# Full-Year Report 2016 Financial Year Ended 30 June 2016

(Previous corresponding period: financial year ended 30 June 2015)





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# Chairman's and CEO's Report



MR JOHN SHARMAN
CHIEF EXECUTIVE
OFFICER



MR DAVID WILLIAMS
CHAIRMAN

## Positioned for growth

Medical Developments International Limited. ('MDI') (ASX: MVP) delivered Earnings Before Interest, Tax, Depreciation and Amortisation of \$3.4 million up 29% and a Net Profit after Tax of \$1.6 million for the year ended 30 June 2016. Revenue grew 33% to \$15.5m.

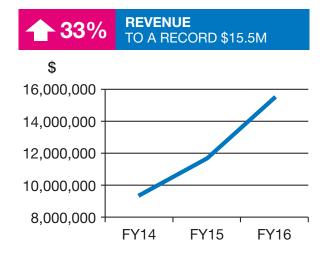
During the year the company incurred 'one off' expenses of \$0.9m relating to partnership transactions, legal fees, share based payments and moving premises. Adjusting for these one off costs means adjusted EBITDA up 63% to \$4.3m.

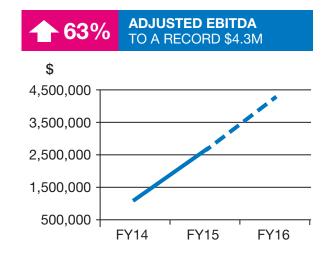
MDI received \$15 million in cash milestone payments from its partners and is debt free.

The near term prospects for Penthrox<sup>®</sup> and our Asthma products are exciting for FY17.

MDI has declared a fully franked dividend of 2 cents per share.

## Full Year Key Performance Highlights





# Key Achievements for FY16

### Penthrox®

- → Strong sales growth for Penthrox<sup>®</sup> globally
- Regulatory approval for Penthrox® in UK, Ireland, France, Belgium and Singapore
- → Launch and first sales into new markets including UK, Ireland and Singapore
- Penthrox<sup>®</sup> is fully reimbursed in the UK and Ireland
- Regulatory submissions made in multiple countries
- → Appointed Mundipharma International as distribution partner for Europe
- Received \$15m in cash milestone payments
- 5 Patent Applications submitted with more planned

### Respiratory Medical Devices

- → Purchased Breath-A-Tech, Australia's largest respiratory devices brand
- Strong sales growth in Australian respiratory device sales
- Strong sales growth from international markets
- New distribution deals signed in Europe
- New distribution deals signed with partners in the USA
- New distribution deals signed with partners in Canada
- New distribution deals signed with partners in Asia
- → FDA approval of range of anti-static respiratory devices in the USA

#### Other

- Relocated Head Office and manufacturing to Scoresby, Victoria, Australia
- Commenced construction of our new Penthrox® Manufacturing Facility
- Ongoing improvement in manufacturing costs and efficiency
- Debt free
- Received R&D Tax Incentive concession of \$0.12m
- Awarded a \$0.37m State Government grant in relation to the new Penthrox® manufacturing facility
- Progress in product development across all business units
- Continued investment in clinical development programs, trials and registrations in new markets
- Resumed dividends in H1 FY16
- Invested in staff to support a worldwide footprint



### Pharmaceuticals

During the year MDI achieved approval to sell Penthrox® in the United Kingdom, Republic of Ireland, France, Belgium and Singapore.

In the UK and Ireland MDI made its first sales and delivered more than \$1 million worth of product as part of an initial order to its marketing partner Galen Limited. In addition, MDI received \$1 million as a second milestone payment from Galen.

MDI entered into a License, Development and Commercialisation Agreement with Mundipharma for Penthrox® in Europe. Mundipharma is one of the world's leading pharma companies specialising in pain and has the exclusive rights for Penthrox® in 39 European markets including France, Germany, Italy and Spain.

Penthrox® has been approved for sale in France and Belgium and MDI has its first order and will deliver its first shipment of Penthrox® into those markets during Q1 FY17. In addition Mundipharma has paid approximately \$14 million in upfront and milestone payments to date. MDI expect further milestone payments to be achieved during FY17.

MDI and Mundipharma are expecting to lodge the application to have Penthrox® approved for sale in the remaining countries in Europe, including Italy, Spain and Germany during Q1 FY17 and approval to sell Penthrox® is anticipated in 2017.

In the USA we have a dialogue with the Food & Drug Administration (FDA) about what is required to get Penthrox® approved for sale. MDI and its advisors are working through the program of work required and we are confident we will satisfy all of the FDA's requirements.

Elsewhere in the world, our Regulatory Dossier, used in the United Kingdom, France, Belgium and Ireland has already been submitted or is in the process of being submitted to regulatory agencies in Saudi Arabia, Israel, Mexico, Hong Kong, Malaysia, Taiwan and Iran. We expect regulatory approvals to sell Penthrox® in these markets to be granted in the future.

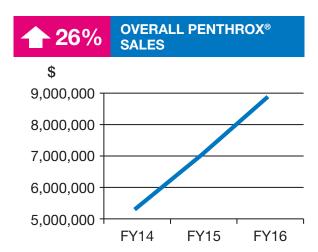
International sales **grew 147%** mainly because of the successful launch of Penthrox® in the UK and Ireland, where we delivered our first sales to our partner Galen Limited.

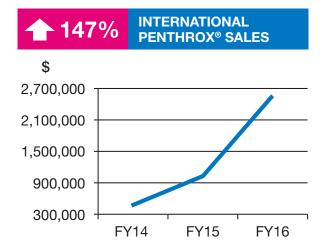
Our Penthrox® business in Australia performed strongly. Sales to Hospitals and General Practitioners **grew 30%** and our Ambulance business **grew 3%**. Sales for our Dental business **grew 15%**.

After receiving approval to sell Penthrox® in Singapore in September 2015, MDI made its first sales into that market in FY16.

Sales in the Middle East **grew 31%** driven by the signing of new distribution arrangements. Sales to South Africa **grew 157%**.

MDI recorded \$1.1m as revenue from the amortisation of upfront and milestone payments received as at 30 June 2016. In line with accounting practices these receipts are required to be amortised over the contract term.





## Clinical Developments

MDI continues to invest significantly in developing its clinical data to support the use of Penthrox®. During the year we progressed/completed and published a number of important studies including:

- Effects of Penthrox® on Psychomotor Function in Humans: A Randomised Placebo Trial
- 2. Derivation of an occupational exposure limit for an inhalation analgesic methoxyflurane (Penthrox®)
- Effects of Penthrox® (methoxyflurane) as an analgesic on cardiovascular and respiratory functions in the prehospital setting: Authored by Dr Harry Oxer
- Drive study: 'Randomised Clinical Trial: Psychomotor and Cognitive Effects of a 15-minute Inhalation of Methoxyflurane in Healthy Volunteers: Implication for Post-Colonoscopy Care'
- Singapore study: Clinical Evaluation of Penthrox® (Methoxyflurane) for the Singapore Emergency Ambulance Service – a head to head study v Tramadol
- 6. Analgesic Use of Inhaled Methoxyflurane: Evaluation of its Potential Nephrotoxicity: Prof Anthony Dayan
- Comparison of safety and clinical outcomes of Penthrox®-assisted colonoscopy versus anaesthesiaassisted colonoscopy in high-risk subjects: a randomised trial at Royal Adelaide.
- Procedural analgesia: Self-administered methoxyflurane for procedural analgesia: experience in a tertiary Australasian centre: Dr Chris Jephcott's paper was published in February 2016.
- TRUS-biopsy: A phase 3 double-blind placebocontrolled randomised trial of methoxyflurane with periprostatic local anaesthesia to reduce the discomfort of transrectal ultrasound-guided prostate biopsy (Pain-Free TRUS B)
- 10. STOP study: Efficacy and safety of methoxyflurane analgesia in adult patients in the emergency department: a randomised, double-blind, placebo-controlled study (STOP!): - additional publications and analysis.

Additional clinical trials and studies are planned for FY17 which will broaden the indications for use of Penthrox®. In the coming financial year and beyond we will undertake:

 PIP Study – a European and USA compliant paediatric study which if successful will extend the use of Penthrox® to the paediatric population in Europe and hopefully in the USA. Preparations for the study are well on the way and enrolment is expected to commence during FY17.

- PASS A Post Authorisation Safety Study designed to track any adverse events to the users of Penthrox® in Europe. The study is scheduled to last two years and the data gathered will be extremely valuable in existing and prospective Penthrox® markets around the world.
- A Phase III Pivotal trial in the USA. Work has commenced on 'Americanising' the study protocol used in MDI's Pivotal Phase III Study conducted in the UK.
- 4. We are developing a program of work to support additional indications for Penthrox®. Our longer term ambition is to extend the use of Penthrox® into:
  - a. post-operative breakthrough pain;
  - b. breakthrough cancer pain;
  - c. repeat use scenarios; and ultimately
  - d. home use.

# Commercial Developments

MDI has filed a Patent Application protecting its new manufacturing technology developed with the CSIRO. We have also commenced the initial planning stages to develop our manufacturing technology and capability further to become a manufacturer and distributor of other analgesic and anaesthetic products.

MDI believe our manufacturing technology has the capability and flexibility for MDI to become a leading player in the world supply of a number of these products. The markets we are focussing on are extremely large.

### New markets

#### France and Belgium

MDI is working with our European partner Mundipharma in relation to the upcoming European launch of Penthrox® in France and Belgium. We expect significant sales during H1FY17.

#### **Rest of Europe**

During FY17 MDI and Mundipharma expect to submit and obtain approval, via the Decentralised Procedure to sell Penthrox® in the rest of the European Union.

#### Mexico

During FY16 MDI submitted our Regulatory Application and met with the Mexican regulatory authorities. Feedback to date has been positive and we are hopeful Penthrox® will be approved during FY17.

#### Iran

After many years the Iranian Ministry of Health requested to meet with MDI re its Regulatory Application. MDI attended a meeting in Tehran during February 2016. The feedback from the authorities has been positive and we are hopeful we will receive approval to sell Penthrox® in Iran during FY17.

#### Saudi Arabia

MDI submitted its Regulatory Application to the Saudi Food & Drug Administration during FY16. The dossier is going through the validation process. MDI is hopeful Penthrox® will be approved for sale in Saudi Arabia during FY17.

#### Iraq and Jordan

MDI submitted its Regulatory Application to the regulatory authorities during FY16. MDI is hopeful Penthrox® will be approved for sale during FY17.

#### Russia

MDI's partner submitted its Regulatory Application to the regulatory authorities during FY15. Political unrest has delayed its progress.

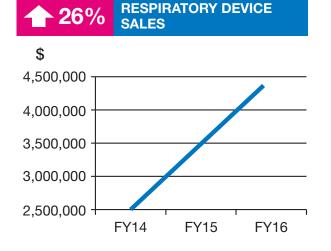
#### **Taiwan**

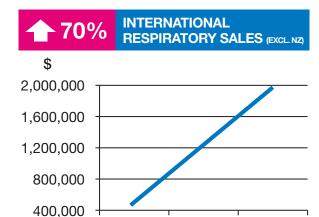
MDI's partner submitted its Regulatory Application to the regulatory authorities during FY16. MDI is hopeful Penthrox® will be approved for sale during FY17.

#### **Other**

MDI has commenced work to get Penthrox® approved for sale in the USA, Canada and Korea.

## Medical Devices: Respiratory

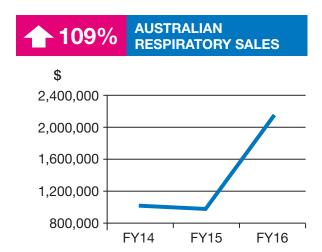




FY15

FY16

FY14



Sales of Respiratory devices across our key markets in Australia, Europe and North America increased by 82% in FY16. Overall sales of our Respiratory Devices increased by 26% which was a pleasing result considering MDI did not continue the Pharmac contract in New Zealand which reduced sales by circa \$1 million.

