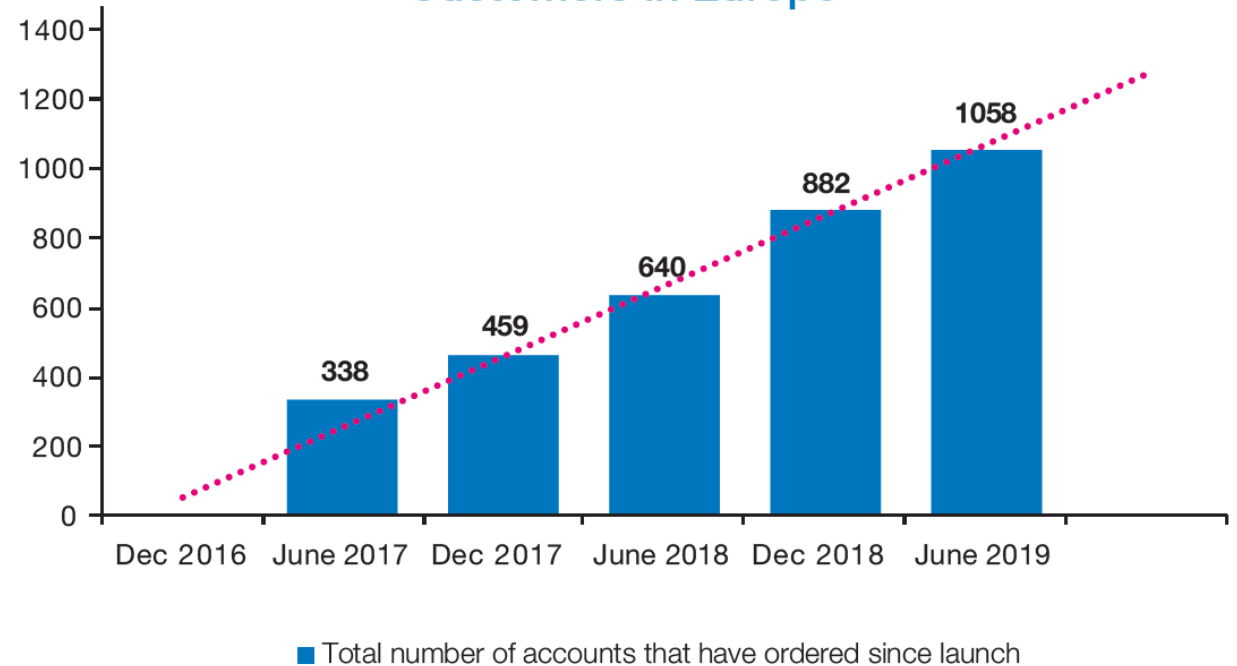
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Penthrox in Europe

“In market” sales in

- UK grew 86%
- France grew 55%
- Europe grew 401%
- Customer numbers grew 65%
- Most major countries in Europe still to launch including Germany, Italy and Spain

Customers in Europe

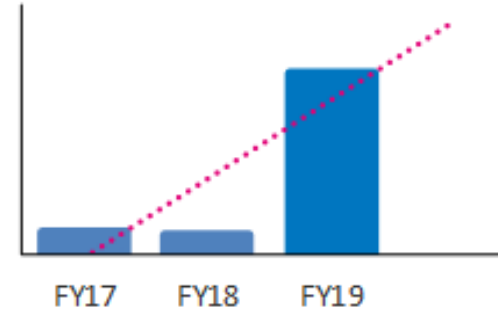


Penthrox Rest of World

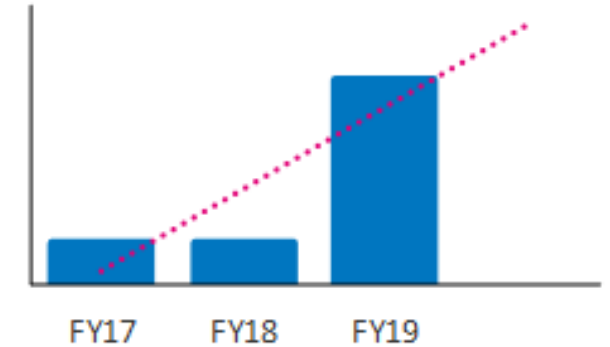
“In market” sales in

- Australia grew 32%
- Australian Ambulance grew 38%
- Customer numbers grew 65%
- New Mundipharma distribution agreement expected to deliver strong sales growth in Australia

