

2018 Reports

Announcement of Full-Year Results

Appendix 4E

2018 Annual Report

PolyNovo Limited
ABN 96 083 866 862
16 August 2018

Announcement of Full-Year Results

16 August 2018



PolyNovo Financial Results Year Ended 30 June 2018

PolyNovo Limited reported revenue for year ended 30 June 2018 of \$5.989 million an increase of \$2.230 million from the prior year's \$3.759 million. Sales of goods revenue was \$1.747 million up \$1.610 million from the prior year's \$136,896. The net loss after tax of \$5.974 million for FY18 was an increase of \$0.968 million from the prior year's \$5.006 million.

The increase in the loss was predominantly driven by the continuing establishment of our US infrastructure, increased research and development activities, clinical trials (both CE and US) and additional regulatory and administrative resources to support the Group's commercialisation initiatives in the US and other markets.

Our US sales infrastructure has expanded with the addition of new sales and marketing people. We now have seven sales people and two marketers. This is enabling an increased number of US hospital clinical evaluations, accelerating our ability to initiate new accounts and to expand the use of NovoSorb BTM in existing accounts. There was a significant increase in US sales in FY18 and we expect to see a sales acceleration growth in FY19.

Increasing focus on the procurement/supply chain side of the hospitals in the next two quarters is critical to driving sales in FY19. Our sales team has many positive case studies supporting the use of NovoSorb BTM, excellent surgeon feedback and the product is better than biological alternatives.

We announced the last patient has been recruited into the Feasibility Trial in the US. This is the BARDA funded full thickness burns PMA trial, phase 1. These patients will be followed for another 12 months to assess the full clinical outcome of the NovoSorb BTM. Concurrent to this we will be preparing for the commencement of the pivotal phase of this trial program. We will submit an additional budget/contract to BARDA to fund this program.

Our Australia/European burn trial to support a CE application has also completed patient recruitment. We will follow these patients for 12 months post-skin grafting and then write up the trial outcomes. This data will provide valuable clinical evidence to support the marketing programs for NovoSorb BTM.

As announced on 14 August 2018 we now have TGA ARTG Listing for the NovoSorb BTM through the Priority Review Designation pathway. PolyNovo was the first company to go through this innovative technology approval process with the TGA. Our NovoSorb BTM has achieved a wide indication for use based on the excellent clinical data compiled by Professor Greenwood, Dr Wagstaff and the team at the Royal Adelaide Hospital.

PolyNovo adopted a direct sales approach for New Zealand and Australia in the past year. This has delivered immediate sales at good margins and has improved our ability to get our marketing messages direct to the surgical teams. We see good opportunities in Australia and New Zealand in FY19 with our TGA listing and will expand the sales team accordingly.

Our South African sales have been solid in the first year. We have been constrained by the health reimbursement structures in South Africa, notwithstanding we have opportunities with cases supported by private health insurance and work place insurance cover.

Looking forward to FY19, we expect initial sales in Saudi Arabia and Israel and have distributors appointed in both markets. Further new markets will be announced as we navigate the various regulatory processes.

In the past year we added research and development resources having focused on hernia market development and signed our development agreement for breast products with Establishment Labs. This increased expenditure on product development is reflected in the cash burn but designed to significantly increase our product range.

Establishment Labs will be conducting the clinical trials and building the regulatory submissions. Initial animal studies have been completed and further work is required once we have the manufacturing processes and designs finalised.

Hernia and breast product development is now entering the manufacturing scale up process. We envisage that we will be able to file US FDA 510(k) documents for hernia in FY20.

Further details of the product pipeline can be found in the Annual Report.

With NovoSorb BTM European market entry anticipated in FY19 and the increased revenue generation from the US, Australian and New Zealand markets, FY19 is expected to be a pivotal year for the Company's performance.

**Preliminary Final report
PolyNovo Limited
ABN 96 083 866 862**

1. Details of the reporting period and the previous corresponding period

Reporting Period: Year ended 30 June 2018

Previous Corresponding Period: Year ended 30 June 2017

2. Results for announcement to the market

	Change from 2017		2018
2.1 Total revenue	up	59.3% to	\$5,989,758
2.2 Loss after tax	up	19.3% to	(\$5,974,132)
2.3 Loss after tax attributable to members	up	19.3% to	(\$5,974,132)
2.4 Dividends	No dividend paid or declared in either period		
2.5 Record date for dividend entitlement	Not applicable		
2.6 Brief explanation of figures in 2.1 to 2.3:	Refer to (i) the enclosed announcement by the Chairman and Chief Executive Officer and (ii) the Chairman's and Chief Executive's Report and separate Directors' Report contained in the enclosed 2018 Annual Report.		