During January 2016, the FDA approved the next generation Anti-Static range of Respiratory Device products for the USA market. We secured distribution deals in the USA with Amerisouce Bergen, Cardinal Health and Norrizon and MINT pharmaceuticals in Canada. We made our first sales and delivered product to these new business partners during H2 FY16. We expect to announce new partnership deals in the coming months with more partners in North America and our business is well placed to deliver strong sales growth in FY17.

In Europe, sales **grew by 70%**. We signed new deals with partners in the UK as well as Portugal. Our business in the Netherlands and Belgium **grew strongly**.

In February 2016 MVP acquired Breath-A-Tech.

Breath-A-Tech is the leading brand of asthma space chambers in the Australian pharmacy and hospital markets.

The acquisition reinforced MDI as market leader in Australia.

Since acquiring Breath-A-Tech, MDI has introduced 6 new Breath-A-Tech products and relaunched the brand. In June, Breath-A-Tech sales were the highest recorded for any month since 2011.

#### **Australia**

Our Australian respiratory sales **grew 109%**. We expect sales growth to continue strongly during FY17 as Breath-A-Tech will contribute a full 12 months of sales.

#### **North America**

Sales in North America **grew 33%**. In January 2016 the FDA approved MDI's leading range of anti-static devices. Since that time we have signed a distribution deal with Amerisource Bergen and Cardinal Health. We delivered our first products to these partners in June 2016. We expect to sign additional partnership/distribution deals in the USA during FY17. Strong sales growth should follow.

Our initial assessment of the USA market is that there are approximately 20 million space chamber devices sold each year. Our products are amongst the world's best and our ambition is to win significant market share over the coming years.

#### **Europe**

Our business in Europe (including the UK) continues to deliver strong sales growth and generate profits. Respiratory sales **grew 70%** in FY16. MDI signed additional deals in the UK, Portugal and Spain. MDI expect to sign further distribution agreements in the coming year.

#### Asia

Sales into this region grew 74%.

### Vet

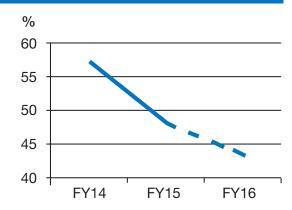
Our Vet business **increased 10%** in FY16. MDI continues to win new orders from China and South East Asia and expects further sales growth in FY17.

# Research and Development

MDI commenced construction of our new Penthrox® manufacturing facility that will house our commercial scale plant for the new methoxyflurane manufacturing process. The facility will house state of the art R&D product testing laboratories and is expected to be operational in early 2017. The new plant will be able to accommodate medium to long term forecasted international demand.

## **Operating Expenses**

#### **ADJUSTED OPEX TO SALES**



During the year, MDI incurred a number of 'one off' costs relating to the future growth of our business. The effect of these one off costs are detailed below.

Our full year result has been impacted by five factors:

- \$0.16m legal expenses incurred in relation to the License, Development and Commercialisation Agreement with Mundipharma;
- \$0.24m costs associated with the acquisition of Breath-A-Tech;
- \$0.318m expense associated with the early vesting of options attached to the CEO Long Term Incentive Plan; and
- \$0.14m relocation cost associated with moving our head office and components of the manufacturing operations to our new Scoresby based site.

Adjusting for the combined impact of these (\$0.9m) results in Earnings Before Interest, Tax, Depreciation and Amortisation increasing to \$4.3m.

## Investing in Operations

\$0.6m was spent on increasing head count during the year. In particular MDI invested heavily in its Quality and Regulatory departments to cater for the demands of global expansion. We are now well placed for the future and do not expect further significant investment.

MDI continues to invest in clinical studies, research and development and product development. Some of these expenses have capitalised to intangible assets where appropriate and the remainder has been taken directly to the profit and loss.

We received a \$0.117 million R&D tax incentive refund during the year and a further \$0.223 million is expected in the coming months in relation to FY16.

### 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 2 September 2016 to be paid to shareholders on 7 October 2016. A Dividend Reinvestment Plan is again being offered.

### Outlook

MDI's ambition is to globalise **Penthrox**® and in doing so make it the main stream analgesic of choice around the world. That process has begun. Over the next 12 months we expect:

- to obtain approval to sell Penthrox® in the remaining markets in the EU and some additional countries around the world;
- complete our manufacturing facility which will have special purpose Research and Development laboratories dedicated to improving the way we manufacture Penthrox®;
- conclude additional distribution partnerships for new countries;
- commence work on producing other Analgesic and Anaesthetic products using the intellectual property that is our new manufacturing process; and
- commence and progress work on gathering the clinical data needed to submit a 'New Drug Application' to the Food & Drug Administration in the USA.

Our **Respiratory Devices** are best in class and we will continue our global expansion and in particular build our USA business. We expect to deliver new partnership deals, expand our product offering and grow sales significantly.

The globalisation of MDI is well underway. The opportunities for a quantum increase in sales and the development of our business globally in FY17 are good.

We would like to thank our staff and our trading partners for their efforts and support and look forward to further success in FY17 and beyond.

Further Information:

MR JOHN SHARMAN

CHIEF EXECUTIVE OFFICER

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MR DAVID WILLIAMS

CHAIRMAN

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# Product Portfolio

### Pharmaceutical

Analgesia Penthrox®

### Medical

Asthma Space Chamber Plus®

Compact Space Chamber Plus®

Space Chamber Plus® Autoclavable spacer

Breath-A-Tech spacer

Breath-A-Tech Hospital spacer Breath-Alert® Peak Flow Meter MyMDI™ Portable Nebuliser MyMDI™ Pulse Oximeter

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<sup>™</sup> 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



# 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 Penthrox®. Penthrox® continues to be used as a 'first line' product for the treatment of pain in trauma by all Ambulance Services in Australia. MVP continued the promotional focus into the Australian Ambulance services ensuring that the strong positioning of Penthrox® is maintained. Moving forward, the strategy is to continue to broaden the range customers (hospitals, general practice, dental and cosmetic) and countries that can be served by Penthrox®. In FY16 Penthrox® was successfully launched into the U.K. and Ireland.

#### **Product Suite**

MVP is continuing to develop additional formulations of Penthrox® to provide improve convenience, utility and value for its customers.



# Medical devices

# Building our product range

MVP's focus in FY17 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
- Penthrox<sup>®</sup> 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 and our distribution partner
- The growth of the OAPL sales in Hospitals and Pharmacies within Australia
- The acquisition of the Breath-A-Tech range of spacers and face masks
- Growing sales of our range of Asthma products through established international partners and new customers.
   Of particular note is the launch of Space Chamber in the USA in FY16.

#### 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 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<sup>™</sup> 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 facilities in Melbourne, Australia.

#### The market

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

- Ambulance services
- Fire brigades
- · Lifesaving clubs
- Military



# Veterinary

## MVP re-invigorates its Veterinary product range

#### **Products**

- · Anaesthetic machines
- Vaporisers
- · Breathing monitors

#### 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, Kruuse (one of Europe's largest veterinary distribution companies), the launch of a new machine, and with a new catalogue veterinary sales continue to grow.

#### **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.



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# **Board of Directors**



#### Mr David Williams

#### Non-Executive Chairman

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



#### Mr Max Johnston

#### Non-Executive Director

Mr Johnston is a non-executive director of Enero Group Limited, Polynovo Limited and Chairman of Probiotec Limited. For 11 years he was President and Chief Executive Officer of Johnson & Johnson Pacific and an Executive Director of Johnson & Johnson. Mr Johnson 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 Johnson has had extensive overseas experience during his career in leading businesses in both 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 ASM

#### **Non-Executive Director**

Dr Oxer is a Medical Consultant to MVP 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 26 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 an Executive Director at Corporate Finance Advisory firm Kidder Williams. Philip is also a Non-executive Director of PolyNovo Limited (ASX:PNV).

Philip is Chairman of MVP's Audit and Risk Committee.



#### Mr Leon Hoare

#### **Non-Executive Director**

Mr Hoare is the Managing Director of Smith & Nephew in Australia & New Zealand (covering all Divisions), which is one of the largest global subsidiaries (outside the USA). In his 24 years with Smith & Nephew, he has held roles in Marketing, Divisional and General Management, and was most recently Asia Pacific President of the Advanced Wound Management (AWM) Division, before advancing to the Managing Director role in 2014. He has also been a member of the Global Executive Management for the AWM Division of Smith & Nephew whilst leading Asia Pacific. External to Smith & Nephew, Mr Hoare previously held board roles (including as Vice-Chair) with Australia's peak medical device body, Medical Technology Association of Australia (MTAA).



#### Mr Allan McCallum

#### **Non-Executive Director**

Mr McCallum has over 15 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.



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# Corporate Governance Statement

The Board of Directors is ultimately responsible for all matters relating to the running of the company and is committed to implementing the highest standards of corporate governance.

The Board's role is to govern the organisation rather than manage it. It is the purpose of senior management to manage the organisation in accordance with the direction of the Board. The Board is responsible for:

- setting the goals of the company, including short-term, medium-term and long-term objectives;
- providing the overall strategic direction of the company;
- appointing and approving the terms and conditions of the Chief Executive Officer and reviewing their ongoing performance;
- endorsing the terms and conditions of senior executives through the Remuneration Committee;
- establishing and determining the powers and functions of the committees of the board, including the Audit & Risk Committee and the Remuneration Committee;
- reviewing the Board's structure and performance from time to time and making decisions on new appointments to the Board;
- approving the annual budget and long-term budgets;
- approving all mergers and acquisitions, and property acquisitions and disposals;
- issuing shares, options, equity instruments or other securities in MDI or its subsidiaries;
- determining the ethos of the company and ensuring that the group adheres to appropriate standards and values and applicable laws; and
- representing the interests of shareholders.

To assist in the execution of these responsibilities, the Board has two Board Committees being:

- Audit and Risk Committee (Mr P Powell and Mr M Johnston).
- Remuneration and Nominations Committee (Mr D Williams and Mr A McCallum).

All other functions of the Board will be dealt with by the Board as a whole. However, from time to time, the Board may determine to establish specific purpose subcommittees to deal with specific issues.

#### Share trading

The Board has adopted a share trading policy for Directors and officers of the company. The Policy regulates dealings by Medical Developments International Limited ('MDI') directors, officers and employees in MDI securities.

The standards and conduct adopted by the Board reflect, where applicable, the standards for Corporate Governance as provided in the ASX Corporate Governance Principles established by the ASX Corporate Governance Council.

The following sections summarise MDI's compliance with these principles. Unless explicitly stated otherwise, the Directors believe MDI complies with the Corporate Governance Council's recommendations.

# Principle 1: Lay solid foundations for management and oversight

Duties of the Board and of management are clearly segregated and stated in the company's Corporate Governance Manual. The Board's role and responsibilities

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are also summarised above. Senior executives are evaluated by the remuneration committee annually, based on the company's performance and specific key performance indicators set for the respective senior executive.

All senior executive appointments involve a formal written agreement that is reviewed and signed off on by both the CEO and relevant Executive.

The Board undertakes formal interviews and reference checks to assess the appropriateness of all candidates. Information relevant to the decision on whether or not to elect or re-elect a director is summarised within the Annual General Meeting Notice of Meeting which is sent to all security holders and also released to the ASX and published on the company website.

Individual agreements with each of the directors do not exist, however the duties and obligations of Directors are specifically outlined in the Corporate Governance Manual and the remuneration of Directors is addressed at least annually by the Remuneration and Nomination Committee.

The Company Secretary reports to the Chairman on all Board functioning and Corporate Governance related matters. The Company Secretary attends Board meetings and has input into materials distributed as part of these meetings. Furthermore, Corporate Governance related matters are addressed as a specific agenda at Board meetings.

