FY18 Results Update

Positioned for long term global growth

MVP invested heavily during FY18 in our people, our clinical development programs, our CSIRO Continuous Flow manufacturing technology and our own manufacturing facility. Penthrox® is well positioned to provide an alternative to opioid medicines in the multi billion dollar global pain market and was approved for sale in another 25 countries during the year. Our ambition is to expand the use of Penthrox® globally and to extend its use into Acute Pain applications including Surgical Procedures, Breakthrough Pain and ultimately Home Use. Our program with the CSIRO could potentially change the way some pharmaceutical products are made, and we look forward to delivering the benefits of our own Penthrox® manufacturing technology and facility as sales increase in the future.

Medical Developments International Limited. ('MDI') (ASX: MVP) delivered unaudited Gross Revenue of $17.929 million (FY17 $18.904 million) and Net Profit after Tax of $0.243m (FY17 $1.820m) for the twelve months ended 30 June 2018.

Key Achievements for FY18

Penthrox®

- Regulatory Approval in 23 new European countries
- Regulatory Approval and first sales in Canada
- Regulatory Approval in Mexico
- Good penetration in France (248 customers used Penthrox®)
- Continued growth in UK and Ireland (385 customers used Penthrox®)
- Fourth purchase order delivered for UK and Ireland
- Penthrox® recommended for use in all ambulances in the UK
- Penthrox® being used in all major hospital and ambulance services in Ireland
- Penthrox® replaced Nitrous Oxide in all New Zealand ambulances
- 52% sales growth in New Zealand
- Commenced patient enrolment in our Paediatric study, recruitment nearing 40%
- First patient enrolled in PK study in Europe via partnership with Mundipharma
- Good progress on other clinical trials
- Regulatory submissions ongoing in USA, Saudi Arabia, Hong Kong, Iran, South Korea, Iraq, Jordan and Russia
- New distribution deal signed with Iran

Respiratory Medical Devices

- Completed a core ranging deal with Walgreens in the USA to supply 2,000 stores
- Completed a core ranging deal with Sam's Club
- Space Chamber Plus selling into circa 13,000 pharmacies in the USA
- North American sales over $1m for the first time
- Sales growth of 35% in UK and Europe
- Launched new Respiratory Device into Australian market - 'Space Chamber Slim'
- Good progress in development of Breath-A-Tech anti-static range of devices
- Launched veterinary respiratory devices into the USA

Other

- Manufacturing facility in Scoresby approved by TGA and European authorities
- Commencement of production of Penthrox® using new technology
- CSIRO project for continuous flow technology for new drugs is ahead of expectations
- Continued investment in clinical development programs and trials
- MVP has a total of 8 Patent and Patent applications, 3 of which were filed in FY18
- MVP has Trademarks in over 30 countries
- Received R&D Tax Incentive of $412,000

Penthrox® Sales

United States of America

Recent developments in the USA around opioid addiction and abuse make the clinical need and market opportunity for Penthrox® more urgent. Given the public and legislative bias expressed by the USA government and its Food Drug Administration (FDA) against the use of opioids, Penthrox® as a non-opioid / non-narcotic, fast acting, safe, easy to use, store and administer acute pain drug should offer a compelling solution.

MVP completed the clinical and non-clinical studies required to open an IND, which we believe to be the critical step in the pathway to approval. The clinical and non-clinical work in several cases repeats work done elsewhere. The data collected reconfirms what we know and what has been accepted by regulators in Europe and elsewhere in the world.

MVP submitted the Investigational New Drug application on 29 June 2018.

On 25 July the FDA contacted MVP stating that it had questions about the IND application and until such time as those questions were answered the IND was on 'Clinical Hold'.

The FDA advised they are writing to MVP to detail its questions and MVP expect to receive FDA's written correspondence within two months.

At this stage MVP remain confident that we will be able to supply the FDA with the additional information it requires. Our confidence is based on our 30+ years of experience, Penthrox® demonstrated safety profile over that time, our recent achievements in getting Penthrox® approval for sale in more than 28 countries in the last few years and our ongoing clinical work being performed around the world.

MVP continues to discuss its commercial plans to sell Penthrox® in the United States with interested parties.