3. Net tangible assets

	30-Jun-18	30-Jun-17
Net tangible asset backing per ordinary security	\$0.042	\$0.015

4. Consolidated Statements of Comprehensive Income, Financial Position, Changes in Equity and Cash Flow are contained in the enclosed 2018 Annual Report.

5. Details of control gained or lost over entities during the period

Not applicable

6. Details of individual dividends and payment dates

Not applicable

7. Details of dividend reinvestment plans

Not applicable

8. Details of associates and joint venture entities

Not applicable

9. For foreign entities, which set of accounting standards is used in compiling the report

International Financial Reporting Standards

10. This report is based on accounts which have been audited. The audit report, which is unmodified is contained in the enclosed 2018 Annual Report.

Date: 16 August 2018

Greg Lewis
Company Secretary



Annual Report 2018

Expansion. Growth. Progression.

Contents

4	Chairman and CEO Report	27	Consolidated Statement of Changes in Equity
6	Director's Report	28	Consolidated Cash Flow Statement
16	Corporate Governance	29	Notes to the Financial Statements
17	Remuneration Report	56	Director's Declaration
24	Auditor's Independence Declaration	57	Independent Auditor's Report
25	Consolidated Statement of Comprehensive Income	62	Additional Information Required by ASX
26	Consolidated Statement of Financial Position	64	Corporate Directory

"PolyNovo's principal activity is the development of innovative medical devices for a number of medical applications, utilising the patented bioabsorbable polymer technology NovoSorb®."

Paul Brennan
Chief Executive Officer



Global Expansion

PolyNovo has considerable commercial opportunity through NovoSorb® polymer platform technology utilised in multiple medical devices. The NovoSorb polymer is currently on sale as a dermal scaffold, NovoSorb BTM, with our current sales markets outlined below. Our research and development team are well advanced in the development of NovoSorb hernia and breast product portfolios with the year ahead focused on commercial manufacturing scale up.



Staff Expansion

PolyNovo has invested in four key areas of resource expansion:

Sales, US and Australia/New Zealand. PolyNovo values the direct customer relationships developed through our own sales teams and the ability to respond to our customer needs. We will see further expansion of our sales teams in response to increasing revenues and customer service requirements.

Marketing (US) where we need to accelerate our sales through specific and targeted marketing programs.

Quality Management as this team ensures we meet all the global standards and facilitate our research and development programs enabling faster market readiness.

Research and Development with addition of two key scientific roles enabling the development of Hernia and Breast product portfolios along with the other projects outlined in the report.



US Focus

The US market will be PolyNovo's single largest market so we continue to focus on the specific marketing programs that will deliver the acceleration in market penetration. We have increased both the Marketing and Sales team in the past year. We currently have eight sales roles with further expansion planned in FY19 in response to revenues. Our sales structure will see increases within the various sales regions as we finalise hospital evaluations of NovoSorb BTM and realise the sales.

In Marketing we have hired two Marketing Directors. One is focused on NovoSorb BTM programs for the US market and the other is dedicated to Hernia market development and market entry strategies.

Five year share price growth





New Zealand

PolyNovo resumed direct sales from Device Technologies in the past year. This has led to immediate sales and a direct customer relationship. We see New Zealand as an import market as the surgical teams are excellent, innovative and well connected globally.



South Africa

Our partners in South Africa, Ascendis Medical, continue to be an excellent organisation. Their team interact with ours seamlessly. Ascendis have excellent customer interactions, have generated sales and have reimbursement strategies in progress. We are committed to supporting them and their customers and look forward to continued success.



Australia

We announced on 14 August 2018 that we had achieved TGA ARTG listing for the NovoSorb BTM. This is an exciting milestone as we can immediately sell and promote NovoSorb BTM for use whenever the dermis has been lost. This means dermal loss through surgical removal, chronic wounds, trauma, reconstructive surgery or burns. These wide indications for use will allow for many surgical uses where an improved cosmetic and functional outcome is required. Our direct sales team will expand in response to revenues and customer service requirements.



Europe

PolyNovo will enter the UK/Ireland through a direct sales structure. We are currently recruiting for a Business Development Manager/Sales within the UK. This role will be focused on pre-market activities and NHS procurement processes in advance of our NovoSorb BTM CE Mark.

Germany/Austria we will be appointing a distributor for NovoSorb BTM before the end of this calendar year. Announcements will follow in due course. Other regions in Europe will be addressed once we have established these two lead markets.



Expanding into the Middle East

We announced on 27 July 2018 the signing of Al Mofadaly as our distributor for Saudi Arabia and adjacent Middle Eastern countries. PolyNovo sees the Middle East as fast growing and advanced medical market. We will work with Al Mofadaly team to establish NovoSorb BTM as the first-choice dermal scaffold in the region.