### Recommendation 1.5-1.6

Companies should establish a policy concerning diversity and disclose the policy or a summary of that policy. The policy should include requirements for the board to establish measurable objectives for achieving gender diversity and for the board to assess annually both the objectives and progress in achieving them.

The Company has established and disclosed (on its website) its Diversity Policy in accordance with the recommendation.

Companies should disclose in each annual report the measurable objectives for achieving gender diversity set by the board in accordance with the diversity policy and progress towards achieving them.

The Board believes in the value of diversity but does not believe that given the size of the company and the resources available to it, that formalising measurable objectives for achieving gender diversity is appropriate. As the company grows, the Board will continue to monitor the Diversity Policy including formalising measurable objectives for achieving gender diversity.

While there is currently no gender diversity on the Board, the Board is made up of individuals from various professions, cultures, and backgrounds.

The Company's workforce is comprised of three distinct employee groups:

- 1. Employees engaged in senior management roles which constitutes 19% of the workforce;
- Employees engaged in middle management roles which constitutes 11% of the workforce; and
- Employees engaged in tier three level activities such as production, sales, and administration type roles which constitutes 70% of the workforce.

# Principle 2: Structure the Board to add value

The directors believe that the composition, size and commitment of the Board will allow it to effectively discharge its responsibilities and duties. To this end, currently five of the six Board members are independent under the definition of the Council. Furthermore, while the Chairman, Mr Williams is not considered independent under the Council definition and thus recommendation 2.2 is not followed, the Board does not believe that Mr Williams being a substantial shareholder has had or will have any adverse impact on the conduct of MDI's affairs or the representation of the interests of other shareholders. Furthermore, the roles of Chairman and CEO are not exercised by the same individual.

A formal Board skills matrix is not presented, however the Annual Report contains key details regarding each Boards members qualifications, career experience and other appointments.

The company has no formal process for evaluating the performance of its Board, committees and individual Directors. As such, recommendation 1.6 is not followed. Instead the Board uses regular informal assessments to evaluate its performance.

To further ensure Directors can fulfil their obligations, the Board has adopted a policy, contained in the company's corporate governance manual that allows directors to take independent professional advice, at the expense of the company.

The information required by recommendation 2.2 regarding the skills, experience and expertise of the individual Directors is included in the Director's Report and is not repeated here.

The Board has established a two member Remuneration and Nominations committee as suggested by recommendation 2.1. Whilst this is less than the three required by recommendation 2.1 & 8.1, the Board believes a three member committee is impractical given the overall size of the Board. A formal charter does not exist, however all Board members are consulted on the appropriateness of new Board candidates to ensure a diverse balance of skills.

knowledge and experience is achieved to enable the Board to discharge its duties and responsibilities effectively.

# Principle 3: Promote ethical and responsible decision-making

The Board actively promotes ethical and responsible decision-making.

Companies should establish a code of conduct and disclose the code or a summary of the code as to the practices necessary to maintain confidence in the company's integrity; the practices necessary to take into account their legal obligations and the reasonable expectations of their stakeholders; and the responsibility and accountability of individuals for reporting and investigating reports of unethical practices.

The Company has established and disclosed (in its Induction Handbook) its Code of Conduct in accordance with this recommendation. The Code of Conduct applies to Directors, managers and employees of the Company. The Code of Conduct is reviewed as necessary to ensure it reflects the high ethical standards of conduct necessary to maintain confidence in the Company's integrity.

The Board has implemented and disclosed a share trading policy covering Directors, senior executives and employees. The directors are aware of their responsibility to communicate any share trading to the company, and the company notifies the ASX of any share transactions within the allowed five business days.

The Board has adopted a policy for trading in Medical Developments International securities by Directors and employees. The purpose of this policy is to define the circumstances in which Directors, employees and any associates are permitted to deal in securities. The updated policy addresses each of the ASX requirements including provisions relating to the prohibition of trading by directors and senior management in the Company's securities during defined periods.

# Principle 4: Safeguard integrity in financial reporting

The Board has ensured there is a structure in place to independently verify and safeguard the integrity of the company's financial reporting.

The Board has established an Audit and Risk Committee comprised of two non-executive Directors. While this is less than the three required by recommendation 4.2 & 7.1, the Board believes a three member committee is impractical given the overall size of the Board and that the current composition of the committee allows it to discharge its mandate effectively. The Committee's Charter is contained within the company's Corporate Governance manual and also included on the company's website.

# Principle 5: Make timely and balanced disclosures

The company has put in place mechanisms designed to ensure compliance with the ASX Listing rules and Corporations Act requirements regarding continuous disclosure. The Corporate Governance Manual details the company policy and all management staff are made aware of it. The company is committed to ensuring all market participants have equal access to information and so updates and presentations continue to be provided to the ASX and posted on the company website. If a presentation contains information that is not public and may have a material effect on the share price, the material is sent to the ASX prior to the presentation being made.

# Principle 6: Respect the rights of shareholders

A formal documented investor relations program does not exist. However the CEO holds regular investor roadshows and information presented at such roadshows is also released to the market. Furthermore, both the Chairman and CEO make themselves available to take calls directly from investors and their contact details are provided within each ASX announcement.

The Board of Directors has adopted a policy to ensure that shareholders are informed of all major developments affecting MDI in a timely manner. In accordance with this policy, information is communicated in a variety of ways including:

- A half-yearly report containing summarised financial information and a review of operations
- An annual report with detailed financial information and review of the operations of the company and future outlook
- Updates on operations and developments lodged with the ASX
- A comprehensive website carrying the latest news and containing an investor relations section which includes

corporate governance information and an archive of periodic reports and ASX releases.

MVP has functionality within its existing website to collect investor email addresses to then have those included on a key company announcement email distribution list. The website also contains a detailed 'Contact Us' page which enables investors to contact MVP via a number of different mediums. Security holders also have the option to receive and communicate with MVP electronically via the security registry (currently Computershare).

The external auditor is required to attend the Annual General Meeting and is available to answer questions. Furthermore, the company encourages shareholders to attend the Annual General Meeting and ask questions.

# Principle 7: Recognise and manage risk

The management of risk is considered by the Audit and Risk Committee. The Board determines whether management has developed and implemented a sound system of risk management and internal control and this review has again taken place in FY16.

The Chief Executive Officer and Group Financial Controller state to the Board in writing that there is a sound system of risk management and internal compliance and control within the company and that this system operates effectively in ensuring that financial reporting risks are managed such that the declaration required by s.295A of the Corporations Act can be provided.

The Company does not have its own internal audit function as it is considered impractical for a company the size of MVP to have one. Instead risk management and internal control matters are addressed as part of the Audit and Risk Committee Charter.

# Principle 8: Remunerate fairly and responsibly

The Board has established a Remuneration committee to ensure Directors, executives and staff are remunerated appropriately. The committee reviews remuneration packages at least annually in the light of market conditions, performance of the individual and the performance of the company. The Remuneration report contained within the Director's Report includes considerable detail on the current remuneration of directors and executives including how performance conditions for performance related payments are chosen and assessed.

### Diversity

The Company has established a policy concerning diversity which is available on its website. The policy outlines the Company's commitment to diversity, which is underpinned by the following key principles:

- Attracting, engaging and retaining a talented and diverse workforce;
- Recognising the need for workplace flexibility to support the role employees at all levels have outside of the workplace;
- Improving the quality of decision-making, creativity, productivity and teamwork;
- Enhancing service delivery through a workforce that respects and reflects the diversity of our customers;
- Building and maintaining a safe work environment by taking action against inappropriate behaviour (including discrimination, harassment, bullying, victimisation and vilification); and
- Facilitating equal employment opportunities by considering a broad and diverse talent pool and making decisions based on merit, ability, performance and potential.

The Company's Diversity Policy outlines the following key areas of focus:

- Conducting recruitment in a structured manner consistent with Equal Employment Opportunity principles and the objectives of this policy;
- Undertaking structured talent management and succession planning reviews;
- Undertaking targeted diversity, culture and engagement initiatives;
- Establishing and reviewing appropriate and aligned human resource policies and procedures; and
- · Consistent messaging in internal communication.

# Annual reporting on the Company's Diversity Policy and proportion of women

There is one woman currently in a senior management role. Overall women represent 47% of the workforce of the Company.

The Company has implemented a strategy designed to increase the representation of women at the senior management level.

To aid in the attraction and retention of female employees, the Company has carer's leave in place as well as making part-time work available. The Company always seeks to accommodate individual circumstances to ensure all employees can manage their work-life balance.

# 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 2016. 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. Mr Williams is Chairman of the Remuneration and Nominations Committee.

#### Mr A D McCallum, Dip.Ag Science, FAICD

#### Non-Executive Director (since 27 October 2003)

Mr McCallum has over 15 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.

#### 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 Enero Group Limited, Polynovo Limited and Chairman of Probiotec Limited. For 11 years he was President and Chief Executive Officer of Johnson & Johnson Pacific and an Executive Director of Johnson & Johnson. Mr Johnson 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 Johnson 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 MDI Audit & Risk Committee.

#### Mr L Hoare

#### Non-Executive Director (since 27 September 2013)

Mr Hoare is the Managing Director of Lohmann & Rauscher (Australia and New Zealand), a privately owned, multinational medical device company. Previously, Mr Hoare was Managing Director of Smith & Nephew (Aus/NZ) until the end of 2015, one of Smith and Nephew's largest global subsidiaries outside the USA. He served as President of Smith & Nephew's Asia Pacific Advanced Wound Management (AWM) business for 5 years and was 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. Leon 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 an Executive Director at Corporate Finance Advisory firm Kidder Williams. Philip is also a Non-executive Director of PolyNovo Limited (ASX: PNV).

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	
Allan McCallum	Tassal Group Ltd (Chairman)	Since October 2003	
	Probiotec Ltd	Since April 2010	
Max Johnston	Enero Group Limited	Since March 2011	
	Polynovo Limited	Since 13 May 2014	
Philip Powell	Polynovo Limited	Since 13 May 2014	
Leon Hoare	Polynovo Limited	Since 27 January 2016	

#### **Company Secretary**

Mr Mark Edwards, CA. Mr Edwards is also the Group Financial Controller 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**

FY16 was a year of significant investment in the future of our business. Launches into a number of new markets were made whilst the business made further investment in its sales, manufacturing, product development and regulatory teams in preparation for planned future growth.

### **Pharmaceuticals**

During the year MDI achieved approval to sell Penthrox® in the United Kingdom, Republic of Ireland, France, Belgium and Singapore.

In the UK and Ireland MDI made its first sales and delivered more than \$1 million worth of product as part of an initial order to its marketing partner Galen Limited. In addition, MDI received \$1 million as a second milestone payment from Galen.

MDI entered into a License, Development and Commercialisation Agreement with Mundipharma for Penthrox® in Europe. Mundipharma is one of the world's leading pharma companies specialising in pain and has the exclusive rights for Penthrox® in 39 European markets including France, Germany, Italy and Spain.

Penthrox® has been approved for sale in France and Belgium and MDI has its first order and will deliver its first shipment of Penthrox® into those markets during Q1 FY17. In addition Mundipharma has paid approximately \$14 million in upfront and milestone payments to date. MDI expect further milestone payments to be achieved during FY17.

MDI and Mundipharma are expecting to lodge the application to have Penthrox® approved for sale in the remaining countries in Europe, including Italy, Spain and Germany during Q1 FY17 and approval to sell Penthrox® is anticipated in 2017.

In the USA we have a dialogue with the Food & Drug Administration (FDA) about what is required to get Penthrox® approved for sale. MDI and its advisors are working through the program of work required and we are confident we will satisfy all of the FDA's requirements.