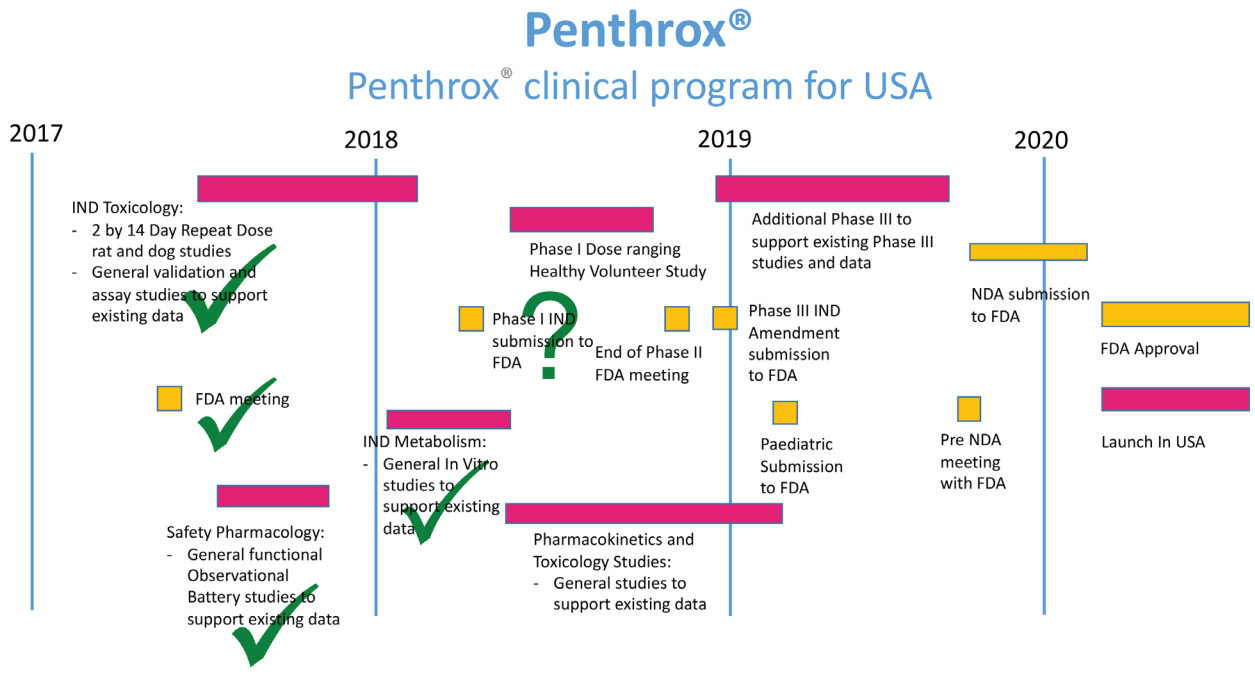
Europe

Bureaucratic delays meant Marketing Authorisations were received for 23 new countries during the last few months of FY18. Consequently, sales into these markets have been pushed into FY19. MVP has sales orders on hand for 7 new European countries and product launches are planned in the coming months. MVP expect the remaining countries to be launched throughout FY19.

In addition, 'National Regulatory Applications' are expected to be filed with the relevant agencies in the Netherlands, Greece, Macedonia, Serbia, Albania, Liechtenstein, Montenegro, Kosovo, San Marino, Vatican City, Bosnia and Herzegovina, Andorra and Monaco in due course.

France

Penthrox® was launched in the French and Belgium markets in 2017 and feedback from these markets continues to be very positive. France now has **approval from 121 hospitals and 248 customers** which are buying and using Penthrox®. In market sales grew 66% for Q3FY18.



UK and Ireland

In the UK and Ireland, Galen continues to make good progress. In May 2018 MVP supplied its fourth order. Sales to the UK and Ireland are **up 51% vs FY17**. Penthrox® sales continue to grow into hospitals in the UK and Ireland. **103 hospitals have now approved Penthrox®** into formulary listing and **385 customers** in total are using the product. These include seven of the eleven major trauma centres in the UK.

The Joint Royal College Ambulance Liaison Committee ('JRCALC') approved the use of Penthrox® across all ambulance services in the UK during November 2017. Three ambulance services have adopted Penthrox® and a number of ambulance trusts are actively engaging in protocol assessments.

Penthrox® is being used in all ambulance services and major hospitals in Ireland.

Australia

Penthrox® maintained its strong presence in its traditional market of Ambulance. Sales to hospitals grew 9%. Penthrox® is now sold into more than 200 hospitals and medical clinics.