In Israel we appointed AMI Technologies as the distributor for NovoSorb BTM. We have been in direct contact with the key plastic surgeons in Israel and look forward to our NovoSorb BTM launch event in September 2018.

PolyNovo will also be attending various tradeshows/medical conferences in the region in the year ahead.

Chairman and CEO Report

Dear Shareholder,

In the past three years PolyNovo has gone from a promising research and development company with a unique, patented polymer to an emerging multi-national with commercial sales and a direct sales team in three countries. NovoSorb® BTM is delivering outstanding clinical results with leading US surgeons now using the product. Several of these surgeons have presented clinical papers at various conferences throughout 2018 endorsing NovoSorb BTM's effectiveness and improved outcomes.

Capital raising

We raised \$23 million (excluding transaction costs), through an institutional placement and a Share Purchase Plan in October 2017. The funds are being used to:

- expand our sales and marketing activities;
- accelerate our research and development program to deliver new products to market;
- acquire additional manufacturing resources for hernia and breast product manufacturing; and
- general corporate purposes.

Having a strong cash position ensures we can drive our commercialisation strategies towards profitability in the shortest possible time frame.

Markets

United States of America

In September 2017, we announced our first US sales. At that time, we had a direct sales team of three. In response to the growing number of hospital evaluations and sites that have become repeat customers we have expanded the sales team to eight. Some regional sales managers and active sales people now have sales associates supporting their territory expansion.

NovoSorb BTM has been used in the US for surgical wounds, limb salvage, reconstruction, trauma, necrotizing fasciitis and burn cases. In all areas, we have seen the NovoSorb BTM continue to perform well with the healed areas being supple, flexible and demonstrating low levels of scarring.

The US market opportunities are large however, it has a protracted procurement process that varies from hospital to hospital. Nevertheless, the momentum is building with account conversion and we see the first half of FY19 as being the inflection point for sales.

In the past year we have had US key opinion leaders (KOLs) present NovoSorb BTM cases and posters at several conferences including Boswick, North America Burns Association and American Burn Association Conferences. Dr Bill Hickerson, University of Tennessee, also published the first full facial reconstruction utilising NovoSorb BTM in Journal of Burns Care & Research.

Our continued success in the US will require further expansion of our sales team funded from NovoSorb BTM sales revenue. We anticipate the US business, PolyNovo North America LLC, will breakeven in FY19.

Australia and Other Markets

Australia and New Zealand

Australia and New Zealand: PolyNovo has recently commenced selling NovoSorb BTM directly and we will expand the sales team as sales grow post Therapeutic Goods Administration (TGA) registration. This will enable PolyNovo to have a direct customer relationship and achieve early sales, as well as scaling the resource required as demand is built. The NovoSorb BTM has been used on a wide range of clinical indications with outstanding results.

Israel

In November we announced the appointment of AMI Technologies as the distributor for Israel and we achieved our Israeli product registration at the end of March 2018. We are currently working through the launch tactics and timelines with AMI Technologies for a September 2018 launch event and expect sales to follow in due course.

Saudi Arabia

We announced on 27 July 2018 the signing of Al Mofadaly as our exclusive distributor for Saudi Arabia and adjacent Middle East markets. This continues our regional expansion and offers PolyNovo access to several growing markets in the Middle East.

We have begun registration processes in various other countries and we will announce market entries once registration has been achieved.

BARDA

Our BARDA funded US clinical program for full thickness burns indication is progressing well. On 2 August 2018 we announced the last patient recruited into the feasibility trial. The six US sites are:

- Wake Forest Baptist Health, Winston-Salem
- University of Tennessee Medical Centre, Memphis
- University of California Davis Medical Centre, Sacramento
- Tampa General Hospital, Tampa
- Arizona Burn Center, Phoenix
- Lehigh Valley Hospital, Allentown

Our relationship with BARDA is strong and the addition of a clinical trial manager based in the US has added value to the research sites through PolyNovo's direct interaction with those sites.

The next phase of the trial program will be the 'pivotal phase' which will be under a new contract with BARDA. We anticipate this trial commencing in July-August 2019. We expect to announce the terms of this new contract in late FY19.

As a requirement of the US FDA Premarket Approval (PMA) process, we are also conducting a 2-year toxicology study funded by BARDA. This program is well advanced and will provide us a detailed degradation profile of the NovoSorb BTM from implantation to full resorption.

CE Mark & Trial

We announced on 22 May 2018 this year that we have recruited the last patient for this important trial. We are required to follow the last patient for 12 months post implant of the NovoSorb BTM. The data from this trial will provide us with excellent clinical data to support the use of NovoSorb BTM in full thickness burns however we anticipate achieving our CE Mark in advance of this.