Elsewhere in the world, our Regulatory Dossier, used in the United Kingdom, France, Belgium and Ireland has already been submitted or is in the process of being submitted to regulatory agencies in Saudi Arabia, Israel, Mexico, Hong Kong, Malaysia, Taiwan and Iran.

International sales **grew 147%** mainly because of the successful launch of Penthrox® in the UK and Ireland, where we delivered our first sales to our partner Galen Limited.

Our Penthrox® business in Australia performed strongly. Sales to Hospitals and General Practitioners grew 30% and our Ambulance business **grew 3%**. Sales for our Dental business **grew 15**%.

After receiving approval to sell Penthrox® in Singapore in September 2015, MDI made its first sales into that market in FY16.

Sales in the Middle East **grew 31%** driven by the signing of new distribution arrangements. Sales to South Africa **grew 157%**.

MDI recorded \$1.1m as revenue from the amortisation of upfront and milestone payments received as at 30 June 2016. In line with accounting practices these receipts are required to be amortised over the contract term.

#### **New markets**

#### France and Belgium

MDI is working with our European partner Mundipharma in relation to the upcoming European launch of Penthrox® in France and Belgium. We expect significant sales during H1FY17.

#### Rest of Europe

During FY17 MDI and Mundipharma expect to submit and obtain approval, via the Decentralised Procedure to sell Penthrox® in the rest of the European Union.

#### Mexico

During FY16 MDI submitted our Regulatory Application and met with the Mexican regulatory authorities. Feedback to date has been positive and we are hopeful Penthrox® will be approved during FY17.

#### Iran

After many years the Iranian Ministry of Health requested to meet with MDI regarding its Regulatory Application. MDI attended a meeting in Tehran during February 2016. The feedback from the authorities has been positive and we are hopeful we will receive approval to sell Penthrox® in Iran during FY17.

#### Saudi Arabia

MDI submitted its Regulatory Application to the Saudi Food & Drug Administration during FY16. The dossier is going through the validation process. MDI is hopeful Penthrox® will be approved for sale in Saudi Arabia during FY17.

#### Iraq and Jordan

MDI submitted its Regulatory Application to the regulatory authorities during FY16. MDI is hopeful Penthrox® will be approved for sale during FY17.

#### Russia

MDI's partner submitted its Regulatory Application to the regulatory authorities during FY15. Political unrest has delayed its progress.

#### Taiwan

MDI's partner submitted its Regulatory Application to the regulatory authorities during FY16. MDI is hopeful Penthrox® will be approved for sale during FY17.

#### Other

MDI has commenced work to get Penthrox® approved for sale in the USA, Canada and Korea.

#### **Clinical Developments**

MDI continues to invest significantly in developing its clinical data to support the use of Penthrox<sup>®</sup>. During the year we progressed/completed and published a number of important studies including:

- Effects of Penthrox® on Psychomotor Function in Humans: A Randomised Placebo Trial
- Derivation of an occupational exposure limit for an inhalation analgesic methoxyflurane (Penthrox®)
- Effects of Penthrox® (methoxyflurane) as an analgesic on cardiovascular and respiratory functions in the prehospital setting: authored by Dr Harry Oxer
- Drive study: "Randomized Clinical Trial: Psychomotor and Cognitive Effects of a 15-minute Inhalation of Methoxyflurane in Healthy Volunteers: Implication for Post-Colonoscopy Care"
- Singapore study: Clinical Evaluation of Penthrox® (Methoxyflurane) for the Singapore Emergency Ambulance Service – a head to head study v Tramadol
- 6. Analgesic Use of Inhaled Methoxyflurane: Evaluation of its Potential Nephrotoxicity: Pr Anthony Dayan
- 7. Comparison of safety and clinical outcomes of Penthrox®-assisted colonoscopy versus anaesthesia-assisted colonoscopy in high-risk subjects: a randomised trial at Royal Adelaide.
- Procedural analgesia: Self-administered methoxyflurane for procedural analgesia: experience in a tertiary Australasian centre: Dr Chris Jephcott's paper was published in February 2016.
- TRUS-biopsy: A phase 3 double-blind placebocontrolled randomised trial of methoxyflurane with periprostatic local anaesthesia to reduce the discomfort of transrectal ultrasound-guided prostate biopsy (Pain-Free TRUS B)

10. STOP study: Efficacy and safety of methoxyflurane analgesia in adult patients in the emergency department: a randomised, double-blind, placebo-controlled study (STOP!): - additional publications and analysis.

Additional clinical trials and studies are planned for FY17 which will broaden the indications for use of Penthrox®. In the coming financial year and beyond we will undertake:

- PIP Study a European and USA compliant paediatric study which if successful will extend the use of Penthrox® to the paediatric population in Europe and hopefully in the USA. Preparations for the study are well on the way and enrolment is expected to commence during FY17.
- PASS A Post Authorisation Safety Study designed to track any adverse events to the users of Penthrox® in Europe. The study is scheduled to last two years and the data gathered will be extremely valuable in existing and prospective Penthrox® markets around the world.
- 3. A Phase III Pivotal trial in the USA. Work has commenced on "Americanising" the study protocol used in MDI's Pivotal Phase III Study conducted in the UK.
- 4. We are developing a program of work to support additional indications for Penthrox®. Our longer term ambition is to extend the use of Penthrox® into:
  - a. post-operative breakthrough pain;
  - b. breakthrough cancer pain;
  - c. repeat use scenarios; and ultimately
  - d. home use.

#### **Commercial Developments**

MDI has filed a Patent Application protecting its new manufacturing technology developed with the CSIRO. We have also commenced the initial planning stages to develop our manufacturing technology and capability further to become a manufacturer and distributor of other analgesic and anaesthetic products.

MDI believe our manufacturing technology has the capability and flexibility for MDI to become a leading player in the world supply of a number of these products. The markets we are focusing on are extremely large.

## Medical Devices: Respiratory

Sales of Respiratory devices across our key markets in Australia, Europe and North America increased by 82% in FY16. Overall sales of our Respiratory Devices increased by 26% which was a pleasing result considering MDI did not continue the Pharmac contract in New Zealand which reduced sales by circa \$1 million.

During January 2016, the FDA approved the next generation

Anti-Static range of Respiratory Device products for the USA market. We secured distribution deals in the USA with Amerisource Bergen, Cardinal Health and Norrizon and MINT pharmaceuticals in Canada. We made our first sales and delivered product to these new business partners during H2FY16. We expect to announce new partnership deals in the coming months with more partners in North America and our business is well placed to deliver strong sales growth in FY17.

In Europe, sales **grew by 70%**. We signed new deals with partners in the UK as well as Portugal. Our business in the Netherlands and Belgium grew strongly.

In February 2016 MDI acquired Breath-A-Tech. Breath-A-Tech is the leading brand of asthma space chambers in the Australian pharmacy and hospital markets. The acquisition reinforced MDI as market leader in Australia. Since acquiring Breath-A-Tech, MDI has introduced 6 new Breath-A-Tech products and relaunched the brand. In June, Breath-A-Tech sales were the highest recorded for any month since 2011. In the almost five months MDI has owned Breath-A-Tech, sales are almost \$0.8 million.

#### Australia

Our Australian respiratory sales **grew 109%**. We expect sales growth to continue strongly during FY17 as Breath-A-Tech will contribute a full 12 months of sales.

#### North America

Sales in North America **grew 33%**. In January 2016 the FDA approved MDI's leading range of anti-static devices. Since that time we have signed a distribution deal with Amerisource Bergen and Cardinal Health. We delivered our first products to these partners in June 2016. We expect to sign additional partnership/distribution deals in the USA during FY17. Strong sales growth should follow.

Our initial assessment of the USA market is that there are approximately 20 million space chamber devices sold each year. Our products are amongst the world's best and our ambition is to win significant market share over the coming years.

#### Europe

Our business in Europe (including the UK) continues to deliver strong sales growth and generate profits. Respiratory sales **grew 70%** in FY16. MDI signed additional deals in the UK, Portugal and Spain. MDI expect to sign further distribution agreements in the coming year.

#### Asia

Sales into this region grew 74%.

#### Vet

Our Vet business **increased 10%** in FY16. MDI continues to win new orders from China and South East Asia and expects further sales growth in FY17.

# Research and Development

MDI commenced construction of our new Penthrox® manufacturing facility that will house our commercial scale plant for the new methoxyflurane manufacturing process. The facility will house state of the art R&D product testing laboratories and is expected to be operational in early 2017. The new plant will be able to accommodate medium to long term forecasted international demand.

## **Operating Expenses**

During the year, MVP incurred a number of 'one off' costs relating to the future growth of our business. The effect of these one off costs are detailed below:-

Our full year result has been impacted by five factors:

- \$0.16m legal expenses incurred in relation to the License, Development and Commercialisation Agreement with Mundipharma;
- \$0.24m costs associated with the acquisition of Breath-A-Tech;
- \$0.318m expense associated with the early vesting of options attached to the CEO Long Term Incentive Plan;
- \$0.14m relocation cost associated with moving our head office and components of the manufacturing operations to our new Scoresby based site.

Adjusting for the combined impact of these (\$0.9m), results in Earnings Before Interest, Tax, Depreciation and Amortisation increasing from \$3.4m to \$4.3m (2015: \$2.6m). Net Profit Before Tax for FY16 increases to \$3.2m when adjusted for these same impacts (2015: \$2.2m).

## Investing in Operations

\$0.6m was spent on increasing headcount during the year. In particular MVP invested heavily in its Quality and Regulatory departments to cater for the demands of global expansion. We are now well placed for the future and do not expect further significant investment.

MVP continues to invest in clinical studies, research and development and product development. Some of these expenses have capitalised to intangible assets where appropriate and the remainder has been taken directly to the profit and loss.

We received a \$0.117 million R&D tax incentive refund during the year and a further \$0.223 million is expected in the coming months in relation to FY16.

### Outlook

MVP's ambition is to globalise Penthrox® and in doing so make it the main stream analgesic of choice around the world. That process has begun. Over the next 12 months we expect

- to obtain approval to sell Penthrox® in the remaining markets in the EU and some additional countries around the world;
- complete our manufacturing facility which will have special purpose Research and Development laboratories dedicated to improving the way we manufacture Penthrox®;
- conclude additional distribution partnerships for new countries;
- commence work on producing other Analgesic and Anaesthetic products using the intellectual property that is our new manufacturing process; and
- commence and progress work on gathering the clinical data needed to submit a 'New Drug Application' to the Food & Drug Administration in the USA.

Our Respiratory Devices are best in class and we will continue our global expansion and in particular build our USA business. We expect to deliver new partnership deals, expand our product offering and grow sales significantly.

The globalisation of MVP is well underway. The opportunities for a quantum increase in sales and the development of our business globally in FY17 are good.

We would like to thank our staff and our trading partners for their efforts and support and look forward to further success in FY17 and beyond.

#### **Financial Position**

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

- Interest bearing liabilities at 30 June 2016 total \$481,000; and
- The debt facility available to the company was unused as at 30 June 2016 and the company is currently assessing the need to retain the facility moving forward.

#### **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**

On 20 May 2016 tranche one of the CEO Long Term Incentive Option Plan vested and were later exercised on 10 August 2016 resulting in the issuing of 400,000 shares.

Tranche 2 of this Plan for a further 400,000 shares also vested on 11 July 2016 and is able to be exercised up until 11 October 2016.

On the 18th August 2016 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 2 September 2016, to be paid to the shareholders on the 7 October 2016. Refer below for further details.

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 the volume weighted average price of all of the company's full paid shares sold on the ASX during the 10 trading days immediately before the record date (no discount applied).