New Zealand

During FY18, New Zealand St John's Ambulance removed nitrous oxide from service and replaced it with Penthrox®. Sales grew 52% during FY18.

Middle East

Sales in the Middle East dropped 14% during FY18, mainly because of regional instability affecting Qatar and the UAE. We expect a number of new Marketing Authorisations will be approved during FY19 including for Saudi Arabia, Jordan, Iraq and Iran which will deliver sales growth in the region.

Hong Kong

We expect Marketing Authorisation to be approved for Penthrox® during H1FY19 and sales to begin.

Singapore and South Africa

Sales into Singapore fell whilst sales into South Africa continue to be frustrated because of bureaucratic delays in 'down-scheduling' Penthrox® so it can be used more freely in ambulance and hospitals.

South Korea

We continue to work with our partners and the regulatory authorities to get Penthrox® approved for sale in South Korea.

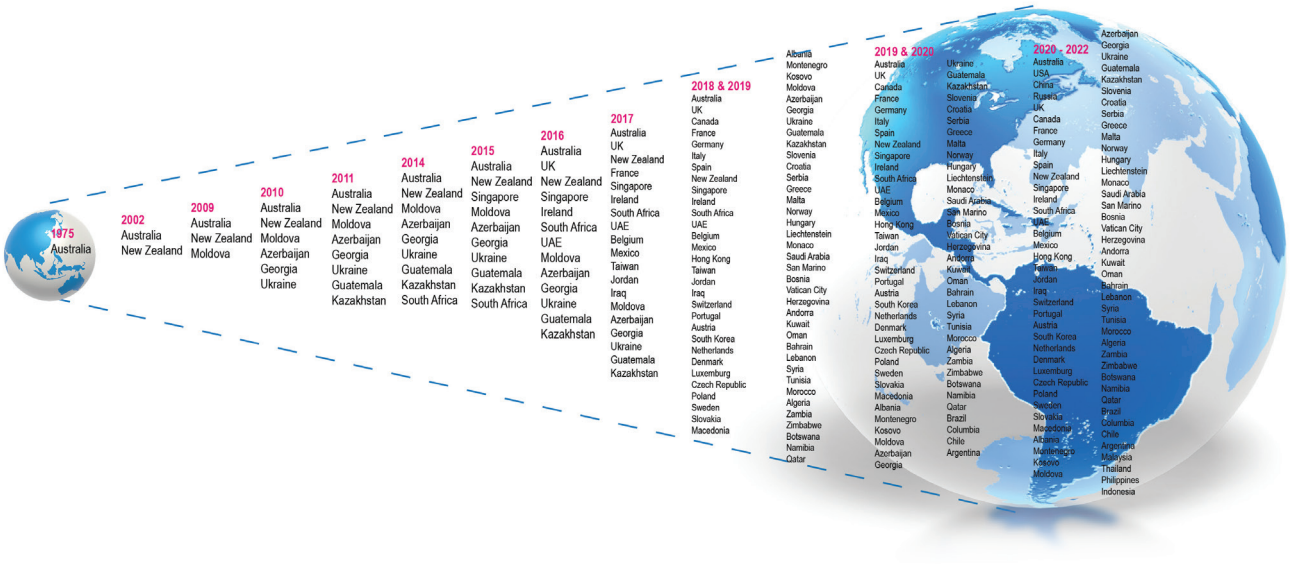
Russia

In May 2017 Russia announced it was coordinating its Marketing Authorisation approval process for pharmaceuticals in the Eurasian Economic Union (EEU). The Union includes Belarus, Kazakhstan, Russia, Armenia and Kyrgyzstan; and Marketing Authorisations granted under the new EEU will mean the product can be sold in all five countries. The formal acceptance of Marketing Authorisation submissions is expected to commence in September 2018.

MVP and its Russian partner plan to submit the Marketing Authorisation application and achieve the approval to sell Penthrox® by FY20.

Future for Penthrox®

MVP continues to negotiate with interested parties from around the world in terms of registering and selling Penthrox®. Several key markets are drawing strong interest and we are encouraged by the responses we are getting from interested parties looking to partner Penthrox® in the USA, China and Asia.



Respiratory Developments

Overall gross revenue from respiratory devices was 2% down.

