

Full-Year Report 2018

Financial Year Ended 30 June 2018

(Previous corresponding period: financial year ended 30 June 2017)



Chairman's and CEO's Report

MR JOHN SHARMAN
CHIEF EXECUTIVE OFFICER

MR DAVID WILLIAMS
CHAIRMAN



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. Pentrox® 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 Pentrox® 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 Pentrox® manufacturing technology and facility as sales increase in the future.

Medical Developments International Limited. ('MDI') (ASX: MVP) delivered 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. MVP has declared a fully franked full year dividend of 2 cents per share.

Key Achievements for FY18

Pentrox®

- 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 Pentrox®)
- Continued growth in UK and Ireland (385 customers used Pentrox®)
- Fourth purchase order delivered for UK and Ireland
- Pentrox® recommended for use in all ambulances in the UK
- Pentrox® being used in all major hospital and ambulance services in Ireland
- Pentrox® 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 Pentrox® 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

Pentrox® Sales

United States of America

Recent developments in the USA around opioid addiction and abuse make the clinical need and market opportunity for Pentrox® more urgent. Given the public and legislative bias expressed by the USA government and its Food Drug Administration (FDA) against the use of opioids, Pentrox® 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, Pentrox® demonstrated safety profile over that time, our recent achievements in getting Pentrox® 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 Pentrox® 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.

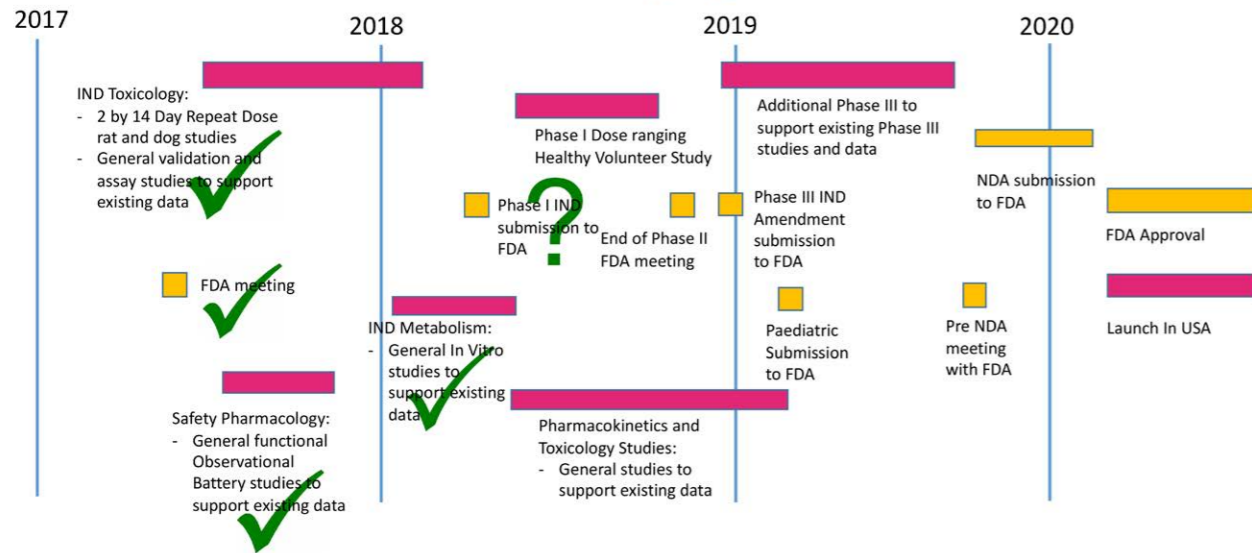
In addition, 'National Regulatory Applications' are expected to be filed with the relevant agencies in the Netherlands, Greece, Macedonia, Serbia, Albania, Liechtenstein, Montenegro, Kosovo, San Marino, Vatican City, Bosnia and Herzegovina, Andorra and Monaco in due course.

France

Pentrox® 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 Pentrox®. In market sales grew 66% for Q3FY18.

Penthrox®

Penthrox® clinical program for USA



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

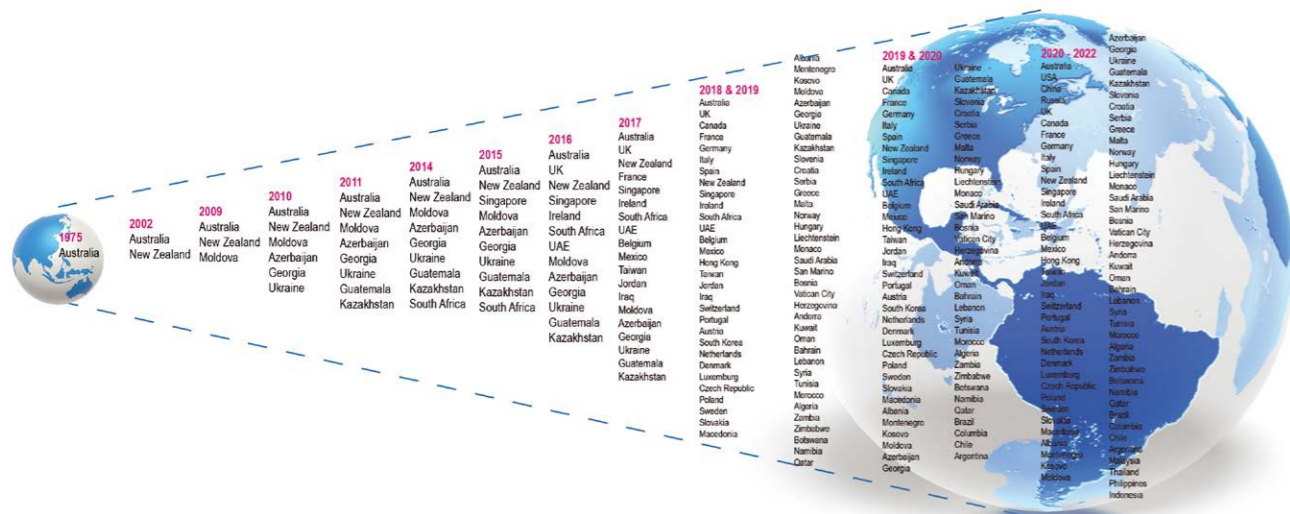
We expect Marketing Authorisation to be approved for Penthrox® during H1FY19 and sales to begin.

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 Pentrox[®] by FY20.

Future for Pentrox[®]

MVP continues to negotiate with interested parties from around the world in terms of registering and selling Pentrox[®]. Several key markets are drawing strong interest and we are encouraged by the responses we are getting from interested parties looking to partner Pentrox[®] 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 Pentrox[®] 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 Pentrox[®] 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 Pentrox[®] extended in jurisdictions worldwide. By way of example, we believe the global market for minor Surgical Procedures is bigger than the global opportunity for Pentrox[®] in Trauma Pain, our traditional market.

Studies completed and underway to develop the Trauma indication and support the use of Pentrox[®] 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 Pentrox[®] 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 Pentrox[®] 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 Pentrox[®] 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. Zalberg 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 (Pentrox[®]) and emergency relief of acute pain in adults. *Prescribe International*. 2018; volume 27, NO 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, Iksheta 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 Pentrox[®] (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 Pentrox® into:

- minor surgical procedures;
- breakthrough post-operative and cancer pain;
- repeat use scenarios; and ultimately
- 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 Pentrox® 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 Pentrox®. 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 Pentrox® delivery device technology. To date and in total, we have filed six Patent Applications to protect Pentrox®.

MVP also refiled its Patent Application to protect its new Pentrox® 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 Full Year Financial Result

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 Pentrox® 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.

Dividend

The Board of Directors has declared a fully franked full year dividend of 2 cents per share to the holders of fully paid ordinary shares as at the record date of 31 August 2018 to be paid to shareholders on 5 October 2018. A Dividend Reinvestment Plan is again being offered.

Cash flow

During the year MVP invested:

- \$7.1 million in clinical trials for Pentrox®;
- \$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 Pentrox®, 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 Pentrox® registration;
- conclude additional distribution partnerships for Pentrox® 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 Pentrox® 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.

Thank you

We would like to thank our staff, our trading partners and shareholders for their efforts and support and look forward to further success in FY19 and beyond.

Further information



MR JOHN SHARMAN
CHIEF EXECUTIVE OFFICER
+61 3 9547 1888



MR DAVID WILLIAMS
CHAIRMAN
+61 414 383 593



Product Portfolio

Pharmaceutical

Analgesia Pentrox®

Medical

Asthma Anti-Static Compact Space Chamber Plus®

Anti-Static Space Chamber Plus®

Breath-A-Tech Spacer

Breath-A-Tech Hospital Spacer

Breath-Alert® Peak Flow Meter

Breath-A-Tech Portable Nebuliser

Compact Space Chamber Plus®

MyMDI™ Pulse Oximeter

Space Chamber Plus®

Space Chamber Plus® Autoclavable spacer

Space Chamber Slim®

Face masks EZ-fit silicone and disposable face masks

Oxygen OXI-Port® oxygen therapy device

OXI-Sok oxygen therapy device

OXI-Pro oxygen resuscitation device

OXI-Life oxygen resuscitation device

OXI-Saver™ closed circuit oxygen resuscitation device

OXI-Dive closed circuit oxygen resuscitation device

OXI-Vac™ suction system

Regulators KDK™ regulator/flow meter with oxygen flush

Absorbers KAB™ carbon dioxide absorber

Veterinary

Anaesthesia MK5 closed circuit anaesthetic machine

LANA closed circuit anaesthetic machine

Mini-KOM™ anaesthetic machine

Breath-Alert® breathing monitor

Veterinary Spacers

Pharmaceuticals

MVP is a world leader in the management of acute and procedural pain.

Building our Business

MVP manufactures its world leading inhaled analgesic from its premises in Springvale, Victoria, Australia. MVP is the sole manufacturer of the active molecule worldwide and continues to develop new markets and applications for the iconic brand Pentrox®. Pentrox® continues to be used as a 'first line' product for the treatment of pain in trauma by all Ambulance Services in Australia and New Zealand. MVP continues the promotional focus into the Australian Ambulance services ensuring that the strong positioning of Pentrox® is maintained. Moving forward, the strategy is to continue to broaden the range customers (hospitals, general practice, dental and cosmetic) domestically and continue to grow the countries that can be served by Pentrox®. FY19 will see Pentrox® launched into multiple new countries.

Product Suite

MVP is continuing to develop additional formulations of Pentrox® to provide improve convenience, utility and value for its customers. This includes investing in the product development of a next generation Pentrox® inhalers.



Medical devices

Building our product range

MVP's focus in FY19 will be to add to our established product range, to build on the solid foundation that

has been established with our current partnerships in Australia and overseas. At the same time MVP will develop new collaborations for future growth. Core to the growth is the development of new and improved models of:

- Asthma/COPD Space Chambers
- Pentrox® Inhaler
- Peak Flow Meters
- Portable Nebulisers
- Pulse Oximeter
- Face Masks
- Tourniquets
- Emergency Medicine consumable equipment

Asthma Devices

MVP's Asthma devices business has been strong for many years and continues to provide solid sales and profit.



The success of this business over recent years has been due to four factors:

- The strength of the Allersearch brand in Australian Hospitals and Pharmacies through our distribution partner
- The acquisition of the Breath-A-Tech range
- Growing sales of our range of Asthma products through established international partners and new customers. Of particular note is the ongoing growth in respiratory sales in the USA with MVP products now in approximately 13,000 pharmacies across the USA.

Product development

MVP's Space Chamber is well known in the market place as the 'Rolls Royce' brand and it offers the greatest opportunity for future growth in the Asthma devices market. To assist in future growth MVP has developed new and improved Space Chambers to assist with product differentiation and local and international penetration.



Oxygen & other Medical equipment

Safe, precision engineering and custom design kits and accessories

MVP manufactures a range of oxygen therapy and resuscitation equipment, providing healthcare professionals and trained personnel with the ability to administer oxygen to patients in an emergency situation. These devices range from basic through to advanced systems of delivering oxygen therapy or resuscitation.

Product suite

- OXI-Port® oxygen therapy device
- OXI-Sok oxygen therapy device
- OXI-Pro oxygen resuscitation device
- OXI-Life oxygen resuscitation device
- OXI-Saver™ closed circuit oxygen resuscitation device
- OXI-Dive closed circuit oxygen resuscitation device
- OXI-Vac™ suction system

These products are all custom assembled and tested at MVP's TGA approved manufacturing facilities in Melbourne, Australia.

The market

The MVP's oxygen equipment is purchased and used by:

- Ambulance services
- Fire brigades
- Lifesaving clubs
- Military
- First aid organisations
- Dental markets



Veterinary

MVP re-invigorates its Veterinary product range

Products

- Anaesthetic machines
- Vaporisers
- Breathing monitors
- Veterinary Spacers

The Market

MVP offers a range of open and closed circuit anaesthetic machines to the veterinary market, which are popularly known as Komesaroff anaesthetic machines. MVP has developed a unique market position regarding the design, manufacture and supply of closed circuit anaesthetic machines to this particular niche market in Europe.

Whilst the majority of MDI's veterinary products continue to be sold in Europe through our distributor, Kruise (one of Europe's largest veterinary distribution companies), the launch of a new machine, and with a new catalogue veterinary sales continue to grow. MVP expect to continue to expand its growth in Asia and North America via various distributors.

New Product Development

MVP's Breath-Alert® breathing monitor (Mark IV) continued to sell well on new but simple selling features such as size (smaller unit), ease of use and battery longevity. Through new products a specifically tailored catalogue and promotion via our Australian distributor will assist future sales growth.