The timetable for the Final Dividend for the year ended 30 June 2016 is:

Key dates	Event
18 August 2016	Declaration of Final Dividend.
2 September 2016	Record Date for eligible shareholders to receive dividend
23 September 2016	Date for shareholders to elect to participate in Dividend Reinvestment Plan
7 October 2016	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

#### **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	17,809,855
A.D. McCallum	381,690
H.F. Oxer	191,622
M. Johnston	30,131
L. Hoare	10,043
P.J. Powell	253,180

Directors hold no options over shares as at 30 June 2016

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

#### **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 2016. 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. Oxer (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 (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

2016	Balance at 30 June 2015 No.	Issued during the year via DRP No.	Net Other Change No.	Balance at 30 June 2016 No.
D.J. Williams	23,371,990	77,865	(5,640,000)	17,809,855
A.D. McCallum	477,497	1,668	(97,475)	381,690
H.F. Oxer	207,013	909	(16,300)	191,622
M. Johnston	30,000	131	-	30,131
L. Hoare	10,000	43	-	10,043
P.J. Powell	352,074	1,106	(100,000)	253,180
J. Sharman	109,230	125	(80,672)	28,683
M. Edwards	-	-	-	-
	24,557,804	81,847	(5,934,447)	18,705,204

2015	Balance at 30 June 2014 No.	Issued during the year No.	Net Other Change No.	Balance at 30 June 2015 No.
D.J. Williams	30,370,890	-	(6,998,900)	23,371,990
A.D. McCallum	477,497	-	-	477,497
H.F. Oxer	207,013	-	-	207,013
M. Johnston	30,000	-	-	30,000
L. Hoare	-	-	10,000	10,000
P.J. Powell*	-	-	352,074	352,074
J. Sharman	609,230	-	(500,000)	109,230
M. Edwards	-	-	-	-
	31,694,630	-	(7,136,826)	24,557,804

<sup>\*</sup> Mr. Powell joined the Board on 17 December 2014 and at that time indirectly held 352,074 shares.

#### Key management personnel share option plan

On 18 January 2016 the company announced it has agreed to a Long Term Incentive Plan 'LTIP' with Mr. John Sharman, the CEO of Medical Developments International Limited to encourage his long term commitment to the business.

The key plan features are summarised as follows:

- A grant of 400,000 options with a strike price of \$2.50 but vesting only when the MVP share price has been above \$4.50 at all times for 60 continuous ASX Trading days. These options will expire 28 February 2017.
- A grant of 400,000 options with a strike price of \$2.50 but vesting only when the MVP share price has been above \$5.50 for 60 continuous ASX Trading days. These options will expire 30 September 2017; and
- A grant of 200,000 options with a strike price of \$2.50 but vesting only when reimbursement is approved for Penthrox® in Germany or Registration is approved in Germany (whichever occurs first). These options will expire on the 31 December 2016.

Each share option converts into one ordinary share of Medical Developments Limited on exercise. No amounts are paid or payable by the recipient on the receipt of the option nor are they tradeable at any time. The options carry neither rights to dividends or voting rights.

Under the terms of the plan, all outstanding options will be cancelled if Mr. Sharman leaves or is otherwise no longer employed at MVP for any reason. When the LTIP delivers an entitlement to an equity interest via the prevailing share price hurdle, Mr. Sharman will have 3 months to exercise the relevant options, after which the relevant options will lapse. In each case, 60% of the new shares issued by exercising options will be escrowed for a period of 12 months from issue date.

There has been no alteration to the terms and conditions of the above share based payment arrangement since grant date.

#### 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.

#### Share options of Medical Developments International Limited

2016	Balance at 30 June 2015 No.	Granted as remuneration No.	Balance at 30 June 2016 No.	Balance vested at 30 June 2016 but not exercised No.	Balance not vested at 30 June 2016 No.	Options vested during the year No.
J. Sharman	-	1,000,000	1,000,000	400,000	600,000	400,000

Share options made to Mr. Sharman were made in accordance with the provisions of the employee share option plan. The above represents the only existing options over shares as at 30 June 2016. All vested options are exercisable. These options do not have the right, by virtue of the option, to participate in share issues or interest issue of the company.

Issuing Entity	Tranche	Number of shares under option	Class of shares	Exercise price of option	Expiry date of options
Medical Developments International Ltd	1	400,000	Ordinary	\$2.50	28-Feb-17
Medical Developments International Ltd	2	400,000	Ordinary	\$2.50	30-Sep-17
Medical Developments International Ltd	3	200,000	Ordinary	\$2.50	31-Dec-16
		1,000,000			

Tranche 1 had satisfied its vesting conditions at 30 June 2016 but remained unexercised.

Tranche 2 of this option plan satisfied its vesting condition on 11 July 2016.

Tranche 3 remains unvested as at 30 June 2016.

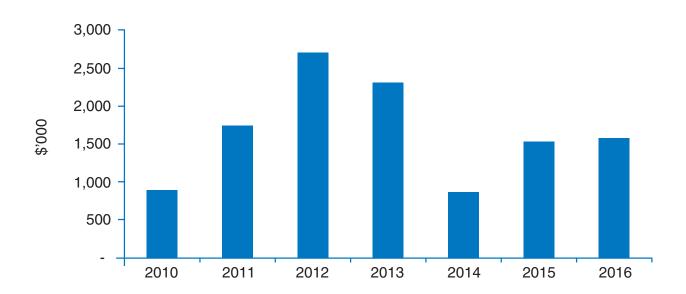
The remuneration and nominations committee, comprised of D.J. Williams and A.D. McCallum, determines the salary package of the CEO of the company and reviews the compensation of the non-executive directors on an annual basis. Changes are approved by the board as a whole.

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

#### **Net Profit After Tax 2010-2016**



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

	2010	2011	2012	2013	2014	2015	2016
Share price - start (\$)	0.18	0.22	0.40	0.79	1.27	1.32	2.68
Share price - end (\$)	0.22	0.40	0.79	1.27	1.32	2.68	6.10
Interim Dividend (cps)*	-	-	3.00	3.00	-	-	2.00
Final Dividend (cps)*	-	3.00	3.00	2.00	-	-	2.00
Basic Earnings per Share (cps)	1.70	3.40	5.10	4.10	1.50	2.65	2.71
Diluted Earnings per Share (cps)	1.70	3.40	5.10	4.10	1.50	2.65	2.68

<sup>\*</sup>Franked to 100% at 30% 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 2016:

2016	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total
2010	Fees \$	Bonus \$	Superannuation \$	service leave \$	Options & Rights \$	\$
Directors						
D. J. Williams	61,644	-	5,856	-	-	67,500
A. D. McCallum	37,671	-	3,579	-	-	41,250
H. F. Oxer	37,671	-	3,579	-	-	41,250
M. Johnston	37,671	-	3,579	-	-	41,250
L. Hoare	37,671	-	3,579	-	-	41,250
P.J. Powell	19,671	-	19,869	-	-	39,540
	231,999	-	40,041	-	-	272,040

2016	Short- Employee		Post Employment	Long-term employee benefits service	Share- Based Payments Options	Total	Remuneration Linked to performance
	Fees \$	Bonus \$	Superannuation \$	leave \$	& Rights \$	\$	,
Executives							
J. Sharman (Chief Executive Officer)	290,664	30,000	26,314	14,425	318,185	679,588	4%
M. Edwards (Company Secretary)	145,453	4,566	14,207	581	-	164,807	3%
	436,117	34,566	40,521	15,006	318,185	844,395	

Both Mr Sharman and Mr Edwards remuneration comprised of a performance related component of \$30,000 and \$4,566 respectively. No directors remuneration contained a performance related component.

The value of the options granted to Mr Sharman as part of his remuneration was calculated at grant date using a Monte Carlo simulation pricing model. The model estimates the achievement of the vesting hurdles and calculated the present value of the payoff on vesting. This value is amortised over potential vesting period and disclosed as part of remuneration for the financial year with an adjustment made to remuneration expense for any options vesting earlier or probable to do so.

The following table discloses the remuneration of the directors of the company in 2015:

2015	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	54,795	-	5,205	-	-	60,000
A. D. McCallum	34,247	-	3,253	-	-	37,500
H. F. Oxer	34,247	-	3,253	-	-	37,500
M. Van Ryn (resigned 28 July 2014)	2,854	-	271	-	-	3,125
M. Johnston	34,247	-	3,253	-	-	37,500
L. Hoare	34,247	-	3,253	-	-	37,500
P.J. Powell (appointed 17 December 2014)	12,843	-	6,928	-	-	19,771
	207,480	-	25,416	-	-	232,896

The following table discloses the remuneration of the key executives of the company in 2015:

2015	Short-Term Employee Benefits		Post Employment	Long-term employee benefits	Share-Based Payments	Total
	Salary & Fees \$	Bonus \$	Superannuation	Long service leave \$	Options & Rights \$	\$
Executives						
J. Sharman (Chief Executive Officer)	275,132	-	24,868	8,161	-	308,161
M. Edwards (Company Secretary)	141,876	-	13,478	277	-	155,631
	417,008	-	38,346	8,438	-	463,792

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 2016 financial year, discretionary bonuses totalling \$34,566 (2015: \$nil) were determined and approved by the Remuneration and Nominations Committee in relation to key management personnel in respect of their performance in the 2015 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 and other accounting and assurance services and totalled \$86,875. 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.

#### Auditor's independence declaration

The auditor's independence declaration is included on page 33 of the annual report.

#### Rounding off of amounts

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 directors' report and the financial report 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.

( Jul W.

#### **David Williams**

Chairman

Melbourne, 18 August 2016



# Deloitte.

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

18 August 2016

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 2016, 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 Vorwerg Partner

Chartered Accountants



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

#### **Report on the Financial Report**

We have audited the accompanying financial report of Medical Developments International Limited, which comprises the statement of financial position as at 30 June 2016, statement of profit or loss and other comprehensive income, the statement of cash flows and the statement of changes in equity for the year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the consolidated entity, comprising the company and the entities it controlled at the year's end or from time to time during the financial year as set out on pages 37 to 68.

#### Directors' Responsibility for the Financial Report

The 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 the 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 Note 1, the directors also state, in accordance with Accounting Standard AASB 101 *Presentation of Financial Statements*, that the consolidated financial statements comply with International Financial Reporting Standards.

#### Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control, relevant to the company's preparation of the financial report that gives a true and fair view, 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 company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

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

#### Auditor's Independence Declaration

In conducting our audit, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the *Corporations Act 2001*,

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### Deloitte.

which has been given to the directors of Medical Developments International Limited, would be in the same terms if given to the directors as at the time of this auditor's report.

#### Opinion

#### In our opinion:

- (a) the financial report of Medical Developments International Limited is in accordance with the *Corporations Act 2001*, including:
  - (i) giving a true and fair view of the consolidated entity's financial position as at 30 June 2016 and of its performance for the year ended on that date; and
  - (ii) complying with Australian Accounting Standards and the Corporations Regulations 2001; and
- (b) the consolidated financial statements also comply with International Financial Reporting Standards as disclosed in Note 1.

#### **Report on the Remuneration Report**

We have audited the Remuneration Report included in pages 27 to 32 of the directors' report for the year ended 30 June 2016. The 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.

#### Opinion

In our opinion the Remuneration Report of Medical Developments International Limited for the year ended 30 June 2016, complies with section 300A of the *Corporations Act 2001*.