PolyNovo's Conformity Assessment submission has also been designated for priority review by the TGA. Through the 'Priority Review Designation' pathway an audit of our production facility and Quality Management System in Melbourne was expedited and completed. Once we have our ARTG listing, we can apply for CE Mark approval through European notified bodies. Post ARTG, the CE filing process and audit requirements mean our CE Mark can be expected anywhere between January-June 2019.

We are currently recruiting for a UK based Business Development Manager to work with the National Health Service (NHS) procurement bodies in advance of achieving our CE Mark. This is to shorten the lead time from approval to sales. The NHS system is fragmented and complex so we have not budgeted sales from the UK in the FY19 financial year.

New Product Development

Our new product development for hernia and breast reconstruction are progressing well with scale up requirements for commercial production currently the focus.

Hernia

We have conducted focus group activities with US surgeons and attended the SAGES Conference in Seattle to garner clinical design inputs for the hernia products. We will bring to market products that demonstrate PolyNovo's innovation, differentiation and improved outcomes for patients. The next phase in the development is the commercial production planning and regulatory dossier building. We anticipate filing our US FDA 510(k) in FY20.

Breast

Our agreement with Establishment Labs for the development of a range of breast cosmetic and reconstructive products is advancing with product design and various laboratory tests. Both teams are working well together as we bring disruptive technology and product design through the process.

Beta-Cell Diabetes application

Beta-Cell (a non-related commercial entity) continue their preliminary work demonstrating the safety and efficacy of NovoSorb BTM and the ability for the Islet cells to secrete insulin. Planning is currently underway, by Beta-Cell, to commence human trials in the near future.

Manufacturing

Our manufacturing facility has been audited in the 2018 financial year by the US FDA, TUV-SUD and TGA with no adverse findings. Our world class facility has sufficient capacity for our foreseeable NovoSorb BTM requirements. We are currently planning for the production requirements of the hernia and breast product lines and how these will be accommodated within the facility.

Summary

In summary, there has been a rapid transformation into a commercial enterprise and we see the financial year ahead delivering strong revenues from NovoSorb BTM from all our markets with North America anticipated to break even. We thank our staff and shareholders for their continued support.



David Williams
Chairman



Paul Brennan
Chief Executive Officer

NovoSorb BTM has been used in the US for surgical wounds, limb salvage, reconstruction, trauma, necrotizing fasciitis and burn cases. In all areas, we have seen the NovoSorb BTM continue to perform well with the healed areas being supple, flexible and demonstrating low levels of scarring.

Director's Report

The Directors of PolyNovo Limited (PolyNovo) present the Directors' Report, together with the Financial Report, of the Company and its controlled entities (the Group) for the year ended 30 June 2018 and the related Auditor's Report.

Board of Directors and Senior Management

The details of Directors and Senior Management during the year and until the date of this report are set out below. Directors were in office for the entire period unless otherwise stated.



Mr David Williams
(B.Ec (Hons), M.Ec, FAICD)
Non-executive Chairman

Mr Williams was appointed as a Non-executive Director on 28 February 2014 and Chairman on 13 March 2014. Mr Williams is an experienced Director and investment banker with a proven track record in business development and strategy, as well as in mergers and acquisitions and capital raising. He possesses 33 years' experience working with and advising ASX-listed companies in the food, medical device and pharmaceutical sectors. Mr Williams was previously the Managing Director of Challenger Corporate Finance, Head of Mergers & Acquisitions – Melbourne, Société Générale Hambros, Head of Mergers & Acquisitions at ANZ McCaughan, and Australian Head of Mergers & Acquisitions Arthur Andersen & Co. He has been Chairman of Tassal Group Ltd and Austin Group Ltd and held numerous other Directorships including with Amcal Ltd and Select Harvests Ltd. and IDT Ltd. Mr Williams is currently Chairman of ASX-listed Medical Developments International Ltd (ASX: MVP), Chairman of RMA Global Limited and is Managing Director of corporate advisory firm Kidder Williams Ltd. Mr Williams resigned as Non-executive Director of IDT (ASX: IDT) on 19 May 2015.



Mr Bruce Rathie
(B.Comm, LLB, MBA, FAIM, FAICD)
Non-executive Director

Mr Rathie is an experienced Company Director with a finance and legal background. He practised as a partner in a large legal firm and acted as Senior In-house Counsel to Bell Resources Limited from 1980 to 1985. He studied for his MBA in Geneva and embarked on his investment banking career in 1986. He was Head of the Industrial Franchise Group at Salomon Smith Barney in the late 1990s and led Salomon's roles in the Federal Government's privatisation of Qantas, Commonwealth Bank (CBA3) and Telstra (T1). He has over 15 years' experience as a professional Non-executive Company Director. He is currently Vice Chairman of Capricorn Society Limited, Chairman of Capricorn Mutual Limited and a Non-executive Director of Australian Meat Processors Limited. In the medical device space, he was previously Chairman of Anteo Diagnostics Limited and a Director of Compumedics Limited and USCOM Limited. He has been a Non-executive Director of PolyNovo since February 2010.