Board of Directors



Mr David Williams

Non-Executive Chairman

Managing Director of Kidder Williams Ltd, with over 30 years' experience in the investment banking sector. He is also Chairman of PolyNovo Ltd and RMA Global Limited. Mr Williams is Chairman of the MVP Remuneration and Nominations Committee.



Mr Max Johnston

Non-Executive Director

Mr Johnston is a non-executive director of Polynovo Limited, Cannpal Animal Therapeutics Limited and a former non-executive Director and Chairman of Probiotec Limited and a former non-executive Director of Enero Group Limited. He is also a Director of Prolife Foods Ltd. For 11 years he was President and Chief Executive Officer of Johnson & Johnson Pacific and an Executive Director of Johnson & Johnson. Mr Johnston has also held several prominent industry roles as a past President of ACCORD Australasia Limited, a former Vice Chairman of the Australian Food and Grocery Council and a former member of the board of ASMI. Mr Johnston has had extensive overseas experience during his career in leading businesses in Western and Central-Eastern Europe, Africa as well as Asia-Pacific. Mr Johnston is also a member of the MVP Audit & Risk Committee.



Dr Harry Oxer AM

Non-Executive Director

Dr Oxer is a Medical Consultant to MDI and St John Ambulance in Western Australia. Dr Oxer was a long-time member of the State Executive for St John Ambulance (WA) until his retirement in rotation in 2012 and was the previous Medical Director for twenty-six years. He has taught, lectured and published extensively over the years, both nationally and internationally. Dr Oxer is also a past Chairman of the Australian Resuscitation Council and has a major interest in resuscitation, oxygen therapy and pain relief.



Mr Philip Powell

Non-Executive Director

Mr Powell, a Chartered Accountant, has an extensive finance background and commenced working in investment banking in 1996 at Hambros Corporate Finance following ten years industry experience in senior finance roles with ASX listed public company OAMPS Limited. Prior to these roles, he worked for ten years within the Assurance Division at Arthur Andersen & Co.

From January 2006 to July 2013 he was a Director at Corporate Finance Advisory firm Kidder Williams. Mr Powell is also a Non-executive Director of PolyNovo Limited and RMA Global Limited. Philip is Chairman of MDI's Audit and Risk Committee.



Mr Leon Hoare

Non-Executive Director

Mr Hoare is the Managing Director of Lohmann & Rauscher Australia/New Zealand (ANZ), a private EU based medical device company. Previously he was Managing Director of Smith & Nephew ANZ, one of the company's largest global subsidiaries outside the USA. Until 2014 he served as President of Smith & Nephew's Asia Pacific Advanced Wound Management (AWM) business for 5 years. He was also a member of the Global Executive Management for the AWM Division. In his 24 years with Smith & Nephew, he also held roles in Marketing, Divisional and General Management. Mr Hoare's career also included a senior role at Bristol-Myers Squibb in surgical products, and Vice-Chair of Australia's peak medical device body, Medical Technology Association of Australia.

He is also a Non-Executive Director of PolyNovo Limited (ASX: PNM).



Mr Allan McCallum

Non-Executive Director

Mr McCallum has over 20 years' public companies experience including an ASX 50 company and has served on numerous committees including: Audit, Remuneration & Nomination, and as an Independent Director on Related Parties (Governance) Committees. Mr McCallum is a member of the Remuneration and Nominations Committee. He is also Chairman of Tassal Group Ltd and Cann Group Limited.

The above-named directors held office during and since the end of the financial year.

Full-Year Report 2018

Financial Year Ended 30 June 2018

(Previous corresponding period: financial year ended 30 June 2017)





Contents

Directors' Report	19
Independence Declaration to the Directors of Medical Developments International Limited	32
Independent Auditor's Report to the Members of Medical Developments International Limited	33
Directors' Declaration	37
Consolidated Statement of Profit or Loss and Other Comprehensive Income for the Financial Year Ended 30 June 2018	38
Consolidated Statement of Financial Position as at 30 June 2018	39
Consolidated Statement of Changes in Equity for the Financial Year Ended 30 June 2018	40
Consolidated Statement of Cash Flows for the Financial Year Ended 30 June 2018	41
Notes to the Financial Statements for the Financial Year Ended 30 June 2018	42



Directors' Report

The directors of Medical Developments International Limited ("MDI") herewith submit the annual financial report of the company for the financial year ended 30 June 2018. In order to comply with the provisions of the Corporations Act 2001, the directors report as follows:

Information about the Directors

The names and particulars of the directors of the company during or since the end of the financial year are:

Mr D J Williams, B.Ec (Hons), M.Ec, FAICD

Non-Executive Chairman (since 16 September 2003)

Managing Director of Kidder Williams Ltd, with over 30 years' experience in the investment banking sector. He is also Chairman of PolyNovo Ltd and RMA Global Limited. Mr Williams is Chairman of the MVP Remuneration and Nominations Committee.

Mr A D McCallum, Dip.Ag Science, FAICD

Non-Executive Director (since 27 October 2003)

Mr McCallum has over 20 years' public companies experience including an ASX 50 company and has served on numerous committees including: Audit, Remuneration & Nomination, and as an Independent Director on Related Parties (Governance) Committees. Mr McCallum is a member of the Remuneration and Nominations Committee. He is also Chairman of Tassal Group Ltd and Cann Group Limited.

Dr H F Oxer, AM, ASM, KStJ MA (Hons), MB.BChir (Cantab), MRCS.LRCP, DA, FFARCS, FRCA, FFARACS, FANZCA, FACAP, DipDHM

Non-Executive Director (since 28 December 2006)

Dr Oxer is a Medical Consultant to MDI and St John Ambulance in Western Australia. Dr Oxer was a long-time member of the State Executive for St John Ambulance

(WA) until his retirement in rotation in 2012 and was the previous Medical Director for twenty-six years. He has taught, lectured and published extensively over the years, both nationally and internationally. Dr Oxer is also a past Chairman of the Australian Resuscitation Council and has a major interest in resuscitation, oxygen therapy and pain relief.

Mr R M Johnston

Non-Executive Director (since 5 November 2012)

Mr Johnston is a non-executive director of Polynovo Limited, Cannpal Animal Therapeutics Limited and a former non-executive Director and Chairman of Probiotec Limited and a former non-executive Director of Enero Group Limited. He is also a Director of Prolife Foods Ltd. For 11 years he was President and Chief Executive Officer of Johnson & Johnson Pacific and an Executive Director of Johnson & Johnson. Mr Johnston has also held several prominent industry roles as a past President of ACCORD Australasia Limited, a former Vice Chairman of the Australian Food and Grocery Council and a former member of the board of ASMI. Mr Johnston has had extensive overseas experience during his career in leading businesses in Western and Central-Eastern Europe, Africa as well as Asia-Pacific. Mr Johnston is also a member of the MVP Audit & Risk Committee.

Mr L Hoare, AssocDipAppSc(Orth), GradDipBus, GAICD

Non-Executive Director (since 27 September 2013)

Mr Hoare is the Managing Director of Lohmann & Rauscher Australia/New Zealand (ANZ), a private EU based medical device company. Previously he was Managing Director of Smith & Nephew ANZ, one of the company's largest global subsidiaries outside the USA. Until 2014 he served as President of Smith & Nephew's Asia Pacific Advanced Wound Management (AWM) business for 5 years. He was also a member of the Global Executive Management for the AWM Division. In his 24 years with Smith & Nephew, he also held roles in Marketing, Divisional and General Management. Mr Hoare's career also included a senior role at Bristol-Myers Squibb in surgical products, and Vice-Chair of Australia's

peak medical device body, Medical Technology Association of Australia.

He is also a Non-Executive Director of PolyNovo Limited (ASX: PNV).

Mr P J Powell, B.Com (Hons) ACA, F Fin, MAICD

Non-Executive Director (since 17 December 2014)

Mr Powell, a Chartered Accountant, has an extensive finance background and commenced working in investment banking in 1996 at Hambros Corporate Finance following ten years industry experience in senior finance roles with ASX listed public company OAMPS Limited. Prior to these roles, he worked for ten years within the Assurance Division at Arthur Andersen & Co.

From January 2006 to July 2013 he was a Director at Corporate Finance Advisory firm Kidder Williams. Mr Powell is also a Non-executive Director of PolyNovo Limited and RMA Global Limited. Philip is Chairman of MDI's Audit and Risk Committee.

The above-named directors held office during and since the end of the financial year.

Directorships of other listed companies

Directorships of other listed companies held by the directors in the 3 years immediately before the end of the financial year are as follows:

Name	Company	Period of Directorship
David Williams	Polynovo Limited (Chairman)	Since 13 March 2014
	IDT Australia Limited	Until 19 May 2015
	RMA Global Limited	Since November 2014
Allan McCallum	Tassal Group Ltd (Chairman)	Since October 2003
	Cann Group Limited (Chairman)	Since 5 May 2017
Max Johnston	Probiotec Ltd	Until 28 November 2016
	Enero Group Limited	Since March 2011
	Polynovo Limited	Since 13 May 2014
Philip Powell	CannPal Animal Therapeutics Limited	Since 21 April 2017
	Polynovo Limited	Since 13 May 2014
Leon Hoare	RMA Global Limited	Since 5 April 2018
	Polynovo Limited	Since 27 January 2016

Company Secretary

Mr Mark Edwards, CA. Mr Edwards is also the Chief Financial Officer of the company.

Principal Activities

The company's principal activities during the course of the financial year were the manufacture and distribution of a pharmaceutical drug and medical and veterinary equipment.

Review of Operations

Penthrox® Developments

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 of the meeting.

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 of Penthrox® to the Australian ambulance was flat. 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 Pentrox® 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 Pentrox® 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 Pentrox® extended in jurisdictions worldwide. By way of example, we believe the global market for minor Surgical Procedures is bigger than the global opportunity for Pentrox® in Trauma Pain, our traditional market.

Studies completed and underway to develop the Trauma indication and support the use of Pentrox® 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 Pentrox® 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 Pentrox® 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 Pentrox® 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, MRCP; 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. Zalberg 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 (Pentrox®) and emergency relief of acute pain in adults. *Prescribe International* 2018; volume 27, NO 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, Iksheta 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 Pentrox® (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 Pentrox® 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 Pentrox® 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 Pentrox®. 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 Pentrox® delivery device technology. To date and in total, we have filed six Patent Applications to protect Pentrox®.

MVP also refiled its Patent Application to protect its new Pentrox® 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.

Vet

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 Full Year Financial Result

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 Pentrox® 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 Pentrox®;
- \$0.8 million in our manufacturing development program with the CSIRO; and
- \$1.8 million in our manufacturing facility

Dividend

The Board of Directors has declared a fully franked full year dividend of 2 cents per share to the holders of fully paid ordinary shares as at the record date of 31 August 2018 to be paid to shareholders on 5 October 2018. A Dividend Reinvestment Plan is again being offered.

Financial Position

The capital structure of the Group remained stable during the period.

- The debt facility available to the company was drawn down \$8.969m as at 30 June 2018 (net bank debt was \$8.2m); and
- A capital raising was announced post year end (refer Subsequent Events discussion below)

Changes in State of Affairs

During the financial year there was no significant change in the state of affairs of the company other than that referred to in the financial statements or notes thereto.

Subsequent Events

1. On 18 July 2018 the Company announced it has agreed to a Long-Term Incentive Plan 'LTIP' with Mr. John Sharman (CEO) to encourage his long-term commitment to the business. Under the plan Mr. Sharman has been granted 300,000 options with a strike price of \$0.01. The options will only vest on the earlier of FDA approval of Pentrox® for sale in the USA or the company receives an unconditional takeover offer worth more than \$300m. When the LTIP has met its vesting criteria, Mr. Sharman will have 3 months to exercise the options, after which the options will lapse. 60% of any new shares issued by exercising options will be escrowed for a period of 12 months from issue date. In the case of an unconditional takeover, the escrow conditions will not apply. All outstanding options will be cancelled if Mr. Sharman leaves or he is no longer employed by MVP for any reason.
2. On 25 July 2018 the Company advised that it met with the Food and Drug Administration ('FDA') for the United States of America. The FDA has advised that the clinical program for Pentrox® to be approved for sale in the USA is to be put on hold pending a letter outlining outstanding issues and concerns. That letter was expected within two months of the announcement.
3. On 8 August 2018 The Company announced that it had completed a capital raising by way of private placement to sophisticated and institutional investors that had raised \$17m. The Company announced that it would also invite existing shareholders to invest in the company via a Share Purchase Plan (SPP). The details relating to the SPP are expected to be finalised and released in a formal offer document by Wednesday 22 August 2018.

4. On the 17th August 2018 the Board of Directors declared a fully franked final dividend of 2 cents per share to the holders of fully paid ordinary shares as at the record date of 31 August 2018, to be paid to the shareholders on the 5 October 2018. This dividend has not been included as a liability in these financial statements.

There has not been any other matter or circumstance that has arisen that has significantly affected, or may significantly affect the operations of the company, the results of those operations, or the state of affairs of the company in future years.

Dividends

The Board of Directors is pleased to declare a Final Dividend of 2 cents per share fully-franked.

MVP intends to implement a Dividend Reinvestment Plan which will allow shareholders to use the proceeds from the Full Year Dividend to purchase MVP shares at a 5% discount to the volume weighted average price of all of the company's fully paid shares sold on the ASX during the 10 trading days immediately before the record date.

The timetable for the Final Dividend for the year ended 30 June 2018 is:

Key dates	Event
17 August 2018	Declaration of Final Dividend
31 August 2018	Record Date for eligible shareholders to receive dividend
21 September 2018	Date for shareholders to elect to participate in Dividend Reinvestment Plan
5 October 2018	Payment Date

Indemnification of Officers and Auditors

During the financial year, the company paid a premium in respect of a contract insuring the directors of the company (as named above) and all executive officers of the company against a liability incurred as such a director, secretary or executive officer to the extent permitted by the Corporations Act 2001. The contract of insurance prohibits disclosure of the nature of the liability and the amount of the premium.