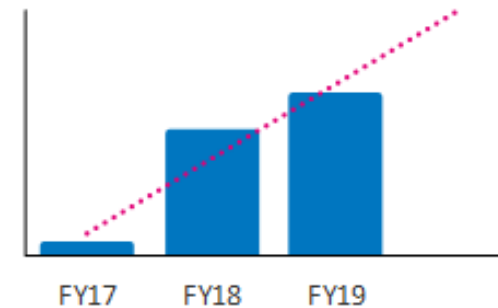
Ambulance Penthrox Sales



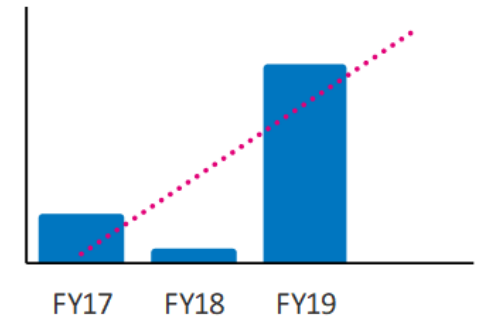
Australian Penthrox Sales



New Zealand Penthrox Sales



Global Penthrox Sales



Penthrox® in USA

Clarity from the FDA

Concession from the FDA on required animal studies

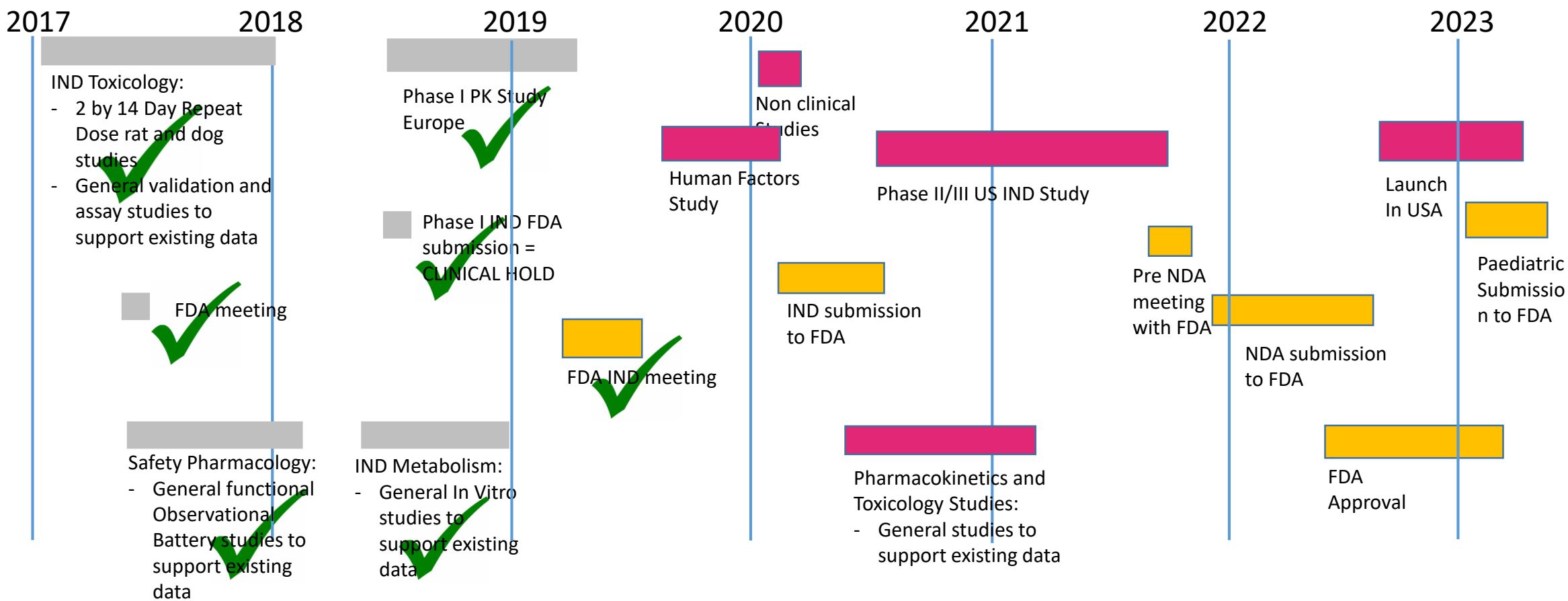
Clear pathway forward to open IND

- One pre-clinical study which mimics human dosing regimen in animals
- One Human Factors Study
- Completion of PASS in Europe
- Complete answers to questions on Penthrox device “whistle”