MVP maintained its market leadership position even though sales in Australia fell 6% (year on year) because we launched six new products during H1FY17 and received strong 'first stocking' orders. Whilst we received follow up orders during FY18, the size of the initial stocking orders was not replicated in FY18. MVP has plans for product launches in FY19 and we expect sales from our Australian business to grow.

Sales into the USA market **grew 15%** and we continue to build our business in that market. We are well on the way to establishing ourselves as a major supplier of respiratory devices in the USA. We expect to deliver significant sales growth in that market in the years ahead.

Sales into Europe and the UK **grew 35%** and this region continues to make a significant contribution to our business.

Clinical Developments

MVP invested $7.1m in clinical and research programs during FY18 (FY17: $2.9m). Our ambition is to extend the use of Penthrox® into Acute Pain applications including Surgical Procedures, Breakthrough Pain and ultimately Home Use. Together with our partners we have begun developing clinical programs to expand the indication for use of Penthrox® to acute pain procedures in the European Union. In parallel we are conducting a large pivotal children study to expand the trauma indication into children within the EU. The benefit of this extension could be available to our partners in Europe and, more importantly, it could provide the additional clinical data to have the market opportunity for Penthrox® extended in jurisdictions worldwide. By way of example, we believe the global market for minor Surgical Procedures is bigger than the global opportunity for Penthrox® in Trauma Pain, our traditional market.

Studies completed and underway to develop the Trauma indication and support the use of Penthrox® around the world

- Spain randomised controlled trial reimbursement study (MVP Partner)
- UK Post Authorisation Safety Study utilising educational material (MVP)
- UK randomised controlled trial Post Authorisation Safety Study (MVP)
- Swiss Post Authorisation Safety Study (MVP Partner)
- Italy randomised controlled trial reimbursement study (MVP Partner)
- Italy reimbursement study, methoxyflurane in arduous environments (MVP Partner)
- Netherlands randomised controlled trial (MVP Partner)
- France market access randomised controlled trial (MVP Partner)
- UK Investigator Initiated Trial (IIT) – ambulance service study
- France IIT – Methoxyflurane as a starter in the treatment of emergency trauma pain
- Singapore IIT comparing methoxyflurane vs tramadol
- Australia IIT retrospective pre-hospital safety outcomes study
- Australian IIT safety of methoxyflurane administered in ambulance services

Studies underway to extend the use of Penthrox® in Trauma for children

European randomised controlled trial comparing methoxyflurane vs placebo in children 6-17 years of age (MVP). This trial recruited its first patient in July 2017 and is now almost 40% recruited. Progress is steady, and we expect to have the initial review of safety data completed before the end of this year. One of the issues for recruitment is that enrolment relies on parental consent of children who have suffered trauma pain, and naturally parents are reluctant to enrol their child, particularly in the younger age groups.

Studies underway to develop the Acute Pain indication and support the expanded use of Penthrox® in Europe and around the world

- Pivotal Registration Study randomised controlled trial with methoxyflurane used in colonoscopy (MVP Partner)
- Phase I Pharmacokinetics study examining 56 patients (MVP Partner)
- Market access wounds management study (MVP Partner)
- Burns & Wounds retrospective study to support regulatory submissions (MVP Partner)

Studies underway and completed to develop Penthrox® in the USA

- US pre clinical studies for IND and NDA - (MVP)
- Australian Investigator Initiated Trial (IIT) – Methoxyflurane in TRUS-biopsy

During the year, a number of important studies were completed and published.

New publications:

- Matt Wilkes, FRCA; Eleanor C. Heath, MRCGP; Nicholas P. Mason, PhD. Methoxyflurane for Procedural Analgesia at 4470m Altitude. Wilderness & Environmental Medicine 2018; 29, 1–4
- R. Ruff, S. Kerr, D. Kerr, D. Zalcberg and J. Stevens. Occupational exposure to methoxyflurane administered for procedural sedation: an observational study of 40 exposures. British Journal of Anaesthesia. 2018; volume 120, Issue 6: 1435–1437
- Methoxyflurane (Penthrox®) and emergency relief of acute pain in adults. Prescrire International. 2018; volume 27, N0 191: 61-62