The company has not otherwise, during or since the end of the financial year, indemnified or agreed to indemnify an officer or auditor of the company against a liability incurred as such an officer or auditor.

Directors' Meetings

The following table sets out the number of directors' meetings (including meetings of committees of directors) held during the financial year and the number of meetings attended by each director (while they were a director or committee member). During the financial year, 9 Board meetings, two Audit and Risk Committee meetings and one Remuneration and Nominations committee meeting were held.

	Board of Directors		Audit & Risk Committee		Remuneration & Nominations Committee	
	Held	Attended	Held	Attended	Held	Attended
D.J. Williams	9	9	-	-	1	1
A.D. McCallum	9	9	-	-	1	1
H.F. Oxe	9	7	-	-	-	-
M. Johnston	9	9	2	2	-	-
L. Hoare	9	9	-	-	-	-
P.J. Powell	9	9	2	2	-	-

Directors' Shareholdings

The following table sets out each director's relevant interest in shares as at the date of this report.

	Fully paid shares
D.J. Williams	9,459,584
A.D. McCallum	267,015
H.F. Oxe	194,465
M. Johnston	30,576
L. Hoare	10,191
P.J. Powell	256,936

Directors hold no options over shares as at 30 June 2018.

Audited Remuneration Report

This remuneration report, which forms part of the directors' report, sets out information about the remuneration of Medical Developments International Limited's key management personnel for the financial year ended 30 June 2018. The term 'key management personnel' refers to those persons having authority and responsibility for planning, directing and controlling the activities of the consolidated entity, directly or indirectly, including any director (whether executive or otherwise) of the consolidated entity. The prescribed details for each person covered by this report are detailed below under the following headings:

- Key management personnel
- Remuneration policy
- Relationship between the remuneration policy and company performance

- Remuneration of key management personnel
- Key terms of employment contracts.

Key Management Personnel Details

The company's key management personnel consist of the following directors and executives:

The directors of the company during or since the end of the financial year were:

- D.J. Williams (Chairman, Non-executive)
- H. F. Oxe (Non-executive)
- A.D. McCallum (Non-executive)
- R.M. Johnston (Non-executive)
- L. Hoare (Non-executive)
- P. Powell (Non-executive)

The company executives during or since the end of the financial year were:

- J. Sharman (Chief Executive Officer)
- M. Edwards (Chief Financial Officer/Company Secretary)

Except as noted, the named persons held their current position for the whole of the financial year and since the end of the financial year.

Key management personnel equity holdings – fully paid ordinary shares

2018	Balance at 30 June 2017 No.	Issued during the year via DRP No.	Received on exercise of options No.	Aquired No.	Net Other Change* No.	Balance at 30 June 2018 No.
D.J. Williams*	17,970,388	113,025	(9,350,000)	750,000	(23,829)	9,459,584
A.D. McCallum	384,671	2,344	(120,000)	-	-	267,015
H.F. Oxe	193,118	1,347	-	-	-	194,465
M. Johnston	30,365	211	-	-	-	30,576
L. Hoare	10,121	70	-	-	-	10,191
P.J. Powell	255,157	1,779	-	-	-	256,936
J. Sharman	510,312	225	(505,412)	-	-	5,125
M. Edwards	-	-	-	-	-	-
	19,354,132	119,001	(9,975,412)	750,000	(23,829)	10,223,892

* During the year, Mr. Williams ceased being trustee for 23,829 shares owned by Ward Williams

2017	Balance at 30 June 2016 No.	Issued during the year via DRP No.	Received on exercise of options No.	Net Other Change No.	Balance at 30 June 2017 No.
D.J. Williams *	17,809,855	139,115	-	21,418	17,970,388
A.D. McCallum	381,690	2,981	-	-	384,671
H.F. Oxe	191,622	1,496	-	-	193,118
M. Johnston	30,131	234	-	-	30,365
L. Hoare	10,043	78	-	-	10,121
P.J. Powell	253,180	1,977	-	-	255,157
J. Sharman	28,683	1,629	800,000	(320,000)	510,312
M. Edwards	-	-	-	-	-
	18,705,204	147,510	800,000	(298,582)	19,354,132

Remuneration Policy

The board continues to set remuneration at a level that will attract directors and executives of high calibre. The two key elements are:

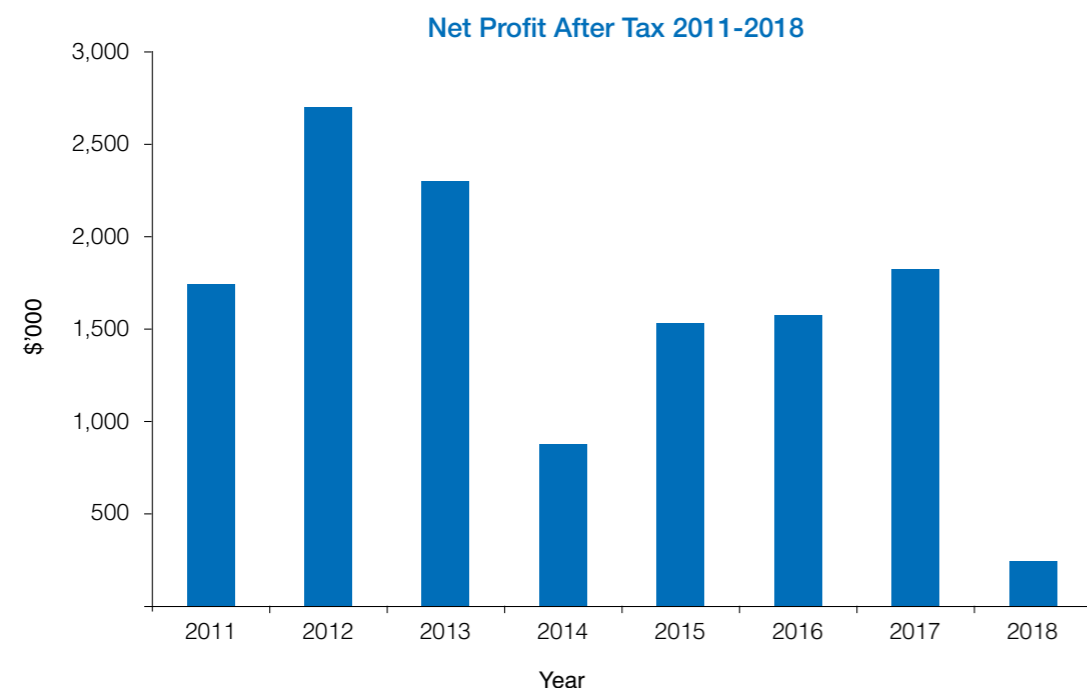
- base salary and fees, which are determined by reference to the market rate based on payments at similar sized companies in the industry; and
- Performance incentives, which have two components – short term incentives based on achieving key performance indicators during the year and payable in cash, and long-term incentives payable in equity, the value of which depends on the share price of the company.

The remuneration and nominations committee, comprised of D.J. Williams and A.D. McCallum, determines the salary package of the CEO of the company and reviews the compensation of the non-executive directors on an annual basis. Changes are approved by the board as a whole.

Relationship between the Remuneration Policy and Company Performance

The board aims to ensure there is a strong link between company performance and remuneration and believes that the use of performance incentives ensures that company performance is reflected in the quantum of payments made to executives. Performance metrics are selected to ensure that the interests of management are aligned with those of shareholders. For short term incentives, key metrics are EBITDA (Earnings Before Interest, Tax, Depreciation and Amortisation and NPAT (Net Profit after Tax), used to directly link company earnings and cash bonuses and other operational measures, the achievement of which provides the basis for future growth and profitability.

The graph and table that follows, depict the company's earnings for the current financial year and the previous seven financial years, which demonstrate that the company has been consistently profitable.



The following table shows the company's share prices for the current financial year and the previous seven financial years.

	2011	2012	2013	2014	2015	2016	2017	2018
Share price - start (\$)	0.22	0.40	0.79	1.27	1.32	2.68	6.10	4.95
Share price - end (\$)	0.40	0.79	1.27	1.32	2.68	6.10	4.95	5.80
Interim Dividend (cps)*	-	3.00	3.00	-	-	2.00	2.00	2.00
Final Dividend (cps)*	3.00	3.00	2.00	-	-	2.00	2.00	2.00
Basic Earnings per Share (cps)	3.40	5.10	4.10	1.50	2.65	2.70	3.10	0.41
Diluted Earnings per Share (cps)	3.40	5.10	4.10	1.50	2.65	2.65	3.10	0.41

*Franked to 100% at 27.5% corporate income tax rate.

Dividends

A further 2c full franked dividend per fully paid ordinary share has been declared for the full year.

Elements of director and executive remuneration

Remuneration packages contain the following key elements:

1. Primary benefits – salary/fees and cash bonuses
2. Post-employment benefits – superannuation
3. Equity – rights to shares granted under the Chief Executive Officer Long Term Incentive Plan (CEO LTIP).

The following table discloses the remuneration of the directors of the company in 2018:

2018	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total
	Salary & Fees \$	Bonus \$	Superannuation \$	Long service leave \$	Options & Rights \$	\$
Directors						
D.J. Williams	68,493	-	6,507	-	-	75,000
A.D. McCallum	41,096	-	3,904	-	-	45,000
H.F. Oxer	41,096	-	3,904	-	-	45,000
M. Johnston	41,096	-	3,904	-	-	45,000
L. Hoare	41,096	-	3,904	-	-	45,000
P.J. Powell	41,096	-	3,904	-	-	45,000
	273,973	-	26,027	-	-	300,000

The following table discloses the remuneration of the key executives of the company in 2018:

2018	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total	Remuneration linked to performance
	Salary & Fees \$	Bonus \$	Superannuation \$	Long service leave \$	Options & Rights \$	\$	
Executives							
J. Sharman (Chief Executive Officer)	343,794	50,000	36,798	16,759	-	447,351	11%
M. Edwards (Company Secretary)	167,657	4,566	16,530	2,950	-	191,703	2%
	511,451	54,566	53,328	19,709	-	639,054	

Both Mr Sharman and Mr Edwards remuneration comprised a performance related component of \$50,000 and \$4,566 respectively. No directors remuneration contained a performance related component.

The following table discloses the remuneration of the directors of the company in 2017:

2017	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total
	Salary & Fees \$	Bonus \$	Superannuation \$	Long service leave \$	Options & Rights \$	\$
Directors						
D.J. Williams	50,493	-	22,797	-	-	73,290
A.D. McCallum	41,096	-	3,904	-	-	45,000
H.F. Oxer	41,096	-	3,904	-	-	45,000
M. Johnston	41,096	-	3,904	-	-	45,000
L. Hoare	41,096	-	3,904	-	-	45,000
P.J. Powell	31,096	-	12,954	-	-	44,050
	245,973	-	51,367	-	-	297,340

The following table discloses the remuneration of the key executives of the company in 2017:

2017	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total	Remuneration linked to performance
	Salary & Fees \$	Bonus \$	Superannuation \$	Long service leave \$	Options & Rights \$	\$	
Executives							
J. Sharman (Chief Executive Officer)	299,834	162,500	25,166	14,425	13,399	515,324	32%
M. Edwards (Company Secretary)	154,642	4,566	15,125	581	-	174,914	3%
	454,476	167,066	40,290	15,006	13,399	690,238	

In FY17, both Mr Sharman and Mr Edwards remuneration comprised a performance related component of \$162,500 and \$4,566 respectively. No directors remuneration contained a performance related component.

No key management personnel appointed during the period received a payment as part of his or her consideration for agreeing to hold the position.

Elements of remuneration related to performance

Fees paid to non-executive directors are not directly tied to performance. Salaries paid to the key executives are also not directly tied to performance. The short term and long-term incentive programmes are directly related to performance, and the conditions and assessment methods are explained below.

Short-term incentives

The determination and approval of any potential bonuses is at the discretion of the Board.

During the 2018 financial year, discretionary bonuses totalling \$54,566 (2017: \$167,066) were determined and approved by the Remuneration and Nominations Committee in relation to key management personnel in respect of their performance in the 2017 financial year.

Contracts for services

Mr Sharman is employed under an open-ended contract with a notice period of three months. The contract does not provide for any termination payments beyond payment for

the notice period and any accrued annual leave.

Mr Edwards is employed under an open-ended contract with a notice period of four weeks. The contract does not provide for any termination payments beyond payment for the notice period and any accrued annual leave.

Non-audit services

The directors are satisfied that the provision of non-audit services, during the year, by the auditor (or by another person or firm on the auditor's behalf) is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The non-audit services related to the provision of taxation services and totalled \$29,790. The directors do not believe that the provision of advice of this nature compromises the general principles relating to auditor's independence, as set out by the Institute of Chartered Accountants in Australia.

Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in note 7 to the financial statements.

Corporate governance statement

A copy of the Company's Corporate Governance statement can be found at www.medicaldev.com/investors-media

Auditor's independence declaration

The auditor's independence declaration is included on page 32 of the annual report.

Rounding off of amounts

The Company is a Company of the kind referred to in ASIC Corporations (rounding in Financial/Director's Reports) Instrument 2016/191 dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in the directors' report and the financial statements are rounded off to the nearest thousand dollars, unless otherwise indicated.

Signed in accordance with a resolution of the directors made pursuant to s.298(2) of the Corporations Act 2001.

On behalf of the directors.