Dr David McQuillan
(PhD)
Non-executive Director

Dr McQuillan was appointed a Director of PolyNovo on 6 August 2012. He has extensive technical, medical, scientific and regulatory knowledge, as well as merger and acquisition expertise. Previously he was a Fogerty Fellow at the NIH (Bethesda, MD), an NH&MRC Fellow at the University of Melbourne, and Associate Professor at Texas A&M University (Houston, TX) where he studied Tissue Engineering, Regenerative Medicine, and Biochemistry of the Extracellular Matrix. Dr McQuillan was with LifeCell Inc/Kinetic Concepts Inc (KCI) for 12 years, holding a number of senior roles, including Vice President for Research and Development at LifeCell and Senior Vice President of Advanced Research and Technology at KCI. He was Chief Science Officer for TELA Bio, a VC-funded development-stage biotechnology company from 2013 to 2015. He is currently a Non-Executive Director for Cell Care Therapeutics Inc (a privately held stem cell company based in Monrovia, CA) and Non-executive Director and Co-Founder of ECM Technologies Inc (a privately held biotechnology company based in Houston, TX).



Mr Max Johnston
Non-executive Director

Mr Johnston was appointed a Director of PolyNovo on 13 May 2014. Mr Johnston held the position of President and Chief Executive Officer of Johnson & Johnson Pacific, a division of the world's largest medical, pharmaceutical and consumer healthcare company for 11 years. Prior to joining Johnson & Johnson, Mr Johnston's career also included senior roles with Diageo and Unilever in Europe. Mr Johnston has also held several prominent industry roles as a past President of ACCORD Australasia Limited, a former Vice Chairman of the Australian Food and Grocery Council and a former member of the board of ASMI. Mr Johnston has had extensive overseas experience during his career in leading businesses in both Western and Central-Eastern Europe and Africa as well as the Asia-Pacific region. Mr Johnston is currently a Non-executive Director of Medical Developments International Ltd (ASX: MVP), CannPal Limited (ASX: CP1) and ProLife Foods NZ and was a former Non Executive Director of Eneo Group Limited (ASX: EGG), and Non-executive Chairman of Probiotec Ltd (ASX: PBP).



Mr Philip Powell
(B.Comm (Hons), ACA, F.Fin, MAICD)
Non-executive Director

Mr Powell was appointed a Director of PolyNovo on 13 May 2014 and was Acting Managing Director from 15 July 2014 to 13 February 2015. Mr Powell has many years' experience in investment banking specialising in capital raisings, Initial Public Offerings (IPOs), mergers and acquisitions and other successful corporate finance assignments across a diverse range of sectors including utilities, IT, pharma, financial services, food and agriculture. He spent 10 years in senior financial roles at OAMPS Ltd, a former ASX-listed financial services group, and 10 years in audit with Arthur Andersen & Co in Melbourne, Sydney and Los Angeles. Mr Powell is currently a Non-executive Director of Medical Developments International Ltd (ASX: MVP) and RMA Global Ltd (ASX: RMY). He is also an alternate Director of the Nature's Dairy Australia group.



Mr Leon Hoare
(GradDipBus, AssocDipAppSc(Ortho), GAICD)
Non-executive Director

Mr Hoare was appointed a Director of PolyNovo on 27 January 2016. He is the Managing Director of Lohmann & Rauscher, Australia & New Zealand (ANZ), a private EU based medical device company. Previously he was Managing Director of Smith & Nephew ANZ until the end of 2015, one of Smith & 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. His career also included a senior role at Bristol-Myers Squibb in surgical products, and as Vice Chair of Australia's peak medical device body, Medical Technology Association of Australia. He is currently a Non-executive Director of Medical Developments International Ltd (ASX: MVP).



Mr Paul Brennan
(MBA, BSc (Nursing) RN RM)
Chief Executive Officer

Mr Brennan was appointed Chief Executive Officer (CEO) of PolyNovo Ltd on 13 February 2015. Mr Brennan has extensive knowledge, exposure and understanding of the health system through his clinical background and commercial exposure with various multinational companies. He has co-ordinated the marketing, global strategy development, new product development and regulatory processes for the Asia-Pacific region for industry-leading organisations in relation to medical products and devices. Mr Brennan has an intimate knowledge of the manufacturing and production processes. Previously he was Marketing Director Australia and New Zealand and Sales Director New Zealand for Smith & Nephew Healthcare from 2008 to his commencement with PolyNovo in February 2015. Mr Brennan holds a MBA from Swinburne University, a Bachelor of Science (Nursing) from the University of New England in NSW, Certificate in Midwifery Central Coast Area Health Service NSW, and General Nursing certificate from St Vincent's Hospital Darlinghurst NSW.