IND approval target H2 FY20

NOTE: The next 2 FDA meetings will be Type C meetings, therefore the FDA has 75 days from request to schedule meeting. MDI has 1 month from request to submit briefing pack.
MDI plans to submit the non-clinical study protocols to FDA for feedback prior to conducting study.
MDI plans to submit HF study protocol in FDA meeting briefing pack.

Penthrox® in USA



Penthrox® in China

IND submitted and validation process has begun

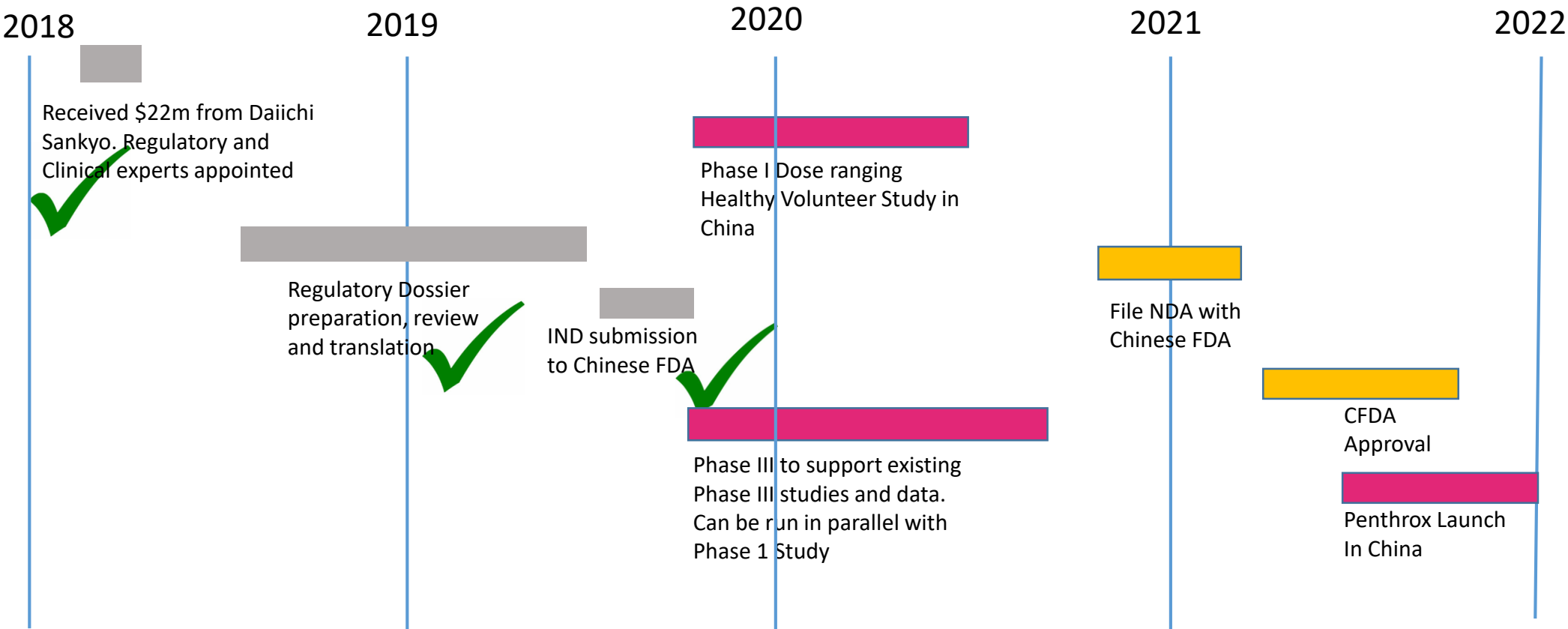
MVP has received questions and the IND approval is expected during 2019

MVP beginning site selections and protocol training for the hospitals, sites and support organisations like labs to participate