David Williams

Chairman

Melbourne, 17 August 2018





Deloitte Touche Tohmatsu
ABN 74 490 121 060

550 Bourke Street
Melbourne VIC 3000
GPO Box 78
Melbourne VIC 3001 Australia

Tel: +61 (0) 3 9671 7000
Fax: +61 (0) 3 9671 7001
www.deloitte.com.au



Deloitte Touche Tohmatsu
ABN. 74 490 121 060

550 Bourke Street
Melbourne VIC 3000
GPO Box 78
Melbourne VIC 3001 Australia

Tel: +61 (0) 3 9671 7000
Fax: +61 (0) 3 9671 7001
www.deloitte.com.au

The Board of Directors
Medical Developments International Limited
4 Caribbean Drive
Scoresby VIC 3179

17 August 2018

Dear Board Members

Medical Developments International Limited

In accordance with section 307C of the Corporations Act 2001, I am pleased to provide the following declaration of independence to the directors of Medical Developments International Limited.

As lead audit partner for the audit of the financial statements of Medical Developments International Limited for the financial year ended 30 June 2018, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) The auditor independence requirements of the Corporations Act 2001 in relation to the audit
- (ii) Any applicable code of professional conduct in relation to the audit.

Yours sincerely

DELOITTE TOUCHE TOHMATSU
DELOITTE TOUCHE TOHMATSU

Samuel Vorweg
Partner
Chartered Accountants

Independent Auditor's Report to the Members of Medical Developments International Limited

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Medical Developments International Limited (the "Company") and its subsidiaries (the "Group") which comprises the consolidated statement of financial position as at 30 June 2018, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies and other explanatory information, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- (i) giving a true and fair view of its financial position as at 30 June 2018 and of its financial performance for the year then ended; and
- (ii) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of the Group, would be in the same terms if given to directors as at the time of this auditor's report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report for the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Member of Deloitte Touche Tohmatsu Limited
Liability limited by a scheme approved under Professional Standards Legislation

Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
<p>Recoverability of Goodwill</p> <p>As at 30 June 2018 the Group's Goodwill balance totals \$9.095m as disclosed in Note 13.</p> <p>Significant judgement is required by management to determine assumptions and estimates involved in preparing a discounted cash flow model ('value in use') for each of the Group's Cash Generating Units ('CGU's), including:</p> <ul style="list-style-type: none"> Forecast EBITDA and free cash flow for each CGU, EBITDA growth rates over the forecast period and terminal value of each CGU, and Discount rates appropriate to the risk profile of each CGU. <p>Changes to these assumptions can materially impact the valuation determined for each CGU.</p>	<p>Our procedures included, but were not limited to:</p> <ul style="list-style-type: none"> Obtaining an understanding of the process undertaken by management to prepare the value in use model for each CGU to identify and test key controls supporting the process. In conjunction with our valuation specialists, evaluating and testing the key assumptions used in management's value in use model including: <ul style="list-style-type: none"> Assessing the consistency and appropriateness of forecast revenue, EBITDA and free cash flows with reference to expected sales by geography and customer, Assessing the appropriateness of EBITDA growth rates applied over the forecast period and terminal value with reference to management's current business plans, Assessing the historical accuracy of forecasts of the Group's operating results, and Comparing the expected discount rate for each CGU to the rate calculated by management. Performing sensitivity analysis on the impairment model by applying varied discount rates and growth projections to simulate alternative market conditions and outcomes. <p>We have also assessed the appropriateness of the disclosures in Note 13 to the financial statements.</p>
<p>Capitalisation of intangible assets</p> <p>As at 30 June 2018 the Group's Intangible assets total \$22.549m as disclosed in Note 14.</p> <p>Capitalisation of other intangible assets requires management judgement to determine whether:</p> <ul style="list-style-type: none"> Expenditure relates to development activity and not research activity, Expected future economic benefits attributable to the intangible assets will flow to the Group, The amortisation of intangible assets should commence when revenue has been generated, and The useful lives assigned to each individual category are appropriate. 	<p>Our procedures included, but were not limited to:</p> <ul style="list-style-type: none"> Obtaining an understanding of the process undertaken by management to determine whether expenditure should be capitalised as intangible assets and to identify and test key controls supporting the process, Assessing the appropriateness of management's accounting policy, Assessing all capitalised intangible assets not yet available for use and a sample of capitalised intangible assets available for use at balance date to determine whether it is probable that expected future economic benefits attributable to those assets will flow to the Group, and Reviewing the listing of capitalised intangible assets at balance date to verify that: <ul style="list-style-type: none"> Amortisation has commenced on intangible assets that are available for use, and The useful lives assigned to each intangible asset are appropriate. <p>We have also assessed the appropriateness of the disclosures in Note 14 to the financial statements.</p>

Other Information

Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2018 (inclusive of the Chairman's and CEO's report and the Director's Report), but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the directors for the Financial Report

Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, directors are responsible for assessing the ability of the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless directors either intend to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.

- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the financial report. We are responsible for the direction, supervision and performance of the Group's audit. We remain solely responsible for our audit opinion.

We communicate with directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with directors, we determine those matters that were of most significance in the audit of the financial report of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on the Remuneration Report

Opinion on the Remuneration Report

We have audited the Remuneration Report of Medical Developments International Limited included in the directors' report for the year ended 30 June 2018.

In our opinion, the Remuneration Report of Medical Developments International Limited, for the year ended 30 June 2018, complies with section 300A of the *Corporations Act 2001*.

Responsibilities

Directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

DELOITTE TOUCHE TOHMATSU

DELOITTE TOUCHE TOHMATSU



Samuel Vorweg
Partner
Chartered Accountants
Melbourne, 17 August 2018

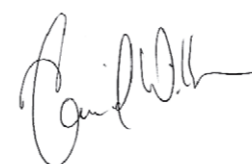
Directors' Declaration

The directors declare that:

- a) in the directors' opinion, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable;
- b) in the directors' opinion, the attached financial statements and notes thereto are in accordance with the Corporations Act 2001, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the consolidated entity;
- c) the attached financial statements are in compliance with International Financial Reporting Standards, as stated in note 1 of the financial statements; and
- d) the directors have been given the declarations required by s.295A of the Corporations Act 2001.

Signed in accordance with a resolution of the directors made pursuant to s.295(5) of the Corporations Act 2001.

On behalf of the Directors



David Williams

Chairman

Melbourne, 17 August 2018

Consolidated Statement of Profit or Loss and Other Comprehensive Income for the Financial Year Ended 30 June 2018

	Note	2018 \$'000	2017 \$'000
Gross revenue from sale of goods and contracts		17,929	18,904
Less discounts and claims		(468)	(557)
Net revenue from sale of goods and contracts	4(a)	17,461	18,347
Cost of sales		(5,097)	(5,764)
Gross profit		12,364	12,583
Other income	4(a)	1	11
Distribution expenses		(1,025)	(941)
Marketing expenses		(3,412)	(2,759)
Occupancy expenses		(900)	(609)
Administration expenses		(3,990)	(3,696)
Regulatory and registration expenses		(1,629)	(1,042)
Finance expenses		(140)	(7)
Other expenses		(968)	(1,077)
Profit before income tax expense		301	2,463
Income tax expense	5(a)	(58)	(643)
Profit for the year		243	1,820
Other Comprehensive Income			
Items that may be reclassified subsequently to profit or loss, net of income tax			
Exchange differences on translating foreign operations	21	47	(6)
Total comprehensive income for the year		290	1,814
Profit for the year attributable to:			
Owners of the parent		243	1,820
Total comprehensive income for the year attributable to:			
Owners of the parent		290	1,814
Earnings per share:			
Basic (cents per share)	23	0.4	3.1
Diluted (cents per share)	23	0.4	3.1

Consolidated Statement of Financial Position as at 30 June 2018

	Note	30 June 2018 \$'000	30 June 2017 \$'000
Current Assets			
Cash and cash equivalents	29(a)	794	1,691
Trade and other receivables	8	4,287	5,232
Inventories	9	3,197	2,424
Current tax receivable	5(c)	96	209
Other	10	373	323
Total Current Assets		8,747	9,879
Non-Current Assets			
Property, plant and equipment	12	8,075	6,637
Deferred tax assets	5(d)	1,082	1,061
Goodwill	13	9,095	9,095
Other intangible assets	14	22,549	15,092
Total Non-Current Assets		40,801	31,885
Total Assets		49,548	41,764
Current Liabilities			
Trade and other payables	15	3,227	2,737
Borrowings	16	102	146
Provisions	17	356	346
Other	19	2,418	2,077
Total Current Liabilities		6,103	5,306
Non-Current Liabilities			
Borrowings	16	9,150	283
Provisions	18	206	159
Other	19	13,048	14,416
Total Non-Current Liabilities		22,404	14,858
Total Liabilities		28,507	20,164
Net Assets		21,041	21,600
Equity			
Issued capital	20	16,121	15,008
Reserves	21	711	264
Retained earnings	22	4,209	6,328
Total Equity		21,041	21,600

Consolidated Statement of Changes in Equity for the Financial Year Ended 30 June 2018

2018	Issued capital \$'000	Retained earnings \$'000	Employee equity settled benefits reserve \$'000	CSIRO Option Reserve \$'000	Foreign currency translation reserve \$'000	Total \$'000
<i>Opening balance</i>	15,008	6,328	331	-	(67)	21,600
Profit for the year	-	243	-	-	-	243
Other comprehensive income for the year, net of income tax	-	-	-	-	47	47
Total comprehensive income for the year	-	243	-	-	47	290
Share based payments	-	-	-	-	-	-
Dividends paid	-	(2,362)	-	-	-	(2,362)
Shares issue as part of ESS	-	-	-	-	-	-
Options issues as part of CSIRO	-	-	-	400	-	400
Dividends reinvested in the form of shares	1,123	-	-	-	-	1,123
Equity raising costs	(10)	-	-	-	-	(10)
Closing balance	16,121	4,209	331	400	(20)	21,041

Financial Year Ended 30 June 2017

2017	Issued capital \$'000	Retained earnings \$'000	Employee equity settled benefits reserve \$'000	CSIRO Option Reserve \$'000	Foreign currency translation reserve \$'000	Total \$'000
<i>Opening balance</i>	11,916	6,852	318	-	(61)	19,025
Profit for the year	-	1,820	-	-	-	1,820
Other comprehensive income for the year, net of income tax	-	-	-	-	(6)	(6)
Total comprehensive income for the year	-	1,820	-	-	(6)	1,814
Share based payments	-	-	13	-	-	13
Dividends paid	-	(2,344)	-	-	-	(2,344)
Shares issue as part of ESS	2,000	-	-	-	-	2,000
Dividends reinvested in the form of shares	1,107	-	-	-	-	1,107
Equity raising costs	(15)	-	-	-	-	(15)
<i>Transfer to retained earnings</i>	-	-	-	-	-	-
Closing balance	15,008	6,328	331	-	(67)	21,600

Notes to the financial statements are included on pages 42-66

Consolidated Statement of Cash Flows for the Financial Year Ended 30 June 2018

	Note	2018 \$'000	2017 \$'000
Cash flows from operating activities			
Receipts from customers		16,233	14,704
Payments to suppliers and employees		(15,482)	(14,049)
Receipts from government grants		118	347
Upfront and milestone payments received		1,020	7,350
Interest paid		(137)	(7)
Income tax received/paid		38	(4,334)
Net cash generated by operating activities	29b	1,790	4,011
Cash flows from investing activities			
Interest received		1	11
Payments for plant and equipment		(2,058)	(4,353)
Payments for other intangible assets		(8,619)	(4,324)
Net cash used in investing activities		(10,676)	(8,666)
Cash flows from financing activities			
Dividends paid (net of DRP)	24	(1,239)	(1,238)
Proceeds from the issue of shares/options		400	2,000
Share issue transaction costs		(10)	(15)
Payments for hire purchase finance		(56)	(52)
Proceeds from borrowings	16	8,878	-
Net cash generated by financing activities	16	7,973	695
Net decrease in cash and cash equivalents		(913)	(3,960)
Cash and cash equivalents at the beginning of the financial year		1,691	5,620
Effects of exchange rate changes on the balance of cash held in foreign currencies		16	31
Cash and cash equivalents at the end of the financial year	29(a)	794	1,691

Notes to the financial statements are included on pages 42-66

Notes to the Financial Statements

for the Financial Year Ended 30 June 2018

1. Significant accounting policies

Statement of Compliance

The financial report is a general purpose financial report which has been prepared in accordance with the Corporations Act 2001, Australian Accounting Standards and Interpretations, and complies with other requirements of the law.

The financial statements comprise the consolidated financial statements of the Group.

For the purposes of preparing the consolidated financial statements, the Company is a for-profit entity. Accounting Standards include Australian Accounting Standards. Compliance with Australian Accounting Standards ensures that the financial statements and notes of the company comply with International Financial Reporting Standards ('IFRS').

The financial statements were authorised for issue by the directors on 17 August 2018.

Basis of Preparation

The consolidated financial statements have been prepared on the basis of historical cost, except for certain non-current assets and financial instruments that are measured at revalued amounts or fair values, as explained in the accounting policies below. Historical cost is generally based on the fair values of the consideration given in exchange for goods and services. All amounts are presented in Australian dollars, unless otherwise noted.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value

for measurement and/or disclosure purposes in these consolidated financial statements is determined on such a basis, except for share-based payment transactions that are within the scope of AASB 2, leasing transactions that are within the scope of AASB 117, and measurements that have some similarities to fair value but are not fair value, such as net realisable value in AASB 2 or value in use in AASB 136.