#### DELOITTE TOUCHE TOHMATSU

**DELOITTE TOUCHE TOHMATSU** 

Samuel Vorwerg

Partner

Chartered Accountants Melbourne, 18 August 2016

## 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;
- 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, 18 August 2016



# Consolidated Statement of Profit or Loss and Other Comprehensive Income for the Financial Year Ended 30 June 2016

	Note	2016 \$'000	2015 \$'000
Revenue from sale of goods and contracts	4(a)	15,471	11,608
Cost of sales		(4,260)	(3,554)
Gross profit		11,211	8,054
Other income	4(a)	22	116
Distribution expenses		(900)	(587)
Marketing expenses		(1,637)	(1,165)
Occupancy expenses		(541)	(396)
Administration expenses		(3,559)	(2,030)
Regulatory and registration expenses		(1,253)	(791)
Finance expenses		(24)	(81)
Other expenses		(1,018)	(944)
Profit before income tax expense		2,301	2,176
Income tax (expense)/benefit	5(a)	(732)	(647)
Profit for the year		1,569	1,529
Other Comprehensive Income			
Items that may be reclassified subsequently to profit or loss, net of income tax			
Exchange differences on translating foreign operations	21	(82)	54
Total comprehensive income for the year		1,487	1,583
Profit for the year attributable to:			
Owners of the parent		1,569	1,583
Total comprehensive income for the year attributable to:			
Owners of the parent		1,487	1,583
Earnings per share:			
	00	0.7	0.6
Basic (cents per share)	23	2.7	2.6
Diluted (cents per share)	23	2.7	2.6

## Consolidated Statement of Financial Position as at 30 June 2016

	Note	30 June 2016 \$'000	30 June 2015 \$'000	
Current Assets				
Cash and cash equivalents	29(a)	5,620	954	
Trade and other receivables	8	7,520	1,819	
Inventories	9	2,667	1,887	
Current tax assets	5(c)	-	-	
Other	10	244	175	
Total Current Assets		16,051	4,835	
Non-Current Assets				
Property, plant and equipment	12	2,614	1,522	
Deferred tax assets	5(d)	1,928	143	
Goodwill	13	8,874	7,368	
Other intangible assets	14	11,772	9,120	
Total Non-Current Assets		25,188	18,153	
Total Assets		41,239	22,988	
Current Liabilities				
Trade and other payables	15	2,518	1,231	
Borrowings	16	143	92	
Provisions	17	254	215	
Current tax liabilities	5(c)	4,124	294	
Other	19	1,772	-	
Total Current Liabilities		8,811	1,832	
Non-Current Liabilities				
Deferred tax liabilities	5(e)	-	1,703	
Borrowings	16	338	1,019	
Provisions	18	114	93	
Other	19	12,951	934	
Total Non-Current Liabilities		13,403	3,749	
Total Liabilities		22,214	5,581	
Net Assets		19,025	17,407	
Equity				
Issued capital	20	11,916	10,946	
Reserves	21	257	21	
Retained earnings	22	6,852	6,440	
Total Equity		19,025	17,407	

## Consolidated Statement of Changes in Equity for the Financial Year Ended 30 June 2016

2016	Issued capital \$'000	Retained earnings \$'000	Employee equity settled benefits reserve \$'000	Foreign currency translation reserve \$'000	Total \$'000
Opening balance	10,946	6,440	-	21	17,407
Profit for the year	-	1,569	-	-	1,569
Other comprehensive income for the year, net of income tax	-	-	-	(82)	(82)
Total comprehensive income for the year	-	1,569	-	(82)	1,487
Share based payments	-	-	318	-	318
Dividends paid	-	(1,157)	-	-	(1,157)
Shares issue related to business acquisition	440	-	-	-	440
Dividends reinvested in the form of shares	534	-	-	-	534
Equity raising costs	(4)	-	-	-	(4)
Closing balance	11,916	6,852	318	(61)	19,025

## Financial Year Ended 30 June 2015

2015	Issued capital \$'000	Retained earnings \$'000	Employee equity settled benefits reserve \$'000	Foreign currency translation reserve \$'000	Total \$'000
Opening balance	10,946	4,911	-	(33)	15,824
Profit for the year	-	1,529	-	-	1,529
Other comprehensive income for the year, net of income tax	-	-	-	54	54
Total comprehensive income for the year	-	1,529		54	1,583
Share based payments	-	-	-	-	-
Dividends reinvested in the form of shares	-	-	-	-	-
Dividends paid	-	-	-	_	-
Closing balance	10,946	6,440	-	21	17,407

## Consolidated Statement of Cash Flows for the Financial Year Ended 30 June 2016

	1		
	Note	2016 \$'000	2015 \$'000
Cash flows from operating activities			
Receipts from customers		12,689	12,135
Payments to suppliers and employees		(11,050)	(9,245)
Receipts from government grants		-	111
Upfront and milestone payments received		10,858	-
Interest paid		(24)	(65)
Income tax received/(paid)		(406)	423
Net cash generated by operating activities	29(b)	12,067	3,359
Cash flows from investing activities			
Interest received		22	5
Payments for plant and equipment		(1,421)	(555)
Payments for other intangible assets		(2,724)	(957)
Payments for business acquisition		(2,029)	-
Net cash used in investing activities		(6,152)	(1,507)
Cash flows from financing activities			
Dividends paid (net of DRP)	24	(623)	-
Share issue transaction costs		(4)	-
Payments for hire purchase finance	16	(92)	(46)
Repayment of borrowings	16	(538)	(2,534)
Net cash (used in)/generated by financing activities		(1,257)	(2,580)
Net (decrease)/increase in cash and cash equivalents		4,658	(728)
Cash and cash equivalents at the beginning of the financial year		954	1,659
,			,
Effects of exchange rate changes on the balance of cash held in foreign currencies		8	23
Cash and cash equivalents at the end of the financial year	29(a)	5,620	954

# Notes to the Financial Statements for the Financial Year Ended 30 June 2016

## 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 18 August 2016.

## **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 cashgenerating 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.

## (I) 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 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 5-20 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.

### Brandnames

Brandnames 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, brandnames 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 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 to the buyer the significant risks and rewards of ownership of the goods.

#### 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 equitysettled share-based payments is expensed on a straightline basis over the vesting period, based on the company's estimate of options that will eventually vest. Details regarding the fair value of equity-settle share based transactions are set out in note 32. 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 2015, and therefore relevant for the current year end:

AASB 2015-3 'Amendments to Australian Accounting Standard arising from the withdrawal of AASB 1031 Materiality' This amendment completes the withdrawal of references to ASSB 1031 in all Australian Accounting Standards and Interpretations, allowing that Standard to effectively be withdrawn.

The application of this 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', and the relevant amending standards	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
AASB 16 'Leases'	1 January 2019	30 June 2020
AASB 1057 'Application of Australian Accounting Standards' and AASB 2015 9 'Amendments to Australian Accounting Standards – Scope and Application Paragraphs'	1 January 2016	30 June 2017
AASB 2014-4 'Amendments to Australian Accounting Standards – Clarification of Acceptable Methods of Depreciation and Amortisation'	1 January 2016	30 June 2017
AASB 2015-1 'Amendments to Australian Accounting Standards – Annual Improvements to Australian Accounting Standards 2012-2014 Cycle'	1 January 2016	30 June 2017
AASB 2015-2 'Amendments to Australian Accounting Standards – Disclosure Initiative: Amendments to AASB 101'	1 January 2016	30 June 2017
AASB 2015-5 'Amendments to Australian Accounting Standards – Investment Entities: Applying the Consolidation Exception'	1 January 2016	30 June 2017
AASB 2016-1 'Amendments to Australian Accounting Standards – Recognition of Deferred Tax Assets for Unrealised Losses'	1 January 2017	30 June 2018
AASB 2016-2 'Amendments to Australian Accounting Standards – Disclosure Initiative: Amendments to AASB 107'	1 January 2017	30 June 2018

# 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 \$8,874,000 (2015: \$7,368,000). Details of the impairment calculation are provided in note 13.

## Useful life of capitalised registration costs

During the year, management reviewed the unamortised balance of registration costs capitalised in previous periods. Consideration was given to the cost for each classification of capitalised costs to determine whether the corresponding benefits are likely to arise. Developments continue on the unamortised categories of registration costs capitalised in prior periods, and once revenue has been generated in these categories, the balances will be amortised. At the reporting date there was no indication that any of the internally generated intangible assets, relating to registration costs, were impaired. Management continually reassess the appropriateness of useful lives assigned to each individual category of registration costs. This situation will be closely monitored, and amortisation will be recognised in future periods as corresponding economic benefits flow. Details of the capitalised registration costs 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 FY16 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 2016 as the Group continues to be profitable, generates positive operating cash flows, Is not currently using its external loan facility balance and continues to be in a positive net asset position, which enables the Group to meets its debts and obligations as and when they fall due.

## **Share Based Payments**

Refer note 1(s) for further discussion on judgements made affecting share based payments.

## 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 Penthrox® 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

	Pharma	ceuticals	Medical E	iquipment	Veter Equip		Unallo	cated	То	tal
	2016 \$'000	2015 \$'000								
Revenues:										
External sales	10,043	7,092	4,943	4,078	485	438	-	-	15,471	11,608
Other income (excluding interest)	-	-	-	-	-	-	-	111	-	111
Total revenue									15,471	11,719
Results:										
Segment results	4,782	3,456	589	270	186	281			5,557	4,007
Unallocated							(2,159)	(1,377)	(2,159)	(1,377)
Profit before interest, income tax depreciation & amortisation	4,782	3,456	589	270	186	281	(2,159)	(1,377)	3,398	2,630
Depreciation & Amortisation	(868)	(235)	(129)	(44)	(15)	(6)	(83)	(93)	(1,095)	(378)
Profit before interest and tax	3,914	3,221	460	226	171	171	(2,242)	(2,242)	2,303	2,252
Net Interest							(2)	(76)	(2)	(76)
Profit before income tax expense							(2,244)	(1,546)	2,301	2,176
Income tax benefit/(expense)							(732)	(647)	(732)	(647)
Net profit for the period from continuing operations							(2,976)	(2,193)	1,569	1,529
Assets and Liabilities										
Assets	22,319	15,504	9,736	5,162	1,064	859	8,120	1,463	41,239	22,988
Liabilities	-	-	-	-	-	-	22,214	5,581	22,214	5,581
Other Segment Information										
Acquisition of segment assets	3,630	1,279	211	193	29	14	274	23	4,144	1,509

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 three principal geographical areas: Australia (country of domicile); New Zealand; 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 2016 \$'000	%	Revenue from external customers 2015 \$'000	%
Australia	9,123	63.5%	7,586	65.4%
New Zealand	323	2.3%	1,394	12.0%
International	4,927	34.3%	2,628	22.6%
	14,373	100.0%	11,608	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	177	-	177
Plant and equipment at cost	2,159	278	2,437
Goodwill at gross carrying amount	8,874	-	8,874
Other intangible assets at cost	11,772	-	11,772
Deferred tax asset	1,841	87	1,928
	24,823	365	25,188

## Information about major customers

The Group had no individual customers who contributed 10% or more to the Group's total 2016 revenue.

## 4. Items included in profit and loss

	2016 \$'000	2015 \$'000
(a) Revenue and other income		
Revenue from sale of goods	14,373	11,608
Interest revenue - bank deposits	22	5
Upfront and milestone income	1,098	-
Government grant income	-	111
	15,493	11,724
(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	(286)	(233)
Amortisation of non-current assets	(810)	(144)
Research & development costs immediately expensed	(77)	(129)
Operating lease rental expenses - minimum lease payments	(292)	(167)
Share based payments (equity settled)	(318)	-
Gain/(loss) on foreign currency transactions	(48)	32
Finance Expenses		
Interest on bank loans	(10)	(58)
Interest on other loans/hire purchase arrangements	(14)	(23)
	(24)	(81)
Employee benefit expense:		
Short-term employee benefits	(3,058)	(2,624)
Superannuation contributions	(426)	(344)

## 5. Income Taxes

	2016 \$'000	2015 \$'000
(a) Income tax recognised in profit or loss		
Tax expense comprises:		
Current tax expense	685	659
Adjustments recognised in the current year in relation to the current tax of prior year	47	41
Deferred tax expense relating to the origination and reversal of temporary differences	-	(53)
Total tax expense/(benefit)	732	647

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

Profit from operations	2,301	2,177
Income tax calculated at 30%	690	653
Research & development expense	(82)	(53)
Effect of expenses that are not deductible in determining taxable profit	99	6
Adjustments recognised in the current year in relation to the current tax of prior year	47	41
Effect of profit or loss items eliminated on consolidation	(11)	-
Effect of different tax rates of subsidiaries operating in other jurisdictions	(11)	-
Income tax expense recognised in the Statement of Profit or Loss and Other Comprehensive Income	732	647

The tax rate used in the above reconciliation is the corporate tax rate of 30% payable by Australian corporate entities on taxable profits under Australian tax law. There has been no change in the corporate tax rate when compared with the previous reporting period.