Director's Report continued



Mr Greg Lewis
(MBA, FPIPA, MAICD)
COO, CFO and Company
Secretary

Mr Lewis is a Fellow of the Institute of Public Accountants, holds a MBA from Southern Cross University and a Member of the Institute of Company Directors. Mr Lewis joined PolyNovo on 24 January 2018 from Jamestrong Packaging where he was CFO/COO overseeing production facilities in Australia & New Zealand. Mr Lewis also has financial and operational experience at Byron Group Holdings, ITL Healthcare, Tapex and Stryker Australia. These businesses manufactured and distributed medical devices and supported customer sales with maintenance service departments. Most recently Mr Lewis was Finance & Operations Director within Jamestrong ANZ, included in his responsibilities was the manufacturing and supply chain across multiple sites within Australia and New Zealand. His business experience covers Australia, New Zealand, Singapore, Malaysia, Indonesia, Taiwan, China, Italy, UK and USA. He has completed some 100+ acquisitions and is accomplished at negotiating, undertaking due diligence reviews, completing legal and contractual agreements and integrating new acquisitions into group business organisations.



Mr Gavin Smith
(B.Ec, CPA, MAICD)
CFO and Company Secretary

Mr Smith was contracted as Chief Financial Officer (CFO) and Company Secretary from 20 January 2017 until 20 February 2018. This role was made redundant by the expansion of the role to include COO accountabilities. Mr Smith is a CPA and a member of the Australian Institute of Company Directors. Mr Smith has extensive experience as a Public Company CFO and Company Secretary across multiple industry sectors including industrial, agribusiness, mining and financial services. He has been involved in several businesses in other regions including North & Central America, Europe and many parts of Asia and has a special interest in linking business and financial processes to supply chain activities.



Ms Andrea Goldie
(CPA, ACA, CTA, GIA(Cert))
CFO and Company Secretary

Ms Goldie was appointed as Chief Financial Officer (CFO) and Company Secretary on 28 October 2015 until 18 October 2017. Ms Goldie is a Chartered Accountant, a Chartered Tax Adviser and certified member of the Governance institute Australia. Ms Goldie holds a Bachelor of Economics (Accounting) and an MBA (Finance).



Director's Report continued

Review of Operations

Corporate and Organisational structure

PolyNovo Limited, the ultimate parent entity of the PolyNovo Group, is a public company listed on the Australian Securities Exchange. As at 30 June 2018, PolyNovo Limited had four wholly owned subsidiaries: PolyNovo Biomaterials Pty Limited, NovoSkin Pty Ltd, NovoWound Pty Ltd and PolyNovo North America LLC (PNA LLC). Three subsidiary companies are Australian proprietary companies whilst PNA LLC is the trading and employment entity for our US commercial operations.

Principal Activities and Operations

PolyNovo's principal activity is the development of innovative medical devices for a number of medical applications, utilising the patented bioabsorbable polymer technology NovoSorb®.

NovoSorb® is a family of proprietary medical grade polymers that can be utilised to manufacture novel medical devices designed to support tissue repair and which then bioabsorb in a defined fashion *in-situ* to harmless by-products. NovoSorb® has significant advantages over competitor bioabsorbable polymers in terms of its design flexibility. PolyNovo can manufacture NovoSorb® polymer devices with a range of mechanical properties and flexible bioabsorption times from months to years that are suitable for many different medical applications.

Key attributes of the NovoSorb® technology include an unparalleled range of mechanical properties and bioabsorption times, excellent biocompatibility and safety profile and harmless bioabsorption. The technology can be utilised as a foam, coating or a thermoplastic structure, with the potential to deliver drugs, biological agent, antimicrobials and cells. In addition, the technology is scalable in terms of manufacturing and processing.

A summary of PolyNovo's lead projects is set out below:



Australia: Head Office Team.

NovoSorb BTM

NovoSorb Biodegradable Temporising Matrix (BTM) is used in a fully debrided clean surgical wound to physiologically 'close the wound'. With the BTM scaffold in place the dermal layer is regenerated within the scaffold. Once fully integrated, the outer layer is delaminated and the wound closes through secondary intention (smaller wounds) or through application of a split skin graft. The BTM is commercially sold in the US, New Zealand, South Africa and Israel. In Australia sales have been achieved under the TGA Authorized Prescriber and Special Access Schemes. Publications and videos relating to NovoSorb BTM applications can be found on our website: www.polyново.com.au.