In addition, for financial reporting purposes, fair value measurements are categorised into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

The company is a company of the kind referred to in ASIC Class Order 98/0100, dated 10 July 1998, and in accordance with that Class Order amounts in the financial report are rounded off to the nearest thousand dollars, unless otherwise noted.

Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities (including special purpose entities) controlled by the Company (its subsidiaries). Control is achieved where the Company has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

Income and expense of subsidiaries acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income from the effective date of acquisition and up to the effective date of disposal, as appropriate. Total comprehensive income of subsidiaries is attributed to the owners of the Company and

to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

Where necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with those used by other members of the Group.

All intra-group transactions, balances, income and expenses are eliminated in full on consolidation.

Changes in the Group's ownership interests in subsidiaries that do not result in the Group losing control are accounted for as equity transactions. The carrying amounts of the Group's interests and the non-controlling interests are adjusted to reflect the changes in their relative interests in the subsidiaries. Any difference between the amount by which the non-controlling interests are adjusted and the fair value of the consideration paid or received is recognised directly in equity and attributed to owners of the Company.

Significant accounting policies

The following significant accounting policies have been adopted in the preparation and presentation of the financial report:

(a) Borrowings

Borrowings are recorded initially at fair value, net of transaction costs.

Subsequent to initial recognition, borrowings are measured at amortised cost with any difference between the initial recognised amount and the redemption value being recognised in profit and loss over the period of the borrowing using the effective interest rate method.

(b) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, cash in banks and investments in money market instruments, net of outstanding bank overdrafts.

(c) Employee benefits

A liability is recognised for benefits accruing to employees in respect of wages and salaries, annual leave, long service leave, and sick leave when it is probable that settlement will be required and they are capable of being measured reliably.

Liabilities recognised in respect of wages and salaries, annual leave and sick leave expected to be settled within 12 months, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement.

Liabilities recognised in respect of annual leave and long service leave which are not expected to be settled within 12 months are measured using an estimate of the present value of the future cash outflows to be made by the company in respect of services provided by employees up to reporting date.

(d) Financial assets

Loans and receivables

Trade receivables, loans, and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'loans and receivables'. Loans and receivables are measured at amortised cost using the effective interest rate method less impairment.

Interest income is recognised by applying the effective interest rate.

Impairment of financial assets

Financial assets, other than those at fair value through profit and loss, are assessed for indicators of impairment at each balance sheet date. Financial assets are impaired where there is objective evidence that as a result of one or more events that occurred after the initial recognition of the financial asset, the estimated future cash flows of the investment have been impacted.

(e) Financial instruments issued by the company

Debt and equity instruments

Debt and equity instruments are classified as either liabilities or as equity in accordance with the substance of the contractual arrangement.

Transaction costs on the issue of equity instruments

Transaction costs arising on the issue of equity instruments are recognised directly in equity as a reduction of the proceeds of the equity instruments to which they relate. Transaction costs are the costs that are incurred directly in connection with the issue of those equity instruments and would not have been incurred had those instruments not been issued.

Interest and dividends

Interest and dividends are classified as expenses or as distributions of profit consistent with the balance sheet classification of the related debt or equity instruments or component parts of compound instruments.

(f) Foreign currency

The individual financial statements of each group entity are presented in the currency of the primary economic environment in which the entity operates (its functional currency). For the purpose of the consolidated financial statements, the results and financial position of each group entity are expressed in Australian dollars ('\$'), which is the functional currency of the Company and the presentation currency for the consolidated financial statements.

In preparing the financial statements of each individual group entity, transactions in currencies other than the entity's functional currency (foreign currencies) are recognised at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences on monetary items are recognised in profit or loss in the period in which they arise, except for:

- exchange differences on foreign currency borrowings relating to assets under construction for future productive use, which are included in the cost of those assets when they are regarded as an adjustment to interest costs on those foreign currency borrowings;
- exchange differences on transactions entered into in order to hedge certain foreign currency risks below for hedging accounting policies; and
- exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur (therefore forming part of the net investment in the foreign operation), which are recognised initially in other comprehensive income and reclassified from equity to profit or loss on repayment of the monetary items.

For the purpose of presenting consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated into Australian dollars using exchange rates prevailing at the end of the reporting period. Income and expense items are translated at the average exchange rates for the period, unless exchange rates fluctuated significantly during that period, in which case the exchange rates at the dates of the transactions are used. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity (attributed to non-controlling interests as appropriate).

(g) Goods and services tax

Revenues, expenses and assets are recognised net of the amount of goods and services tax (GST), except:

- where the amount of GST incurred is not recoverable from the taxation authority, it is recognised as part of the cost of acquisition of an asset or as part of an item of expense; or
- for receivables and payables which are recognised inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows are included in the Consolidated Statement of Cash Flows on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

(h) Goodwill

Goodwill, representing the excess of the cost of acquisition over the fair value of the identifiable net assets acquired, is recognised as an asset and not amortised but tested for impairment annually and whenever there is an indication that the goodwill may be impaired. Any impairment is recognised immediately in the Consolidated Statement of Profit or Loss and Other Comprehensive Income and is not subsequently reversed. Refer also to note 1(j).

(i) Government grants

Government grants are assistance by the government in the form of transfers of resources to the company in return for past or future compliance with certain conditions relating to the operating activities of the company. Government grants include government assistance where there are no conditions specifically relating to the operating activities of the company other than the requirement to operate in certain regions or industry sectors.

Government grants relating to income are recognised as income over the periods necessary to match them with the related costs. Government grants that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the company with no future related costs are recognised as income of the period in which it becomes receivable.

Government grants relating to assets are treated as deferred income and recognised in the profit and loss over the expected useful lives of the assets concerned.

(j) Impairment of assets

At each reporting date, the company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the company estimates the recoverable amount of the cash generating unit to which the asset belongs.

Goodwill, intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually and whenever there is an indication that

the asset may be impaired. An impairment of goodwill is not subsequently reversed. Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognised in the Consolidated Statement of Profit or Loss and Other Comprehensive Income immediately, unless the relevant asset is carried at fair value, in which case the impairment loss is treated as a revaluation decrease.

Where an impairment loss (other than Goodwill) subsequently reverses, the carrying amount of the asset (or cash generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognised in profit or loss immediately, unless the relevant asset is carried at fair value, in which case the reversal of the impairment loss is treated as a revaluation increase.

(k) Income tax

Current tax

Current tax is calculated by reference to the amount of income taxes payable or recoverable in respect of the taxable profit or loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantively enacted by reporting date. Current tax for current and prior periods is recognised as a liability (or asset) to the extent that it is unpaid (or refundable).

Where the Group qualifies for the research and development tax incentive refund (at 45%), this reduces the current tax expense recognised in profit and loss for the period.

Deferred tax

Deferred tax is accounted for using the comprehensive balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and the corresponding tax base of those items.

In principle, deferred tax liabilities are recognised for all taxable temporary differences. Deferred tax assets are recognised to the extent that it is probable that sufficient taxable amounts will be available against which deductible

temporary differences or unused tax losses and tax offsets can be utilised. However, deferred tax assets and liabilities are not recognised if the temporary differences giving rise to them arise from the initial recognition of assets and liabilities (other than as a result of a business combination) which affects neither taxable income nor accounting profit. Furthermore, a deferred tax liability is not recognised in relation to taxable temporary differences arising from goodwill.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period(s) when the asset and liability giving rise to them are realised or settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by reporting date. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the company intends to settle its current tax assets and liabilities on a net basis.

Current and deferred tax for the period

Current and deferred tax is recognised as an expense or income in the Consolidated Statement of Profit or Loss and Other Comprehensive Income, except when it relates to items credited or debited directly to equity, in which case the deferred tax is also recognised directly in equity, or where it arises from the initial accounting for a business combination, in which case it is taken into account in the determination of goodwill or excess.

(l) Intangible assets

Patents, trademarks and licenses

Patents, trademarks and licenses are recorded at cost less accumulated amortisation and impairment. Amortisation is charged on a straight-line basis over their estimated useful lives of 10 years. The estimated useful life and amortisation method is reviewed at the end of each annual reporting period.

Research and development costs

Expenditure on research activities is recognised as an expense in the period in which it is incurred. Where no internally-generated intangible asset can be recognised, development expenditure is recognised as an expense in the period as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognised if, and only if, all of the following are demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset; how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Internally-generated intangible assets in respect of development costs are stated at cost less accumulated amortisation and impairment and are amortised on a straight-line basis over their estimated useful life of 5-10 years commencing from the date that revenue results.

Registration costs

Items of expenditure on registrations are capitalised to the extent that such costs can be measured reliably, future economic benefits are attributable to the expenditure, and it is probable that such future economic benefits will eventuate.

Any capitalised registration costs are amortised over a period of 5 - 10 years in which the corresponding benefits are expected to arise, commencing from commercial sales to any of the countries for which the registration costs contributed to a successful registration.

The unamortised balance of registration costs capitalised in previous periods is reviewed regularly at each reporting date, to ensure the criteria for deferral continue to be met. Where such costs are no longer recoverable, they are written off as an expense in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

Brand names

Brand names arising on acquisition of a business are carried at cost as established at the date of acquisition of the business less any applicable impairment charge (if any). They are not amortised but subject to annual tests for impairment. For the purposes of impairment testing, brand names are allocated to the relevant Group cash generating unit to which they relate.

(m) Inventories

Inventories are valued at the lower of cost and net realisable value. Costs, including an appropriate portion of fixed and variable overhead expenses, are assigned to inventory on hand by the method most appropriate to each particular class of inventory, with the majority being valued on a first in first out basis. Net realisable value represents the estimated selling price less all estimated costs of completion and costs to be incurred in marketing, selling and distribution.

(n) Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. The company currently does not have any finance leases. All other leases are classified as operating leases.

Operating lease payments are recognised as an expense on a straight-line basis over the lease term, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed.

(o) Financial liabilities

Trade payables and other accounts payable are classified as financial liabilities and are recognised when the company becomes obliged to make future payments resulting from the purchase of goods and services. Financial liabilities are initially measured at fair value, net of transaction costs.

Financial liabilities are subsequently measured at amortised cost using the effective interest rate method, with interest expense recognised on an effective yield basis.

The effective interest rate method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or where appropriate, a shorter period.

(p) Plant and equipment

Plant and equipment and leasehold improvements are stated at cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item. In the event that settlement of all or part of the purchase consideration is deferred, cost is determined by discounting the amounts payable in the future to their present value as at the date of the acquisition. Other than the charge over the groups assets held in relation to the bank bill loan, all other assets are not encumbered by any additional charge or mortgage.

Depreciation

Depreciation is provided on plant and equipment and is calculated on a straight-line basis so as to write off the cost of each asset over its expected useful life to its estimated residual value. Leasehold improvements are depreciated over the period of the lease or estimated useful life, whichever is the shorter, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each annual reporting period.

The following estimated useful lives are used in the calculation of depreciation:

Leasehold improvements	5-10 years
Plant and equipment	4 -10 years

(q) Provisions

Provisions are recognised when the Group has a present obligation, the future sacrifice of economic benefits is probable, and the amount of the provision can be measured reliably.

The amount recognised as a provision is the best estimate of the consideration required to settle the present obligation at reporting date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cashflows estimated to settle the present obligation, its carrying amount is the present value of those cashflows.

When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, the receivable is recognised as an asset if it is probable that recovery will be received and the amount of the receivable can be measured reliably.

Dividends

A liability is recognised for dividends when they have been declared, determined or publicly recommended by the directors on or before the reporting date.

(r) Revenue recognition

Sale of goods

Revenue from the sale of goods is recognised when the company has transferred control of the product to the buyer. Settlement and volume discounts granted to customers are accounted as offsets against sales.

Interest income

Interest income is recognised on a time proportionate basis that takes into account the effective yield on the financial asset.

(s) Share based payments

Equity-settled share-based payments granted are measured at fair value at the date of grant. Fair value is measured by use of a Monte Carlo valuation model.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the company's estimate of options that will eventually vest.

The fair value determined at the grant date of the equity settled share based payments is expensed on a straight line based over the vesting period, based on the Group's estimated of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of the reporting period, the Group revises its estimate of the number of equity instruments expected to vest and the impact of any revision on the original estimates is also recognised in the profit and loss.

(t) Research and development recoveries

R&D tax credits receivable as compensation for expenses or losses already incurred by the Company with no future related costs are recognised in profit or loss in the period in which they are quantified and become receivable. The company applies the income tax approach for the accounting and presentation of the R&D tax credit. Accordingly, the tax benefit is presented as a reduction of income tax expense in the Statement of Profit or loss and other Comprehensive Income.

(u) Application of new and revised Accounting Standards

In the current year, the Group has applied an amendment to AASBs issued by the Australian Accounting Standards Board (AASB) that are mandatorily effective for an accounting period that begins on or after 1 July 2017, and therefore relevant to the Group for the current year end:

- AASB 1048 Interpretation of Standards
- AASB 2016-1 Amendments to Australian Accounting Standards – Recognition of Deferred Tax Assets for Unrealised Losses.
- AASB 2016-2 Amendments to Australian Accounting Standards - Disclosure Initiative: Amendments to AASB107.
- AASB 2017-2 Amendments to Australian Accounting Standards – Further Annual Improvements 2014-2016.

The application of these amendment does not have any material impact on the disclosures or the amounts recognised in the Group's consolidated financial statements.

Standards and Interpretations in issue not yet adopted

At the date of authorisation of the financial statements, the Standards and Interpretations that were issued but not yet effective are listed below. The Company does not expect that upon adoption that there will be any significant impact on the financial statements.