## (b) Income tax recognised directly in equity

No current and deferred tax amounts have been charged directly to equity during the period (2015: \$nil)

## (c) Current tax assets/liabilities

Income tax receivable (payable)/receivable	(4,124)	(294)
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MVP has received substantial upfront payments during the current year 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, whilst a tax liability also arises.

## (d) Deferred tax asset (non-current)

Temporary differences	1,928	143
(e) Deferred tax liabilities		
Temporary differences	_	(1.703)

2016	Opening balance \$'000	Charged to income \$'000	Closing balance \$'000
Deferred tax assets/(liabilities):			
Accrued expenses	192	(57)	135
Deferred revenue	95	4,322	4,417
Other assets	(2)	2	-
Other Intangibles	(2,027)	(971)	(2,998)
Property, Plant & Equipment	12	(4)	8
Provisions	142	67	209
Tax losses	-	87	87
Unrealised foreign exchange losses	28	42	70
	(1,560)	3,488	1,928

2015	Opening balance \$'000	Charged to income \$'000	Closing balance \$'000
Deferred tax assets/(liabilities):			
Accrued expenses	51	141	192
Deferred revenue	95	-	95
Other assets	(2)	-	(2)
Other Intangibles	(1,678)	(349)	(2,027)
Property, Plant & Equipment	20	(8)	12
Provisions	95	47	142
Tax losses	104	(104)	-
Unrealised foreign exchange losses	5	23	28
	(1,310)	(250)	(1,560)

## 6. Key management personnel compensation

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

	2016 \$'000	2015 \$'000
Short-term employee benefits	703	625
Post employment benefits	81	64
Long term employee benefits	15	8
Share based payments	318	-
	1,117	697

## 7. Remuneration of auditors

	2016 \$	2015 \$
Auditor of the parent entity		
Audit or review of the financial report	84,530	79,000
Taxation services	36,875	18,800
Other services	50,000	30,000
	171,405	127,800

The auditor of the entity is Deloitte Touche Tohmatsu. The other services relate to corporate advisory services.

## 8. Current receivables

	2016 \$'000	2015 \$'000
Trade receivables	3,396	1,777
Other debtors	4,032	-
Allowance for doubtful debts	-	-
GST recoverable	92	42
	7,520	1,819

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 \$124,323 (2015: \$91,046) 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

	2016 \$'000	2015 \$'000
60-90 days	48	9
> 90 days	76	82
Total	124	91

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

	2016 \$'000	2015 \$'000
Raw materials:		
At cost	1,041	709
Work in progress:		
At cost	480	334
Finished goods:		
At cost	1,166	858
Provision for obsolesence	(20)	(14)
	2,667	1,887

The provision for obsolescence at 30 June 2016 represents predominantly obsolete packing materials.

## 10. Other current assets

	2016 \$'000	2015 \$'000
Prepayments	244	175

## 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	Proportion of ownersh power held b	nip interest and voting by the Group
		and operation	30/06/16	30/06/15
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%	-

## 12. Property, Plant & Equipment

	Leasehold improvements at cost \$'000	Plant and equipment at cost \$'000	Total \$'000
Gross carrying amount			
Balance at 30 June 2014	555	2,870	3,425
Additions	64	490	554
Transfers from other intangible assets	-	77	77
Balance at 30 June 2015	619	3,437	4,056
Additions	44	1,376	1,420
Disposals	(248)	(4)	(252)
Balance at 30 June 2016	415	4,809	5,224
Accumulated depreciation			
Balance at 30 June 2014	(288)	(2,012)	(2,300)
Depreciation expense	(80)	(154)	(234)
Disposals	-	-	-
Balance at 30 June 2015	(368)	(2,166)	(2,534)
Depreciation expense	(75)	(210)	(285)
Disposals	205	4	209
Balance at 30 June 2016	(238)	(2,372)	(2,610)
Net book value			
As at 30 June 2015	251	1,271	1,522
As at 30 June 2016	177	2,437	2,614

## 13. Goodwill

	2016 \$'000	2015 \$'000
Gross carrying amount		
Balance at beginning of financial year	7,368	7,368
Additions	1,506	-
Balance at end of financial year	8,874	7,368
Net book value		
Balance at beginning of financial year	7,368	7,368
Balance at end of financial year	8,874	7,368

During the year, the company assessed the recoverable amount of goodwill and determined that there was no impairment (2015: \$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:

	2016 \$'000	2015 \$'000
Pharmaceuticals	3,808	3,808
Medical devices	4,485	2,979
Veterinary equipment	581	581
	8,874	7,368

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 12.24% per annum (2015: 14.06% 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 continue to improve 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

2016	Development \$'000	Patents & trademarks \$'000	Capitalised registration costs \$'000	Brandnames \$'000	Other \$'000	Total \$'000
Gross carrying amount						
Balance at 30 June 2014	1,538	383	6,946	-	-	8,867
Additions	132	65	696	-	63	956
Transfer to PP&E	(77)	-	-	-	-	(77)
Balance at 30 June 2015	1,593	448	7,642	-	63	9,746
Additions	381	118	1,644	738	581	3,462
Balance at 30 June 2016	1,974	566	9,286	738	644	13,208
Accumulated amortisation						
Balance at 30 June 2014	(48)	(136)	(298)	-	-	(482)
Amortisation expense	(71)	(41)	(32)	-	-	(144)
Balance at 30 June 2015	(119)	(177)	(330)	-	-	(626)
Amortisation expense	(87)	(49)	(621)	-	(53)	(810)
Balance at 30 June 2016	(206)	(226)	(951)	-	(53)	(1,436)
Net book value						
As at 30 June 2015	1,474	271	7,312	-	63	9,120
As at 30 June 2016	1,768	340	8,335	738	591	11,772

The amortisation charge for the year of \$810,000 (2015: \$144,000) has been included in administration expenses. For an explanation of amortisation periods refer Note 1(l).

## 15. Current trade and other payables

	2016 \$'000	2015 \$'000
Trade payables (i)	1,989	810
Accrued expenses	491	387
Employee benefits payable	37	32
PAYG witholding tax payable	1	2
	2,518	1,231

<sup>(</sup>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

	2016 \$'000	2015 \$'000
Secured - at amortised cost		
Hire Purchase (i)	82	115
Hire Purchase (ii)	37	52
Bank Bill (iii)	-	538
Other (iv)	362	406
	481	1,111
Current	143	92
Non-current	338	1,019
	481	1,111

## 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 6.76% 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 6.51%. 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. As at 30 June 2016, the facility is unused. The weighted average effective interest rate on the bill when used through the year was 4.17% p.a. 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 Penthrox®. 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 2016, the stage 1a and 1b 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%. The funding for stage 2 is interest free.
- (v) The Group has an overdraft facility of \$200,000. As at 30 June 2016, this remains unused.

## 17. Current provisions

	2016 \$'000	2015 \$'000
Employee benefits	254	215

## 18. Non-current provisions

	2016 \$'000	2015 \$'000
Employee benefits	114	93

The company has 42.35 full time equivalent employees at 30 June 2016 (2015: 29.5)

## 19. Other liabilities

	2016 \$'000	2015 \$'000
Revenue received in advance	14,431	616
Unearned government grant income	292	318
	14,723	934
Current	1,772	-
Non-current	12,951	934
	14,723	934

MVP has received further substantial upfront and milestone payments during the current year, in addition to the upfront payment of approximately \$0.6m received in FY15. 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 2016 \$14.431m remains unamortised.

Unearned government grant income represents funds received through the Commercial Ready Programme from the Federal Government.

## 20. Issued Capital

## 20(a) Fully paid ordinary shares

	2016 No.	2016 \$'000	2015 No.	2015 \$'000
Fully paid ordinary shares				
Balance at beginning of financial year	57,725,143	10,946	57,725,143	10,946
Shares Issued - Business Acquisition	117,894	440	-	-
Shares Issued - Dividends Reinvestment Plan	117,019	534	-	-
Capital raising costs	-	(4)	-	-
Balance at end of financial year	57,960,056	11,916	57,725,143	10,946

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

20(b) Share options granted under the CEO Long Term Incentive Plan.

At 30 June 2016, the CEO held options over 1,000,000 ordinary shares of the Company. Share options granted to the CEO carry no rights to dividends and no voting rights.

## 21. Reserves

	2016 \$'000	2015 \$'000
(a) Foreign currency translation reserve		
Balance at beginning of year	21	(33)
Exchange differences arising on translating the foreign operations	(82)	54
Balance at end of year	(61)	21

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.

	2016 \$'000	2015 \$'000
(b) Employee equity-settled benefits reserve		
Balance at beginning of year	-	-
Share-based payment recognised	318	-
Balance at end of year	318	-

The above equity settled employee benefits reserve related to share options granted by the company to its CEO under its employee share option plan. Further information about share-based payments to employees is set out in note 32.

## 22. Retained earnings

	2016 \$'000	2015 \$'000
Balance at beginning of financial year	6,440	4,911
Dividends paid	(1,157)	-
Net profit attributable to members	1,569	1,529
Balance at end of financial year	6,852	6,440

## 23. Earnings per share

	2016 Cents per share	2015 Cents per share
Basic earnings per share	2.7	2.6
Diluted earnings per share	2.7	2.6

## 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:

	2016 \$'000	2015 \$'000
Earnings	1,569	1,529
	2016	2015

	2016 No.	2015 No.
Weighted average number of ordinary shares	57,798,709	57,725,143

## 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. However for the purposes of the dilutive earnings per share, the following options are potentially dilutive as they have vested at 30 June 2016 (or soon after) and are therefore included in the weighted average number of ordinary shares for the purposes of diluted earnings per share calculation.

	2016 No.
Weighted average number of ordinary shares used in the calculation of basic EPS	57,798,709
Shares deemed to be issued for no consideration in respect of:	
- CEO LTIP - Tranche 1 and 2	340,844
Weighted average number of ordinary shares for diluted EPS	58,139,553

## 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 full year ended 30 June 2016.

The interim dividend paid during the 30 June 2016 year resulted in the company paying dividends of \$623,000 and the balance of \$534,000 issued as shares under the Dividend Reinvestment Plan.

There were no dividends declared in respect to the prior year.

	2016 \$'000	2015 \$'000
Adjusted franking account balance	4134	106

	2016		2015	
	cents per share	\$'000	cents per share	\$'000
Recognised amounts				
Fully paid ordinary shares				
Interim dividend - fully franked	2.0	1,157	-	-
	2.0	1,157	-	-
Unrecognised amounts				
Fully paid ordinary shares				
Final dividend - fully franked	2.0	1,157	-	-
	2.0	1,157	-	-

## 25. Operating leases

Operating leases primarily relate to factory leases with remaining lease terms ranging from 2.5 to 9.5 years. The company does not have the option to purchase the leased asset at the expiry of the lease period.

	2016 \$'000	2015 \$'000
Non cancellable operating lease payments:		
Not longer than 1 year	108	82
Longer than 1 year and not longer than 5 years	1,331	13
Greater than 5 years	1,540	-
	2,979	95

## 26. Commitments for expenditure

### (a) Capital expenditure commitments

There were no capital expenditure commitments at 30 June 2016.