In September 2017 we released the enhanced NovoSorb BTM with fenestrations in response to clinician's feedback. We were also issued with a new US FDA 510(k) approval for use in surgical wound repair. This enables PolyNovo to incorporate many process improvements in the manufacturing of the NovoSorb BTM under the new 510(K).

PolyNovo is actively selling NovoSorb BTM in the US through our own directly employed sales team. PolyNovo North America LLC is the commercial entity undertaking this function. In addition to the US we have a direct sales team for Australia & New Zealand. In other

NovoSorb® has significant advantages over competitor biodegradable polymers in terms of its design flexibility.

markets we utilise a distributor business model. Distributors have been appointed in South Africa, Saudi Arabia and Israel with further market entries to be announced in due course.

Subject to regulatory approval, PolyNovo is planning for United Kingdom and Ireland entry with a direct sales organisation in FY19. Other European market entries are anticipated to be through a distributor model with sales possible but not budgeted in FY19.

NovoSorb BTM indication for full thickness burns

NovoSorb BTM is an innovative treatment for any loss of the dermis. Full thickness burns treatment for regulatory 'claim' requires additional clinical evidence generation (trials).



US: Sales and Marketing Team.

The pathway for US regulatory approval of the NovoSorb BTM, for full thickness burn claims, requires extensive clinical trials that are being funded through a BARDA contract. These trials will lead to a Premarket Approval (PMA) application with the US FDA. An outline of this clinical trial process is set out below.

USA Burns Trial – BARDA

Our Biomedical Advanced Research and Development Authority (BARDA) contract, funded by the U.S. Department of Health and Human Services (Office of the Assistant Secretary for Preparedness and Response) commenced on 28 September 2015. This is a non-dilutive contract that supports the feasibility trial to conclusion in 2019. We will negotiate the pivotal trial contract with BARDA in FY19. The timeline and value of that contract will be dependant on the final protocol which will be developed in the months ahead. We anticipate BARDA contracting to be agreed late CY19 given US budget cycles commence in October of each year. Successful completion of the pivotal trial lead to a PMA application with the US FDA and the use of our scaffold in full thickness acute burns. The contract is a cost-plus-fixed-fee contract.

The feasibility trial is currently in progress at University of South Florida at Tampa General Hospital, UC Davis Medical Centre (California), University of Tennessee Medical Centre Memphis, Maricopa Health, Phoenix and Lehigh Valley, Allentown.

In addition, PolyNovo has completed the feasibility phase of the concurrent toxicology study looking at mapping the full degradation pathway of the NovoSorb BTM. The final phase of this toxicology study is in progress. This will provide valuable data to support our PMA application.

CE Mark Certification

PolyNovo announced on 22 May 2018, that the last patient had been enrolled in the NovoSorb Biodegradable Temporising Matrix (BTM) Full Thickness Burn clinical trial. In total, 30 patients across five study sites have been enrolled at: The Alfred Hospital, Royal North Shore Hospital, Concord Hospital, Royal Brisbane and Women's Hospital and St Anne's in Toulon (France).

Dr Marcus Wagstaff is acting as PolyNovo Medical Director overseeing the clinical conduct of PolyNovo trials. In addition to the clinical trials PolyNovo has submitted a Conformity Assessment application to the Australia Therapeutic Goods Administration (TGA) through the 'Priority Review Designation' pathway. An audit of our production facility and Quality Management System in Melbourne was expedited and completed in April 2018. We announced our ARTG listing on 14 August 2018. We can now apply for CE Mark approval through European notified bodies.

Hernia Repair

PolyNovo has advanced our prototypes through various surgeon focus groups to refine the design. We have two innovative products for the hernia market that now require commercial manufacturing scale up. This is in progress. Further testing and biocompatibility studies are required before we file a regulatory dossier.

Breast Sling Development

PolyNovo is developing a range of breast augmentation and reconstructive products in partnership with Establishment Labs. Establishment Labs will undertake the clinical trials, regulatory processes, sales & marketing activities related to this product range. PolyNovo will undertake all the development and manufacturing processes which will be sold under the Motiva brands globally by Establishment Labs.

The two teams are working well together, and the project is progressing well. Further updates will occur with significant milestone announcements.

NovoSorb Dermal Beta Cell Implant

PolyNovo is collaborating with Beta Cell Technologies Pty Ltd, Adelaide on a research project exploring the potential of integrated NovoSorb BTM to host pancreatic islets in the skin. In a porcine trial, pig islets were successfully seeded into NovoSorb BTMs for 100 days and survived producing



porcine insulin. Included within this study, human islets were implanted into NovoSorb BTMs treated to prevent cellular rejection in pigs and the cells also survived producing human insulin. BetaCell with funding supported by the Juvenile Diabetes Research Foundation (JDRF, US) will commence human trials once US FDA approval of the protocol is achieved. This expanded use of NovoSorb BTM is not resource intensive for PolyNovo and offers a significant commercial opportunity in the near term.