Standard/Interpretation	Effective for annual reporting periods beginning on or after	Expected to be initially applied in the financial year ending
AASB 9 'Financial Instruments'	1 January 2018	30 June 2019
AASB 15 'Revenue from Contracts with Customers', AASB 2014-5 'Amendments to Australian Accounting Standards arising from AASB 15', AASB 2015-8 'Amendments to Australian Accounting Standards – Effective Date of AASB 15', and AASB 2016-3 'Amendments to Australian Accounting Standards – Clarifications to AASB 15'	1 January 2018	30 June 2019
Interpretation 22 'Foreign Currency Transactions and Advance Consideration'	1 January 2018	30 June 2019
AASB 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Share-based payment Transactions	1 January 2018	30 June 2019
AASB 2017-2 'Amendments to Australian Accounting Standards - Further Annual Improvements 2015-2017 Cycle'	1 January 2019	30 June 2020
AASB 16 'Leases'	1 January 2019	30 June 2020
Interpretation 23 – Uncertainty over Income Tax Treatment	1 January 2017	30 June 2018
AASB 15 'Revenue from Contracts with Customers' - Following an assessment of the requirements of this standard, the Group expects that there will not be a material impact on the revenue recognition criteria currently applied by The Group.	The Group will adopt AASB 15 from 1 July 2018.	
AASB 9 Financial Instruments - This standard includes new requirements for classification and measurement, impairment and hedge accounting of financial instruments compared with the requirements of AASB 139 Financial Instruments: Recognition and Measurement. Following a detailed assessment of the requirements of the standard, the Group expects that there will not be a material impact on the financial statements on application.	The Group will adopt AASB 9 from 1 July 2018.	
AASB 16 Leases - This standard contains requirements about lease classification and recognition, measurement and presentation and disclosures of leases for lessees and lessors. On the adoption of AASB 16, MVP will recognise office leases as right-of-use assets and lease liabilities. The occupancy expenses will be replaced by depreciation charge and finance cost.	The Group have yet to assess the financial impact of the adoption of this Standard in future periods on the financial statements of the Group.	

Change in accounting policy – deferred tax measurement relating to indefinite life intangible assets

During the period, the IFRS Interpretations Committee issued its agenda decision related to the expected manner of recovery of indefinite life intangible assets. The Committee was asked to clarify how an entity determines the expected manner of recovery of an intangible asset with an indefinite useful life for deferred tax measurement purposes. The Committee indicated that the fact that an entity does not amortise an indefinite life intangible asset does not necessarily mean that the carrying amount will be recovered only through sale and not use. Therefore, the entity should determine the expected manner of recovery of the carrying amount of the intangible asset. Previously the Group measured deferred tax liabilities on the assumption of the tax consequences that would arise solely from the sale of the assets. Under its new policy, the Group considers its expected manner of recovery.

The Group has implemented this guidance on a retrospective basis as a change in accounting policy to AASB 112 Income Taxes. The impact on the 30 June 2018 financial statements was to increase Goodwill and Deferred Tax Liabilities by \$221,500.

2. Critical accounting judgements and key sources of estimation uncertainty

The following are the key assumptions concerning the future, and other key sources of estimation uncertainty at the balance sheet date, that have significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

Impairment of goodwill

Determining whether goodwill is impaired requires an estimation of the value in use of the cash-generating units to which goodwill has been allocated. The value in use calculation requires the entity to estimate the future cash flows expected to arise from the cash generating unit and a suitable discount rate in order to calculate the present value.

The carrying amount of goodwill at the balance sheet date was \$9,095,000 (2017: \$9,095,000). Details of the impairment calculation are provided in note 13.

Useful life of capitalised registration costs

Capitalisation of other intangible assets requires judgement by management to determine whether:

- Expenditure relates to development activity and not research activity,

- Expected future economic benefits attributable to the intangible assets will flow to the Group,
- The timing of the commencement of the amortisation of the asset which should commence when revenue has been generated, and
- The useful lives assigned to each individual category are appropriate.

Details of the other intangible assets are provided in Note 14.

Useful life of plant and equipment

Refer note 1(p) for further discussion on useful life assessments relating to plant and equipment.

Deferred tax assets

The carrying amount of deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will eventuate to enable recovery of the asset.

Going Concern

The FY18 Financial statements have been prepared on a going concern basis. The going concern assumption continues to apply to Medical Developments International Ltd as at 30 June 2018 as the Group is profitable, generates positive operating cash flows, has completed a capital raising subsequent to year end, has access to a loan facility and continues to be in a positive net asset position, which enables the Group to meet its debts and obligations as and when they fall due.

3. Segment information

Products and services within each business segment

For management purposes, the company is organised into three business units – Pharmaceuticals, Medical Devices and Veterinary products. These units are the basis on which the company reports its primary segment information. The principal products and services of each of these divisions are as follows:

- Pharmaceuticals – the sale of Pentrox® primarily within Australia and the UK and some sales in New Zealand, Eastern Europe, the Middle East, and South Africa.
- Medical Devices – the sale of medical devices, particularly the Space Chamber and Breath-Alert Peak-Flow meters, primarily within Australia and New Zealand, but with some sales in Asia, Europe, the Middle East and North America.
- Veterinary Products – the sale of veterinary products within Australia, Europe, and Asia.

No operating segments have been aggregated in arriving at the reportable segments of the group.

There have also been no sales between reportable segments.

Segment revenues and results

	Pharmaceuticals		Medical Equipment		Veterinary Equipment		Unallocated		Total	
	2018 \$'000	2017 \$'000	2018 \$'000	2017 \$'000	2018 \$'000	2017 \$'000	2018 \$'000	2017 \$'000	2018 \$'000	2017 \$'000
Revenues										
External revenue (gross)	10,246	11,029	6,928	7,195	755	680			17,929	18,904
Sales discounts and claims	-	-	(468)	(557)	-	-			(468)	(557)
Total external revenue (net)	10,246	11,029	6,460	6,638	755	680	-	-	17,461	18,347
Results										
Segment results	4,425	5,288	420	712	259	244			5,104	6,244
Unallocated							(2,881)	(2,452)	(2,881)	(2,452)
Profit before interest, income tax Depreciation & Amortisation										
Depreciation & Amortisation	(1,417)	(1,086)	(192)	(143)	(37)	(16)	(137)	(88)	(1,783)	(1,333)
Profit before interest and tax	3,008	4,202	228	569	222	228	(3,018)	(2,540)	440	2,459
Net Interest							(139)	4	(139)	4
Profit before income tax expense							(3,157)	(2,536)	301	2,463
Income tax expense							(58)	(643)	(58)	(643)
Net profit for the period from continuing operations							(3,215)	(3,179)	243	1,820
Assets and Liabilities										
Assets	35,046	26,415	9,981	9,813	1,120	1,063	3,401	4,473	49,548	41,764
Liabilities	-	-	-	-	-	-	28,507	20,164	28,507	20,164
Other Segment Information										
Acquisition of segment assets	10,062	8,141	328	481	63	64	224	728	10,677	9,414

The accounting policies of the reportable segments are the same as the Group's accounting policies described in Note 1. This is the measure reported to the chief operating decision maker for the purposes of resource allocation and assessment of segment performance.

Liabilities are not disclosed per segment as it is not possible to track these on a segment basis.

Revenue from major products and services

Revenue from major products and services has not been presented as it is not considered practicable to do so.

Geographical information

The Group operates in two principal geographical areas: Australia (country of domicile); and 'International' comprising predominately Europe, North America, Middle East, Asia and South Africa.

The Group's revenue from continuing operations from external customers and information about its non-current assets by location of assets are detailed below:

Geographical Information	Revenue from external customers 2018 \$'000	%	Revenue from external customers 2017 \$'000	%
Australia	9,705	54.1%	10,557	55.8%
International	8,224	45.9%	8,347	44.2%
	17,929	100.0%	18,904	100.0%

The Group's non-current assets by location are detailed below:

Non-Current Segment Assets	Australia \$'000	Overseas \$'000	Total \$'000
Leasehold improvements at cost	205	-	205
Plant and equipment at cost	7,616	254	7,870
Goodwill at gross carrying amount	9,095	-	9,095
Other intangible assets at cost	22,549	-	22,549
Deferred tax asset	1,044	38	1,082
	40,509	292	40,801

Information about major customers

The Group had no individual customers who contributed 10% or more to the Group's total 2018 sales revenue.

4. Items included in profit and loss

	2018 \$'000	2017 \$'000
(a) Revenue and other income		
Gross revenue from sale of goods	15,763	17,003
Sales discounts and claims	(468)	(557)
Upfront and milestone income	2,166	1,901
Total Revenue (net)	17,461	18,347
Interest revenue - bank deposits	1	11
	17,462	18,358
(b) Expense items included in profit and loss		
Profit before income tax has been arrived at after charging the following expenses:		
Depreciation of non-current assets	(620)	(330)
Amortisation of non-current assets	(1,162)	(1,004)
Research & development costs	(156)	(111)
Operating lease rental expenses - minimum lease payments	(322)	(321)
Share based payments (equity settled)	-	(13)
Loss on foreign currency transactions	(103)	(196)
	(3,363)	(3,975)
Finance Expenses		
Interest on bank loans	(134)	-
Interest on other loans/hire purchase arrangements	(6)	(7)
	(140)	(7)
Employee benefit expense:		
Short-term employee benefits	(3,945)	(3,893)
Superannuation contributions	(560)	(525)

5. Income taxes

	2018 \$'000	2017 \$'000
(a) Income tax recognised in profit or loss		
Tax expense comprises:		
Current tax expense	2,247	1,199
Deferred tax expense relating to origination and reversal of temporary differences	(2,319)	(610)
Adjustments recognised in the current year in relation to the current tax of prior year	23	54
Deferred tax expense relating to change in company tax rate	107	-
Total tax expense	58	643

The prima facie income tax expense on pre-tax accounting profit reconciles to the income tax expense in the financial statements as follows:

	2018 \$'000	2017 \$'000
Profit from operations	301	2,463
Income tax calculated at 27.5% (2017: 30%)	83	739
Research & development expense	(167)	(133)
Non deductible expenses	2	6
Adjustments recognised in relation to the current tax of prior year	23	54
Deferred tax expense relating to change in company tax rate	107	-
Effect of profit or loss items eliminated on consolidation	-	(11)
Effect of different tax rates of subsidiaries operating in other jurisdictions	10	(12)
Income tax expense recognised in the Statement of Profit or Loss and Other Comprehensive Income	58	643

The tax rate used in the above reconciliation is the corporate tax rate of 27.5% payable by Australian corporate entities on taxable profits under Australian tax law.

(b) Income tax recognised directly in equity

No current and deferred tax amounts have been charged directly to equity during the period (2017: \$nil)

(c) Current tax assets/liabilities

Income tax receivable/(payable)	96	209
---------------------------------	----	-----

MVP has received upfront payments during the current and prior years and for tax purposes these are deemed as assessable on a cash received basis or when unconditional entitlement arises. This has resulted in the recognition of a net deferred tax asset.

(d) Deferred tax asset (non-current)

Temporary differences	4,644	5,357
Tax losses	2,391	51
	7,035	5,408

(e) Deferred tax liabilities

Temporary differences	(5,953)	(4,347)
Net Deferred Tax Asset	1,082	1,061

Taxable/Deductible temporary differences arise from the following:

2018	Opening balance \$'000	Charged to income \$'000	Closing balance \$'000
Deferred tax assets/(liabilities):			
Accrued expenses	131	(14)	117
Deferred revenue	4,948	(695)	4,253
Other Intangibles	(4,103)	(1,625)	(5,728)
Property, Plant & Equipment	2	(6)	(4)
Provisions	276	(2)	274
Goodwill	(221)	-	(221)
Unrealised foreign exchange losses	(23)	23	-
	1,010	(2,319)	(1,309)

2017	Opening balance \$'000	Charged to income \$'000	Closing balance \$'000
Deferred tax assets/(liabilities):			
Accrued expenses	135	(4)	131
Deferred revenue	4,417	531	4,948
Other Intangibles	(2,998)	(1,105)	(4,103)
Property, Plant & Equipment	8	(6)	2
Provisions	209	67	276
Goodwill	(221)	-	(221)
Unrealised foreign exchange losses	70	(93)	(23)
	1,620	(610)	1,010

6. Key management personnel compensation

The aggregate compensation of the key management personnel of the company and the Group is set out below:

	2018 \$'000	2017 \$'000
Short-term employee benefits	830	867
Post employment benefits	88	92
Long term employee benefits	20	15
Share based payments	-	13
	938	987

7. Remuneration of auditors

	2018 \$	2017 \$
Audit or review of the financial report	79,785	82,685
Taxation services	29,790	20,675
Other services	-	5,400
	109,575	108,760

The auditor of the entity is Deloitte Touche Tohmatsu. The other services in the prior year related to additional assurance services.

8. Current receivables

	2018 \$'000	2017 \$'000
Trade receivables	4,233	5,122
GST recoverable	54	110
	4,287	5,232

The average credit period on sales of goods to domestic customers is 30 days, international customers 60 days. No interest is charged on trade receivables.

Included in the trade receivable balance are debtors with a carrying amount of \$368,225 (2017: \$109,640) which are past due at the reporting date for which the Group has not provided as there has not been a significant change in credit quality and the amounts are still considered recoverable. The Group does not hold any collateral over these balances.

Ageing of past due but not impaired	2018 \$'000	2017 \$'000
60-90 days	84	26
> 90 days	284	83
Total	368	109

In determining the recoverability of trade receivables, the Group considers any change in the credit quality of the trade receivable from the date the credit was initially granted up to the reporting date. The concentration of credit risk is limited due to the fact that the customer base is large and unrelated.

The directors believe that there is no further credit provision required in excess of the allowance for doubtful debts.