- C. Jephcott, J. Grummet, N. Nguyen and O. Spruyt. Department of a review of the safety and efficacy of inhaled methoxyflurane as an analgesic for outpatient procedures. British Journal of Anaesthesia. 2018; 120 (5): 1040-1048
- Keith M Porter, Mohd Kashif Siddiqui, Ikksheta Sharma, Sara Dickerson, Alice Eberhardt. Management of trauma pain in the emergency setting: low-dose methoxyflurane or nitrous oxide? A systematic review and indirect treatment comparison. Journal of Pain Research 2018:11, 11–21
- Ria Dancel, Edmund Allen Liles and Darren Fiore. Acute Pain Management in Hospitalized Children. Review Article Reviews on Recent Clinical Trials, 2017, 12, 1-7
- Serah J. Allison. Paul D. Docherty, Dirk Pons, J. Geoffrey Chase. A Bootstrap Approach for Predicting Methoxyflurane Occupational Exposure in Paramedicine. IFAC-PapersOnLine 2017; Volume 50, Issue 1: 6666-6671
- Paolo Mura, Elisabetta Serra, Franco Marinangeli, Sebastiano Patti, Mario Musu, Ilenia Piras, Maria Valeria Massidda, Giorgio Pia, Maurizio Evangelista, Gabriele Finco. Prospective study on prevalence, intensity, type, and therapy of acute pain in a second-level urban emergency department. Journal of Pain Research 2017:10 2781–2788
- Edward Griffiths. Efficacy and safety of methoxyflurane: managing trauma associated pain in UK SAR helicopter paramedic practice. Journal of Paramedic Practice. 2017; Vol 9 No 3
- KJH Lim, ZX Koh, NA Zafirah, S Fook, D Nausheen, YY Ng, MEH Ong. Clinical Evaluation Of Penthrox® (Methoxyflurane) And Tramadol For The Singapore Emergency Ambulance Service. ABSTRACT In: Society for Emergency Medicine in Singapore Annual Scientific Meeting International Resuscitation Science Symposium. 2016.
- A Kingon, T Yap, C Bonanno, P Sambrook, M McCullough. Methoxyflurane: a review with emphasis on its role in dental practice. Australian Dental Journal 2016; 61:157-162
- Paul Cloves. 21st Century First-on-scene pain relief. Ambulance today. 2016; Issue 1, Volume 13

Our longer-term ambition is to gather sufficient clinical and safety data to extend the use of Penthrox® into:

a. minor surgical procedures;

b. breakthrough post-operative and cancer pain;

c. repeat use scenarios; and ultimately

d. home use.

Commercial Developments

New Manufacturing Facility

Our new purpose-built state of the art manufacturing facility in Scoresby was completed during 2017 and was audited and approved by the TGA and European regulatory authorities. MVP received the GMP Licence from the TGA for the facility in March 2018 and production has begun. To give some perspective as to the capability of our new technology, we expect to be able to manufacture the equivalent of our global 2017 demand for Penthrox® in only 8 weeks.

Our facility also houses MVP's state of the art R&D product testing laboratories.

CSIRO Project

In June 2017, MVP entered into an agreement with the CSIRO to further develop our manufacturing technology and capability for application to other pharmaceutical products. Our collective ambition is to develop the next generation of manufacturing technologies to make pharmaceutical products at a significantly reduced cost, improved quality, and lower risk to commercial scale compared with traditional processes.

In February, MVP announced it has successfully completed a small-scale production run for Lidocaine using MVP's new continuous flow manufacturing technology. Since then we have successfully run a series of pilot scale continuous flow production runs proving a successful scale up and commercial viability. Whilst these production runs are typically not considered to be commercially competitive in terms of costing, our results are extremely positive, and we have initiated preliminary discussions with commercial parties.

Lidocaine has worldwide sales of approximately $3.4 billion. It is a common local anaesthetic and antiarrhythmic drug. It is injected as a local anaesthetic for minor surgery and used as a dental anaesthetic.

The platform technology is the same as that used for the manufacture of Penthrox®. Accordingly, MVP expects the benefits of the new technology may include significant cost reductions, improved consistency in terms of quality and yield, better scalability and improved safety, than that currently used to manufacture the drug.