- Phase I PK
- Phase III Bridging Trauma
- Phase III Bridging Acute Pain

Approval expected 2021

Penthrox® in China



Clinical Trial Pipeline



Start up Ongoing Completed * Partner study

Respiratory devices

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

- Space Chamber Plus™ anti-static spacer range
- Space Chamber Plus™ spacer
- Space Chamber™ Autoclavable
- Compact Spacer Chamber Plus™
- Space Chamber Slim™
- Breath-A-Tech™ spacer range
- Breath-A-Tech® Cardboard Spacer
- Breath-Alert® peak flow meter
- EZ-fit face masks
- KDK oxygen regulators
- Respiratory Functional Testing (RFT) Spacer
- Econo Spacer



Respiratory devices

USA

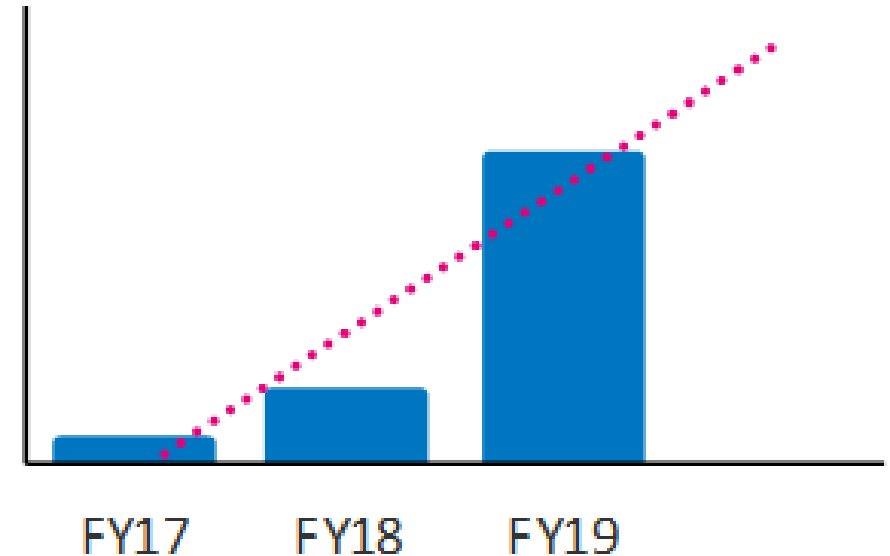
- Sales to USA grew 62%
Strong growth expected in FY20
- Pilot program with 200 CVS stores and own label Walmart launch expected FY20



Other

- Global sales down 5% but due almost entirely to UK issue
- Strong sales growth in Asia which is expected to continue

USA Respiratory Sales (Gross)



Continuous Flow 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.

Continuous Flow technology

Our Continuous Flow technology delivers:-

- Increased yields – though better process conversion
- Increased purity – through better process control
- Better control over entire process – test in real time
- Lower cost of production
- Lower capex
- Less waste
- Smaller footprint
- Quicker to scale-up
- Safer

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.

Continuous Flow technology

Benefits of Continuous Flow vs Batch Process for Penthrox

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)

Continuous Flow technology

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
- **DICHLORFENAC:** Estimated USD \$6.0 billion global sales
- **SALBUTAMOL:** Estimated USD \$6.0 billion global sales
- **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%)

Continuous Flow technology

Lidocaine update

- Lidocaine (base/HCl) produced at >99.9% purity – meets USP42 & EP8.0
- Pilot scale capable of producing kilograms/hr (completed)
- Commercial scale expected to produce >100kgs per day (under qualification)
- Minimal change to footprint from Pilot Plant to Commercial scale
- Material has been tested to and passes all specifications of Lidocaine USP monograph

Financial Performance

Cash receipts were \$62.2m
(including capital raise and China deal)

Nil debt

Net Profit after Tax increased 327%

EBITDA increased 55%

Fully Franked ordinary dividends of 4.0 cps

EBITDA
\$3.4m

\$25.6m
Net
Cash

\$6.8m
invested
into
Penthrox

Gross
Profit
\$14.2m

Outlook

Strong sales growth across Pentrox and Respiratory Devices

Regulatory approvals for development program in China and USA and Russia

Commercialisation of first Continuous Flow technology for Lidocaine

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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;
8. loss or inability to obtain adequate protection for intellectual property rights;
9. litigation;
10. loss of key executives or other employees; and
11. adverse publicity and news coverage.

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