9. Current inventories

	2018 \$'000	2017 \$'000
Raw materials:		
At cost	1,111	1,115
Work in progress:		
At cost	647	331
Finished goods:		
At cost	1,479	978
Provision for obsolescence	(40)	-
	3,197	2,424

The provision for obsolescence at 30 June 2018 represented predominantly obsolete packing materials.

10. Other current assets

	2018 \$'000	2017 \$'000
Prepayments	372	319
Other receivables	1	4
	373	323

11. Subsidiaries

Details of the Group's subsidiaries at the end of the reporting period are as follows.

Name of Subsidiary	Principle activity	Place of incorporation and operation	Proportion of ownership interest and voting power held by the Group	
			2018	2017
Medical Developments UK Limited	Distribution of pharmaceutical drug and medical and veterinary equipment	United Kingdom	100%	100%
Medical Developments USA Inc.	Distribution of medical devices	United States of America	100%	100%

12. Property, plant & equipment

	Leasehold improvements at cost \$'000	Manufacturing Facility	Plant and equipment at cost \$'000	Total \$'000
Gross carrying amount				
Balance at 30 June 2016	415	-	4,809	5,224
Additions	80	-	4,273	4,353
Transfers	-	3,818	(3,818)	-
Balance at 30 June 2017	495	3,818	5,264	9,577
Additions	68	269	1,720	2,057
Balance at 30 June 2018	563	4,087	6,983	11,634
Accumulated depreciation				
Balance at 30 June 2016	(238)	-	(2,372)	(2,610)
Depreciation expense	(57)	-	(273)	(330)
Balance at 30 June 2017	(295)	-	(2,645)	(2,940)
Depreciation expense	(63)	(136)	(421)	(620)
Balance at 30 June 2018	(358)	(136)	(3,066)	(3,560)
Net book value				
As at 30 June 2017	200	3,818	2,619	6,637
As at 30 June 2018	205	3,952	3,918	8,075

13. Goodwill

	2018 \$'000	2017 \$'000
Gross carrying amount		
Balance at beginning of financial year	8,874	8,874
Additions	-	-
Balance at end of financial year	8,874	8,874
Net book value		
Balance at beginning of financial year	8,874	8,874
Balance at end of financial year	8,874	8,874

During the year, the company assessed the recoverable amount of goodwill and determined that there was no impairment (2017: \$nil).

Allocation of goodwill to cash-generating units

Goodwill has been allocated for impairment testing purposes to three individual cash-generating units: pharmaceutical business, medical devices business and veterinary equipment business. The carrying amount of goodwill allocated to cash-generating units is as follows:

	2018 \$'000	2017 \$'000
Pharmaceuticals	3,808	3,808
Medical devices	4,706	4,706
Veterinary equipment	581	581
	9,095	9,095

The recoverable amount of all three cash-generating units is based on a value in use calculation for each unit which uses cash flow projections based on a five-year projection period and terminal value. The Board of Directors approved financial budget for the following year is used to determine the cash flows for year 1.

Recoverable amount testing has been based on EBITDA growth rates for years 2-5 of:

- Pharmaceuticals: 12.5% based on expansion into new markets
- Medical Devices: 15% based on expansion of existing markets
- Veterinary Equipment: 7.5% based on expansion of existing markets

A terminal value after 5 years based on a long-term growth rate of 2.5%, and a pre-tax discount rate of 14.66% per annum (2017: 14.64% per annum) have been used to calculate the carrying value of the intangible assets.

The key assumptions used in the value in use calculations for all units are:

- EBITDA growth – described above; and
- Gross margin – it is assumed that gross margin of the Pharmaceutical & Medical Devices segments will be maintained following investment and activities aimed at improvement in the manufacturing process and procedures.

Management believes that any reasonably possible change in the key assumptions on which the recoverable amount for each of the three units is based would not cause the carrying amounts to exceed their recoverable amounts.



14. Other intangible assets

2018	Development \$'000	Patents & trademarks \$'000	Capitalised registration costs \$'000	Brand names \$'000	Other \$'000	Total \$'000
Gross carrying amount						
Balance at 30 June 2016	1,974	566	9,286	738	644	13,208
Additions	47	189	3,865	-	223	4,324
Balance at 30 June 2017	2,021	755	13,151	738	867	17,532
Additions	1,062	288	7,270	-	-	8,620
Balance at 30 June 2018	3,083	1,043	20,421	738	867	26,152
Accumulated amortisation						
Balance at 30 June 2016	(206)	(226)	(951)	-	(53)	(1,436)
Amortisation expense	(88)	(65)	(762)	-	(89)	(1,004)
Balance at 30 June 2017	(294)	(291)	(1,713)	-	(142)	(2,440)
Amortisation expense	(203)	(90)	(783)	-	(86)	(1,162)
Balance at 30 June 2018	(497)	(381)	(2,496)	-	(228)	(3,602)
Net book value						
As at 30 June 2017	1,727	464	11,438	738	725	15,092
As at 30 June 2018	2,586	662	17,924	738	639	22,549

The amortisation charge for the year of \$1,162,000 (2017: \$1,004,000) has been included in administration expenses. For an explanation of amortisation periods refer Note 1(i).

15. Current trade and other payables

	2018 \$'000	2017 \$'000
Trade payables (i)	2,063	1,785
Accrued expenses	1,116	899
Employee benefits payable	46	51
PAYG withholding tax payable	2	2
	3,227	2,737

(i) The average credit period on purchase of goods is 30 days. No interest is charged on trade payables. The company has financial risk management policies in place to ensure that all payables are paid within the credit timeframe.

16. Borrowings

	2018 \$'000	2017 \$'000
Secured - at amortised cost		
Hire Purchase (i)	7	39
Hire Purchase (ii)	4	17
Bank Bill (iii)	8,969	-
Other (iv)	272	373
	9,252	429
Current	102	146
Non-current	9,150	283
	9,252	429

Summary of borrowing arrangements

- (i) On 1 March 2013 the Group entered into a commercial loan agreement to fund the purchase of a new bottling station. The current weighted-average effective interest rate on the loan is 6.83% p.a. The agreement is secured by a registered charge over the equipment.
- (ii) On 4 September 2013 the Group entered into a Hire Purchase Agreement in relation to plant and equipment. The term is 5 years and the current weighted average effective interest rate on the loan is 6.26%. The agreement is secured by a registered charge over the equipment financed.
- (iii) The Bank Bill Facility with a variable interest rate and 90 day roll over period was renegotiated during the year and has a limit of \$11m. The current weighted-average effective interest rate on the bill is 3.59% p.a. As at 30 June 2018, the facility has been drawn down to \$8.969m. The Bank Bill is secured by a registered charge over all of the Group's assets.
- (iv) On 29 June 2012, the group entered into an agreement with the Commonwealth Scientific and Industrial Research Organisation ('CSIRO') to fund the development of a new production process for the pain-relieving ingredient used in Pentrox®. Funding is receivable at the commencement of each of three stages of development and is payable over a three year term upon the completion of the relevant stage. As at 30 June 2018, the stage 1a, 1b and Stage 2 are complete. Should MDI default on the loan, CSIRO has the option to convert the debt into shares in MDI at fair market value. This funding is interest-free until the first anniversary of the completion of stages 1a and 2 and is then calculated at the Westpac Bank Lending Rate at the date the relevant note was issued, plus 2%.
- (v) The Group has an overdraft facility of \$200,000. As at 30 June 2018, this remains unused.

17. Current provisions

	2018 \$'000	2017 \$'000
Employee benefits	356	346

18. Non-current provisions

	2018 \$'000	2017 \$'000
Employee benefits	206	159

The company has 55 full time equivalent employees at 30 June 2018 (2017: 53)

19. Other liabilities

	2018 \$'000	2017 \$'000
Revenue received in advance	14,785	15,886
Unearned government grant income	681	607
	15,466	16,493
Current	2,418	2,077
Non-current	13,048	14,416
	15,466	16,493

MVP has received additional upfront and milestone payments during the current year. For accounting purposes these non-refundable payments are deferred and amortised into the income statement over the term of the agreement to which the payments relate. As at 30 June 2018 \$14.785 (2017: \$15.886m) remains unamortised.

Unearned government grant income represents funds received through the Commercial Ready Programme from the Federal Government and Futures Industries Manufacturing Program of the Victorian State Government.

20. Issued Capital

20(a) Fully paid ordinary shares

	2018 No.	2018 \$'000	2017 No.	2017 \$'000
Fully paid ordinary shares				
Balance at beginning of financial year	58,975,176	15,008	57,960,056	11,916
Shares Issued - Dividends Reinvestment Plan	196,916	1,123	215,120	1,107
Share issued - Employee Share Scheme	-	-	800,000	2,000
Capital raising costs	-	(10)	-	(15)
Balance at end of financial year	59,172,092	16,121	58,975,176	15,008

Fully paid ordinary shares carry one vote per share and carry the right to dividends.

21. Reserves

	2018 \$'000	2017 \$'000
(a) Foreign currency translation reserve		
Balance at beginning of year	(67)	(61)
Exchange differences arising on translating the foreign operations	47	(6)
Balance at end of year	(20)	(67)

Exchange differences relating to the translation of the results and net assets of the Group's foreign operations from their functional currencies to the Group's presentation currency (i.e. Australian dollars) are recognised directly in other comprehensive income and accumulated in the foreign currency translation reserve. Gains and losses on hedging instruments that are designated as hedging instruments for hedges of net investments in foreign operations are included in the foreign currency translation reserve. Exchange differences previously accumulated in the foreign currency translation reserve (in respect of translating both the net assets of foreign operations and hedges of foreign operations) are reclassified to profit or loss on the disposal of the foreign operation.

	2018 \$'000	2017 \$'000
(b) Employee equity-settled benefits reserve		
Balance at beginning of year	331	318
Share-based payment recognised	-	13
Balance at end of year	331	331

The above equity settled employee benefits reserve related to share options granted by the company to its CEO under its employee share option plan.

	2018 \$'000	2017 \$'000
(c) CSIRO Option Reserve		
Balance at beginning of year	-	-
Option issues for services provided	400	-
Balance at end of year	400	-

The above CSIRO option reserve at 30 June 2018, relates to 72,056 options over ordinary shares of the Company. These options are in relation to the MVP/CSIRO Manufacturing Technologies Project announced on 5 June 2017. Options are exercisable for no consideration when a developed technology has been proven to be commercially viable. The share options granted to the CSIRO carry no rights to dividends and no voting rights.

22. Retained earnings

	2018 \$'000	2017 \$'000
Balance at beginning of financial year	6,328	6,852
Dividends paid	(2,362)	(2,344)
Net profit attributable to members	243	1,820
Balance at end of financial year	4,209	6,328

23. Earnings per share

	2018 Cents per share	2017 Cents per share
Basic earnings per share	0.4	3.1
Diluted earnings per share	0.4	3.1

Basic earnings per share

The earnings and weighted average number of ordinary shares used in the calculation of basic earnings per share are as follows:

	2018 \$'000	2017 \$'000
Earnings	243	1,820

	2018 No.	2017 No.
Weighted average number of ordinary shares	59,080,452	58,711,471

Diluted earnings per share

Earnings used in the basic earnings per share calculation are identical to those used for the diluted earnings per share calculation. There potentially dilutive options outstanding as at 30 June 2018.

	2018 No.	2017 No.
Weighted average number of ordinary shares used in the calculation of basic EPS	59,080,452	58,711,471
Shares deemed to be issued for no consideration in respect of:		
Dilutive Options	-	-
Weighted average number of ordinary shares for diluted EPS	59,080,452	58,711,471

24. Dividends

An interim dividend of 2 cents per share was declared and paid in the current year and a final dividend of 2 cents per share was declared in respect of the year ended 30 June 2018.

The interim dividend paid during the 30 June 2018 year resulted in the company paying dividends of \$649,000 and the balance of \$533,000 issued as shares under the Dividend Reinvestment Plan.

The 2017 full year dividend paid during the 30 June 2018 year resulted in the company paying dividends of \$590,000 and the balance of \$590,000 issued as shares under the Dividend Reinvestment Plan.

	2018		2017	
	cents per share	\$'000	cents per share	\$'000
Recognised amounts				
<i>Fully paid ordinary shares</i>				
Interim dividend - fully franked	2.0	1,182	2.0	1,167
2016 full year dividend - fully franked	2.0	1,180	2.0	1,177
	4.0	2,362	4.0	2,344
Unrecognised amounts				
<i>Fully paid ordinary shares</i>				
Final dividend - fully franked	2.0	1,183	2.0	1,180
		1,183		1,180

	2018 \$'000	2017 \$'000
Adjusted franking account balance	2,286	3,127

25. Operating leases

Operating leases primarily relate to factory leases with remaining lease terms ranging from 0.5 to 7.5 years. The company does not have the option to purchase the leased asset at the expiry of the lease period.

	2018 \$'000	2017 \$'000
Non cancellable operating lease payments:		
Not longer than 1 year	385	373
Longer than 1 year and not longer than 5 years	1,845	1,348
Greater than 5 years	496	1,203
	2,726	2,924

26. Commitments for expenditure

(a) Capital expenditure commitments

There were no capital expenditure commitments at 30 June 2018.

27. Related party disclosures

There were no related party transactions during the 2018 financial year.

Balances and transactions between the Company and its subsidiaries which are related parties of the company have been eliminated on consolidation and are not disclosed in this note.

Please also refer to note 6 for details of Key Management Personnel compensation.

28. Subsequent events

- On 18 July 2018 the Company announced it has agreed to a Long-Term Incentive Plan 'LTIP' with Mr. John Sharman (CEO) to encourage his long-term commitment to the business.