Our scientific development team includes some of Australia's and the world's leading experts in small molecule manufacture and continuous flow technology. Good progress is being made on several pharmaceutical products which we detail as follow:

- Lidocaine – Proven manufacturing process using continuous flow technology at commercially viable manufacturing scale. Writing invention statement and developing patent. Discussion have commenced with potential interested parties
- Diclofenac – Proven manufacturing process using continuous flow technology. Moving to small scale production testing. Writing invention statement and developing patent
- Salbutamol - Proven manufacturing process using continuous flow technology. Moving to small scale production testing. Writing invention statement and developing patent
- Sevoflurane – New batch manufacturing process invented. Continuous flow technology being developed
- Synthetic cannabinoids - Continuous flow technology being developed
- Other target products include Ziprasidone, Isoflurane, Donepezil and Salmeterol. Some of these products share the same continuous flow technology being developed for the targets listed above. These products will be pursued once the technology for the priority target products is proven at a commercially viable scale.

As part of our project we have discovered and are proceeding to patent an important 'new intermediate molecule' used to manufacture Diclofenac using traditional manufacturing techniques. On face value this new intermediate molecule may deliver significant benefits to the existing 'batch' manufacturing process.

We are very pleased with the progress of this initiative and confident it will deliver several valuable commercial opportunities to our business.

Product Development

In November 2017 MVP filed an additional Patent Application protecting a new Penthrox® delivery device technology. To date and in total, we have filed six Patent Applications to protect Penthrox®.

MVP also refiled its Patent Application to protect its new Penthrox® manufacturing technology and we expect valuable intellectual property to be generated from our CSIRO project in due course also.

MVP expects to submit additional patent applications as we extend our respiratory product offering.

Veterinary

Our Vet business grew 11% in FY18 on the back of a significant new deal with one of the USA's largest veterinary medical device companies.

FY18 Half Year Financial Result (Unaudited)

Financial Result

$'000	FY18	FY17
Revenue (Gross)	17,929	18,904
Revenue (Net)	17,461	18,347
Gross Margin	12,364	12,583
GM%	71%	69%
Expenses	10,475	8,991
EDITDA	2,223	3,792
NPAT	243	1,820

Whilst revenue was down year on year, gross margins increased 3% to 71%.

MVP recorded $2.2m as revenue from the amortisation of upfront and milestone payments received as at 30 June 2018.

Operating Expenses grew 17% for the period. In FY18 MVP experienced increased 'pharmacovigilance' costs as a result of expanding geographic sales for Penthrox® and Medical Devices. Marketing expenses also increased because of increased promotional activity in the USA. Other key expense increases were utilities, insurance and loan finance costs.

MVP continues to invest in our business and people. MVP has employed over 30 additional people since the beginning of 2016 to cater for the workload resulting from the ongoing registration activity and planned new market launches over the next 6-12 months. We are now well placed for the future and do not expect further significant investment.

The tax rate applying to MVP in FY18 has lowered from 30% to 27.5% and resulted in the required restatement of the company's opening deferred tax asset as at 1 July 2017. This accounting change resulted in the lowering of the opening deferred tax asset, creating an additional $107k charge to income tax expense in FY18, thereby further reducing reported net profit after tax.

Cash flow

During the year MVP invested:

- $7.1 million in clinical trials for Penthrox®;
- $0.8 million in our manufacturing development program with the CSIRO; and
- $1.8 million in our manufacturing facility.

At year end MVP's net bank debt was $8.2 million.

Outlook

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

Over the next 12 months we expect to:

- commence sales into a further 23 new European countries, Mexico, Saudi Arabia, Iran, Jordan, South Korea and Hong Kong;
- consolidate and grow our Respiratory Device sales in the USA, Europe and elsewhere;
- progress our USA Penthrox® registration;
- conclude additional distribution partnerships for Penthrox® and Respiratory Devices for new countries;
- advance work on producing other analgesic and pharmaceutical products using the intellectual property that is our new manufacturing process; and
- continue our clinical program to extend the indication for use of Penthrox® globally.

Over the next few years our global market approvals and 'indication extensions' are expected to deliver strong growth.

Our Respiratory Devices are leaders in the field. We will continue our global expansion and build our USA business.

We expect to deliver new partnership deals, expand our product offering and grow sales significantly.

Our initiative to develop new production technologies is progressing as well and we have identified several potential products which we think will deliver value to shareholders.

Our portfolio of respiratory devices is growing and we are delivering good sales growth. The opportunities across the world for our respiratory devices, and especially in the USA in the shorter term, are significant. We are well on the way to delivering on these expectations.

We look forward to reporting our progress and successes.

Further Information:

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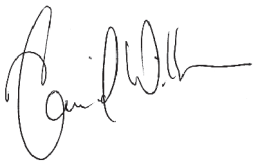

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