## 27. Related party disclosures

During the current year Medical Developments Limited paid \$150,000 to Kidder Williams Limited as a success fee related to corporate advisory services provided in relation to the acquisition of Breath-A-Tech (refer note 33 for further details associated with this acquisition). This transaction was made on an arm's length basis on normal commercial terms. Medical Developments International Chairman, David Williams, is the owner and Managing Director of Kidder Williams.

There were no other related party transactions during the 2016 or 2015 financial years.

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.

## 28. Subsequent events

On 10 August 2016 it was announced that tranche one of the CEO Long Term Incentive Option Plan had vested and been exercised resulting in the issuing of 400,000 shares. Tranche 2 of this Plan for a further 400,000 shares also vested on 11 July 2016 and is able to be exercised up until 11 October 2016.

On the 18th August 2016 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 2 September 2016, to be paid to the shareholders on the 7 October 2016. This dividend has not been included as a liability in these financial statements.

There has not been no 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

	2016 \$'000	2015 \$'000
a) Reconciliation of cash and cash equivalents		
For the purposes of the Consolidated Statement of Cash Flows, cash includes cash on land 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	5,620	954
	5,620	954
b) Reconciliation of profit for the period to net cash flows from operating activities		
Profit for the period		
nterest received	1,569	1,529
Depreciation and amortisation of non-current assets	(22)	(5)
Net foreign exchange (gain)	1,096	377
Share based payments	202	(32)
oss on disposal of property, plant and equipment	6	_
	0	
mpairment loss on trade receivables	-	79
ncrease in tax payable	3,830	806
ncrease in deferred tax liability	(3,488)	250
Movements in working capital		
Decrease/(increase) in assets:		
Current receivables	(5,701)	(11)
Current inventories	(780)	(441)
Other current assets	(69)	(22)
ncrease/(decrease) in liabilities:		
Current payables	1,258	155
Current provisions	39	35
Other liabilities	13,789	616
Non-current provisions	21	23
Net cash from operating activities	12,067	3,359
c) Financing facilities		
Insecured 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	-	538
Amount unused	2,960	3,262
	2,960	3,800

## 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 2016 is -27% (see below).

	2016 \$'000	2015 \$'000
Debt (i)	481	1,111
Cash and bank balances	(5,620)	(954)
Net debt / (cash)	(5,139)	157
Equity (ii)	19,025	17,407
Net debt to equity ratio	-27%	1%

- (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 includes financial covenants whereby the current ratio must be no less than 2 times, a debt cover ratio that must be no less than 2 times and the operating leverage ratio must be no higher than 3 times. 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	
	2016 \$'000	2015 \$'000	2016 \$'000	2015 \$'000
USD	1,160	404	5,872	755
GBP	524	257	1,249	131
NZD	-	-	-	28
EUR	1	-	92	32
CND	5	4	84	4
	1,690	665	7,297	950

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	
	2016 \$'000	2015 \$'000
Profit or Loss	(471)	(35)

	GBP Impact	
	2016 \$'000	2015 \$'000
Profit or Loss	(72)	13

This is attributable to the exposure outstanding on USD 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 2016 and 30 June 2015.

		Variable interest rate maturity					
2016	Average interest rate %	Less than 1 year \$'000	1 to 5 years \$'000	More than 5 years \$'000	Non- interest bearing \$'000	Total \$'000	
Financial assets							
Cash	0.03%	5,620	-	-	-	5,620	
Receivables	-	-	-	-	7,520	7,520	
		5,620	-	-	7,520	13,140	
Financial liabilities							
Payables	-	-	-	-	2,518	2,518	
Borrowings	5.43%	143	338	-	-	481	
		143	338	-	2,518	2,999	

	Variable interest rate maturity					
2015	Average interest rate %	Less than 1 year \$'000	1 to 5 years \$'000	More than 5 years \$'000	Non- interest bearing \$'000	Total \$'000
Financial assets						
Cash	0.06%	954	-	-	-	954
Receivables	-	-	-	-	1,819	1,819
		954	-	-	1,819	2,773
Financial liabilities						
Payables	-	-	-	-	1,231	1,231
Borrowings	4.92%	92	1,019	-	-	1,111
		92	1,019	-	1,231	2,342

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

### Interest rate table

	2016 \$'000	2015 \$'000
Profit or Loss	26	(1)

## (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
2016					
Payables	-	2,518	-	-	2,518
Borrowings	5.43%	143	338	-	481
		2,661	338	-	2,999
2015					
Payables	-	1,231	-	-	1,231
Borrowings	4.92%	92	1,019	-	1,111
		1,323	1,019	-	2,342

## 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 2016 \$'000	30 June 2015 \$'000
Assets		
Current Assets	16,419	4,631
Non-Current Assets	25,093	18,003
Total Assets	41,512	22,634
Liabilities		
Current Liabilities	6,958	1,678
Non-Current Liabilities	15,175	3,151
Total Liabilities	22,133	4,829
Equity		
Issued capital	11,916	10,946
Reserves	318	-
Retained earnings	7,145	6,859
Total Equity	19,379	17,805

## **Financial Performance**

	2016 \$'000	2015 \$'000
Profit for the year	1,443	1,564
Dividends paid	(1,157)	-
Other comprehensive income	-	-
Total comprehesive income	286	1,564

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

## 32. Employee share option plan

## 32.1 CEO share option plan

The following share-based payment arrangements were in existence during the current reporting period.

On 18 January 2016 the company announced it has agreed to a Long Term Incentive Plan 'LTIP' with Mr. John Sharman, the CEO of Medical Developments International Limited to encourage his long term commitment to the business.

The key plan features are summarised as follows:

- A grant of 400,000 options with a strike price of \$2.50 but vesting only when the MVP share price has been above \$4.50 at all times for 60 continuous ASX Trading days. These options will expire 28 February 2017.
- A grant of 400,000 options with a strike price of \$2.50 but vesting only when the MVP share price has been above \$5.50 for 60 continuous ASX Trading days. These options will expire 30 September 2017; and
- A grant of 200,000 options with a strike price of \$2.50 but vesting only when reimbursement is approved for Penthrox<sup>®</sup> in Germany or Registration is approved in Germany (whichever occurs first). These options will expire on the 31 December 2016.

Each share option converts into one ordinarily share of Medical Developments Limited on exercise. No amounts are paid or payable by the recipient on the receipt of the option nor are they tradeable at any time. The options carry neither rights to dividends or voting rights.

Under the terms of the plan, all outstanding options will be cancelled if Mr. Sharman leaves or is otherwise no longer employed at MVP. When the LTIP delivers an entitlement to an equity interest via the prevailing share price hurdle, Mr. Sharman will have 3 months to exercise the relevant options, after which the relevant options will lapse. In each case, 60% of the new shares issued by exercising options will be escrowed for a period of 12 months from issue date.

There has been no alteration to the terms and conditions of the above share based payment arrangement since grant date.

## 32.2 Fair value of share options granted during the year

Options with share market price performance hurdles were priced using a Monte Carlo valuation model. The Monte Carlo model estimates the achievement of the vesting hurdles and calculates the present value of the pay off on vesting. It enables specific modelling of the hurdles specified under the plan, in particular the requirement for a share price minimum to be maintained for a specified time. Options with other performance hurdles vesting conditions where the outcome is binary, were priced using a Binomial option pricing model. Where relevant, the expected useful life used in the model has been adjusted based on management's best estimate for the effects of non-transferability and exercise restrictions (including the probability of meeting market conditions attached to the option). Expected volatility is based on the historical share price volatility over the past 2 years.

Inputs into the option pricing model were as follows:

	Tranche 1	Tranche 2	Tranche 3
Grant date share price	\$2.91	\$2.91	\$2.91
Exercise price	\$2.50	\$2.50	\$2.50
Option Fair Value	\$0.42	\$0.52	\$0.00
Expected volatility	56%	50%	56%
Option life	1.1 yrs	1.7 yrs	0.95 yrs
Dividend (Bi-annually)	2c	2c	2c
Risk-free interest rate	1.94%	1.93%	1.94%

## 32.3 Movement in share options during the year

There were no share options exercised during the year.

## 32.4 Share based payments expense

	2016 \$'000	2015 \$'000
Share-based payments	318	-

## 33. Business Combinations

On 5 February 2016 Medical Developments International Limited acquired the respiratory business assets of Avita Medical Limited. This acquisition included the Breath-A-Tech branded range of products, which is the leading brand of asthma space chambers in the Australian pharmacy and hospital markets and will help establish Medical Developments International as market leader throughout Australia in asthma respiratory devices.

### (a) Consideration

	\$'000
Cash	\$2,029
Equity (shares in MVP) *	\$ 440
Total	\$2,469

\*- 117,894 MVP shares based on the 5-day VWAP prior to completion (escrowed for 6 months).

Acquisition-related costs amounting to \$238,313 have been excluded from the consideration transferred and have been recognised as an expense in the income statement during the current year.

### (b) Assets acquired at the date of acquisition

	\$'000
Current assets	
Inventories	225
Non-current assets	
Brandnames	738

The initial accounting for the acquisition has only been provisionally determined at the end of the reporting period.

### (c) Goodwill arising on acquisition

	\$'000
Consideration transferred	2,469
Less: fair value of identifiable net assets acquired	(963)
Goodwill arising on acquisition	1,506

Goodwill arose on the acquisition because of the expected synergistic benefits, revenue growth and market development expected to arise. These benefits are not able to be separately recognised from goodwill because they do not meet the recognition criteria that exists for identifiable intangible assets.

## (d) Impact of acquisitions on the results of the Group

Revenue attributed to the additional business generated by Breath-A-Tech in the current year since acquisition on 5 February 2016 totals \$789,000, whilst the profit after tax result contribution is \$362,000 (excluding acquisition related costs). An annualised profit contribution has not been determined given the seasonality of the business and the difficulty in providing a reliable estimate within the first 6 months under new ownership.

## 34. 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 2016

## Number of holders of equity securities

### Ordinary share capital

58,360,056 fully paid ordinary shares held by 2,716 individual shareholders. All issued ordinary shares carry one vote per share.

## Distribution of holders of equity securities

### Fully paid ordinary shares

1 – 1,000	879
1,001 – 5,000	1,061
5,001 – 10,000	329
10,001 – 100,000	384
100,001 and over	63
	2,716
Holding less than a marketable parcel	91

SUBSTANTIAL SHAREHOLDERS	Number	%
MR DAVID JOHN WILLIAMS	17,809,855	30.52

TWENTY LARGEST HOLDERS OF EQUITY SECURITIES	Number	%
MR DAVID JOHN WILLIAMS	17,809,855	30.52
HSBC CUSTODY NOMINEES	3,358,450	5.75
J P MORGAN NOMINEES AUSTRALIA	2,963,978	5.08
RBC INVESTOR SERVICES	1,880,074	3.22
DR RUSSELL KAY HANCOCK	1,500,727	2.57
NATIONAL NOMINEES LIMITED	1,172,285	2.01
LUJETA PTY LTD	891,256	1.53
UBS NOMINEES PTY LTD	658,976	1.13
MR ALISTAIR DAVID STRONG	630,000	1.08
HSBC CUSTODY NOMINEES	628,606	1.08
BNP PARIBAS NOMS PTY LTD	603,177	1.03
LONCETA PTY LTD	502,195	0.86
SANDHURST TRUSTEES LTD	444,102	0.76
MR JOHN SHARMAN	428,683	0.73
MR RAYMOND WILLIAM WALTER & MR ALEXANDER SCOTT HAGAN	403,500	0.69
IMAJ PTY LTD	390,000	0.67
MULLACAM PTY LTD	381,690	0.65
MIRRABOOKA INVESTMENTS LIMITED	370,000	0.63
CITICORP NOMINEES PTY LIMITED	348,802	0.60
MR MICHAEL GERARD SUGERMAN	300,000	0.51