Under the plan Mr. Sharman has been granted 300,000 options with a strike price of \$0.01. The options will only vest on the earlier of FDA approval of Pentrox® for sale in the USA or the company receives an unconditional takeover offer worth more than \$300m.

When the LTIP has met its vesting criteria, Mr. Sharman will have 3 months to exercise the options, after which the options will lapse. 60% of any new shares issued by exercising options will be escrowed for a period of 12 months from issue date. In the case of an unconditional takeover, the escrow conditions will not apply.

All outstanding options will be cancelled if Mr. Sharman leaves or he is no longer employed by MVP for any reason.

- On 25 July 2018 the Company advised that it met with the Food and Drug Administration ('FDA') for the United States of America. The FDA has advised that the clinical program for Pentrox® to be approved for sale in the USA is to be put on hold pending a letter outlining outstanding issues and concerns. That letter was expected within two months of the announcement.
- On 8 August 2018 The Company announced that it had completed a capital raising by way of private placement to sophisticated and institutional investors that had raised \$17m. The Company announced that it would also invite existing shareholders to invest in the company via a Share Purchase Plan (SPP). The details relating to the SPP are expected to be finalised and released in a formal offer document by Wednesday 22 August 2018.
- On the 17th August 2018 the Board of Directors declared a fully franked final dividend of 2 cents per share to the holders of fully paid ordinary shares as at the record date of 31 August 2018, to be paid to the shareholders on the 5 October 2018. This dividend has not been included as a liability in these financial statements.

There has not been any other matter or circumstance that has arisen that has significantly affected, or may significantly affect the operations of the company, the results of those operations, or the state of affairs of the company in future years.

29. Notes to the Consolidated Statement of Cash Flows

	2018 \$'000	2017 \$'000
(a) Reconciliation of cash and cash equivalents		
For the purposes of the Consolidated Statement of Cash Flows, cash includes cash on hand and in banks. Cash at the end of the financial year as shown in the Consolidated Statement of Cash Flows is reconciled to the related item in the Statement of Financial Position as follows:		
Cash and cash equivalents	794	1,691
	794	1,691
(b) Reconciliation of profit for the period to net cash flows from operating activities		
Profit for the period	243	1,820
Interest received	(1)	(11)
Depreciation and amortisation of non-current assets	1,782	1,334
Net unrealised foreign exchange (gain)/loss	11	(53)
Share based payments	-	13
Loss on disposal of property, plant and equipment	-	-
Increase/(decrease) in tax payable	113	(4,333)
Decrease/(increase) in deferred tax asset	(21)	646
Movements in working capital		
Decrease/(increase) in assets:		
Current receivables	945	2,288
Current inventories	(773)	243
Other current assets	(50)	(79)
Increase/(decrease) in liabilities:		
Current payables	490	219
Current provisions	10	92
Other liabilities	(1,006)	1,787
Non-current provisions	47	45
Net cash from operating activities	1,790	4,011
(c) Financing facilities		
Unsecured bank overdraft facility, reviewed annually and payable at call:		
Amount unused	200	200
	200	200
Bank bill facility with a 90 day roll over period:		
Amount used	8,969	-
Amount unused	2,031	4,440
	11,000	4,440

30. Financial Instruments

(a) Capital risk management

The Group manages its capital to ensure that it will be able to continue as a going concern while maximising the return to stakeholders. The Group does not enter into or trade financial instruments, including derivatives, for speculative purposes.

The capital structure of the Group consists of net debt (borrowings as detailed in note 16) and equity of the Group (comprising issued capital, reserves, retained earnings, and cash and cash equivalents as detailed in notes 20, 21, 22, and 29(a), respectively).

The Group's Audit and Risk Committee reviews the capital structure of the Group on a semi-annual basis. As part of this review, the committee considers the cost of capital and the risks associated with each class of capital. The gearing ratio at 30 June 2018 is 40% (see below).

	2018 \$'000	2017 \$'000
Debt (i)	9,252	429
Cash and bank balances	(794)	(1,691)
Net debt / (cash)	8,458	(1,262)
Equity (ii)	21,041	21,600
Net debt to equity ratio	40%	-6%

(i) Debt is defined as long-term and short-term borrowings as described in note 16.

(ii) Equity includes all capital and reserves of the group that are managed as capital.

The bank bill facility included a financial covenant whereby the debt service cover ratio must be greater than 2.0 times. From 1 July 2018 an Operating Leverage ratio of less than 2.50 times is also required. Monitoring of said covenants is performed monthly by management and signed off quarterly by management.

There have been no breaches in the current year and there are no forecasted breaches for forthcoming periods.

(b) Significant accounting policies

Details of significant accounting policies and methods adopted, including the criteria for recognition, the basis of measurement and the basis on which revenues and expenses are recognised, in respect of each class of financial asset, financial liability and equity instrument are disclosed in note 1 to the financial statements.

These policies were consistent throughout the current year and the prior year.

(c) Financial risk management objectives

The Group's finance function provides services to the business, co-ordinates access to domestic and international financial markets, monitors and manages financial risks relating to the operations of the Group. These risks include market risk (including currency risk, fair value interest rate risk and price risk), credit risk, liquidity risk and cash flow interest rate risk.

(d) Credit risk management

Credit risk refers to the risk that a counter party will default on its contractual obligations resulting in financial loss to the Group. The Group has adopted a policy of only dealing with creditworthy counterparties. The Group's exposure is continually monitored and the aggregate value of transactions concluded is spread amongst approved counterparties.

Trade receivables consist of a large number of customers. Ongoing credit evaluation is performed on the financial condition of these accounts receivable and advance payments are requested where deemed appropriate.

The carrying amount of financial assets recorded in the financial statements, net of any allowance for losses, represents the Group's maximum exposure to credit risk without taking account of the value of any collateral or other security obtained.

Apart from the three largest customers of the Group (refer to Notes 3 and 8), the Group does not have significant credit risk exposure to any single counterparty or any group of counterparties having similar characteristics. The Group defines counterparties as having similar characteristics if they are related entities. Concentration of credit risk to any other counterparty did not exceed 5% of gross monetary assets at any time during the year.

(e) Foreign currency risk management

The Group undertakes certain transactions denominated in foreign currencies, hence exposures to exchange rate fluctuations arise.

The carrying amount of the Group's foreign currency denominated monetary assets and monetary liabilities at the reporting date is as follows:

	Liabilities		Assets	
	2018 \$'000	2017 \$'000	2018 \$'000	2017 \$'000
USD	1,512	723	1,212	1,765
GBP	126	162	1,125	1,271
NZD	22	-	287	253
EUR	-	-	148	148
CND	3	-	11	17
	1,663	885	2,784	3,455

Amounts of exposure are not currently significant and as such forward contracts and currency swap agreements are not used.

Foreign currency sensitivity analysis

The Group predominantly trades in Australian dollars (AUD), but has limited exposure to the US dollar (USD) and Great Britain Pound (GBP) based on a portion of its overseas sales and purchases.

The following table details the Group's sensitivity to a 10% increase and decrease in the Australian Dollar against the USD and GBP. 10% is the sensitivity rate used when assessing foreign currency risk internally by key management and represents management's assessment of the possible change in foreign currency rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period end for a 10% change in foreign currency rates. A positive number indicates an increase in profit or loss where the Australian Dollar strengthens against the respective currency. For a weakening of the Australian Dollar against the respective currency there would be an equal and opposite impact on the profit.

	USD Impact	
	2018 \$'000	2017 \$'000
Profit or Loss	30	(104)

	GBP Impact	
	2018 \$'000	2017 \$'000
Profit or Loss	(100)	(111)

This is attributable to the exposure outstanding on USD and GBP receivables and payables at year end in the Group. The exposure to movement in NZD, EUR, and CAD is not deemed to be significant.

(f) Fair value of financial instruments

The Directors consider that the carrying amount of financial assets and liabilities recorded at amortised cost in the financial statements approximates their respective net fair values, determined in accordance with the accounting policies disclosed in note 1 to the financial statements.

The Group does not recognise any financial instruments that are measured subsequent to initial recognition at fair value.

(g) Interest rate risk management

The Group is exposed to interest rate risk as it holds cash at floating interest rates. The following table details the Group's exposure to interest rate risk as at 30 June 2018 and 30 June 2017.

2018	Variable interest rate maturity					
	Average interest rate %	Less than 1 year \$'000	1 to 5 years \$'000	More than 5 years \$'000	Non-interest bearing \$'000	Total \$'000
<i>Financial assets</i>						
Cash	0.01%	794	-	-	-	794
Receivables	-	-	-	-	4,287	4,287
		794	-	-	4,287	5,081
<i>Financial liabilities</i>						
Payables	-	-	-	-	3,227	3,227
Borrowings	3.46%	102	9,150	-	-	9,252
		102	9,150	-	3,227	12,479

2017	Variable interest rate maturity					
	Average interest rate %	Less than 1 year \$'000	1 to 5 years \$'000	More than 5 years \$'000	Non-interest bearing \$'000	Total \$'000
<i>Financial assets</i>						
Cash	0.02%	1,691	-	-	-	1,691
Receivables	-	-	-	-	5,232	5,232
		1,691	-	-	5,232	6,923
<i>Financial liabilities</i>						
Payables	-	-	-	-	2,737	2,737
Borrowings	5.04%	146	283	-	-	429
		146	283	-	2,737	3,166

The following table details the Group's sensitivity to a 50-basis point increase or decrease in interest rates.

Interest rate risk table

	2018 \$'000	2017 \$'000
Profit or Loss	(42)	6

(h) Liquidity risk management

The Group manages liquidity risk by maintaining adequate cash reserves, banking facilities and reserve borrowing facilities by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities.

Liquidity risk table

The following table details the Group's remaining contractual maturity for its non-derivative financial liabilities. The table has been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group can be required to pay. The table includes the principal cash flows.

	Weighted average effective interest rate %	Less than 1 year \$'000	1 to 5 years \$'000	More than 5 years \$'000	Total \$'000
2018					
Payables	-	3,227	-	-	3,227
Borrowings	3.46%	102	9,150	-	9,252
		3,329	9,150	-	12,479
2017					
Payables	-	2,737	-	-	2,737
Borrowings	5.04%	146	283	-	429
		2,883	283	-	3,166

31. Parent Entity Information

The accounting policies of the parent entity, which have been applied in determining the financial information shown below, are the same as those applied in the consolidated financial statements.

Refer to note 1 for a summary of the significant accounting policies relating to the Group.

Financial Position

	30 June 2018 \$'000	30 June 2017 \$'000
Assets		
Current Assets	8,884	10,003
Non-Current Assets	40,758	31,828
Total Assets	49,642	41,831
Liabilities		
Current Liabilities	3,623	3,090
Non-Current Liabilities	24,822	16,934
Total Liabilities	28,445	20,024
Equity		
Issued capital	16,121	15,008
Reserves	731	332
Retained earnings	4,345	6,467
Total Equity	21,197	21,807

Financial Performance

	2018 \$'000	2017 \$'000
Profit for the year	240	1,666
Dividends paid	(2,362)	(2,344)
Other comprehensive income	-	-
Total comprehensive income	(2,122)	(678)

The commitments of the parent are the same as those of the overall consolidated group.

32. Additional company information

Medical Developments International Limited is a listed public company, incorporated and domiciled in Australia.

Company Secretary

Mr. Mark Edwards

Registered office and principal place of business

4 Caribbean Drive, Scoresby
VIC 3179

Tel: (03) 9547 1888

Share registry

Computershare Investor Services Pty Ltd

452 Johnston Street, Abbotsford
VIC 3067

Tel: 1300 850 505

Additional Stock Exchange Information as at 31 August 2018

Number of holders of equity securities

Ordinary share capital

63,422,092 fully paid ordinary shares held by 4,345 individual shareholders. All issued ordinary shares carry one vote per share.

Distribution of holders of equity securities

Fully paid ordinary shares

1 – 1,000	1,554
1,001 – 5,000	1,721
5,001 – 10,000	535
10,001 – 100,000	488
100,001 and over	47
	4,345
Holding less than a marketable parcel	223

SUBSTANTIAL SHAREHOLDERS	Number	%
MR DAVID JOHN WILLIAMS	9,459,584	14.93

TWENTY LARGEST HOLDERS OF EQUITY SECURITIES	Number	%
HSBC CUSTODY NOMINEES	9,682,143	15.27
MR DAVID JOHN WILLIAMS	9,459,584	14.93
J P MORGAN NOMINEES AUSTRALIA	4,457,865	7.03
SANDHURST TRUSTEES	1,870,827	2.95
DR RUSSELL KAY HANCOCK	1,614,214	2.55
NATIONAL NOMINEES LIMITED	1,520,193	2.40
MERRILL LYNCH (AUSTRALIA) NOMINEES	1,007,762	1.59
CS FOURTH NOMINEES	998,512	1.57
UBS NOMINEES	915,000	1.44
NETWEALTH INVESTMENTS LIMITED	754,698	1.19
HSBC CUSTODY NOMINEES	660,656	1.04
MR ALISTAIR DAVID STRONG	630,000	0.99
SANDHURST TRUSTEES	628,271	0.99
MORGAN STANLEY AUSTRALIA SECURITIES	596,695	0.94
MRS VIRGINIA CATHERINE HANCOCK	509,660	0.80
BRISPOL NOMINEES PTY LTD	432,925	0.68
ECAPITAL NOMINEES PTY LTD	389,606	0.61
MR RAYMOND WILLIAM WALTER & MR ALEXANDER SCOTT HAGAN	300,000	0.47
IMAJ PTY LTD	290,000	0.46
JJ OPPERMAN SUPERANNUATION PTY LTD	281,711	0.44