NovoSorb Drug Elution Depot (pellet)

PolyNovo worked with a US firm in the development of a subcutaneous drug eluting depot. This project has been bought in-house as we believe we will obtain better licence terms with a more developed product in a more matured project timeline. This is a 'pellet' form of the NovoSorb containing a nominated drug. As the NovoSorb hydrolyses (bio-reabsorbs) the drug is released at a sustained and regular dose. Laboratory data has been very good and additional patent applications are in progress.

Bone Void Filler

PolyNovo has a licence agreement with Smith & Nephew for the use of NovoSorb two-part polymer for bone void filler in orthopaedic applications. Smith & Nephew have not progressed this product through the commercial phase and we will review the status of this agreement in due course.

Capital investment

PolyNovo is planning to purchase production machinery, in the next six months, for the manufacture of hernia and breast products. These final 'production' versions will then be used for various regulatory approval test.

Further investment is planned with the move to an electronic Quality Management System. This will commence in the second quarter of FY19 and take six months to complete.

Significant Changes in the State of Affairs

Except as otherwise set out in this report, the Directors are unaware of any significant changes in the principal activities of PolyNovo during the year ended 30 June 2018.

Strategic Overview and Likely Developments

PolyNovo's focus over the next twelve months will be to:

- acceleration of commercial NovoSorb BTM sales in the US
- market and sell NovoSorb BTM in Australia, South Africa, Saudi Arabia, Israel and New Zealand
- finalise commercial partnerships for the BTM product in markets where regulatory approval can be achieved within the year

- write CE Mark trial medical report and submission of findings
- achieve CE Mark
- finalise the hernia product design files and move towards US FDA 510(k) submission
- advance the breast product portfolio development with Establishment Labs
- further develop NovoSorb drug eluting depot
- support the BetaCell expansion of NovoSorb BTM use as a dermal depot for Type I diabetes
- continue the BARDA trial and progress to pivotal period
- enter the UK/Ireland with a direct sales structure
- assess entering Germany and Austria through a distributor
- realise sales in Saudi Arabia/Middle East and Israel through a distributor

Significant Events after the Balance date

On 2 August 2018, it was announced that the last patient has been recruited into the BARDA funded Feasibility Trial in the US. These patients will be followed for another 12 months to assess the full clinical outcome of the NovoSorb BTM. Concurrent to this we will be preparing for the commencement of the pivotal phase of this trial program and submission of an additional budget/contract to BARDA to fund this program.

As announced on 14 August 2018 we achieved TGA ARTG Listing for the NovoSorb BTM through the Priority Review Designation pathway. PolyNovo was the first company to go through this innovative technology approval process with the TGA. Our NovoSorb BTM has achieved a wide indication for use based on the excellent clinical data compiled by Professor Greenwood, Dr Wagstaff and the team at the Royal Adelaide Hospital.

The Directors are not aware of any other matters or circumstances since the end of the financial year other than those described above, nor otherwise dealt with in this report, which have significantly affected, or may significantly affect, the operations of the Group, the results of those operations or the state of affairs of the Group in subsequent financial years.

Financial results

PolyNovo Limited reported revenue for year ended 30 June 2018 of \$5,989,758, an increase of \$2,230,726 from the prior year's \$3,759,032. The net loss after tax of \$5,974,132 for FY18 was an increase of \$986,118 from the prior year's \$5,006,014. A number of factors contributed to the increased loss of \$968,118 in 2018 as follows:

- Research and development expenses increased by \$670,106 which reflects a higher level of support required for BARDA and general R&D activities.
- Employee related expenses increased by 26% to \$5,656,333 as PolyNovo increased headcount to meet the resource requirements to service and support our commercial enterprises and clinical programs.



- Depreciation increased by \$295,962 with the commencement of amortisation of intangible assets.
- Interest income in 2018 was \$136,397 higher than 2017 due to higher cash balances.

The investment in an increased direct sales and support team is seen as a vital investment to service our entry into the ANZ and US markets. Inventory has been built over the year with stocks housed in US and New Zealand distribution/logistics partner's facilities.

R&D Tax Incentives

During the 2018 financial year, the Company submitted an application for the Research and Development (R&D) Tax Incentive scheme managed by AusIndustry and the Australian Taxation Office (ATO).

In October 2017, the Company applied to claim eligible 2017 R&D expenditure and later that month received a 43.5% refundable tax offset of \$833,125 (cash). Additionally, the Company submitted an R&D overseas finding for the 2017 financial year and in April 2018 received an additional refundable tax offset of \$45,143 (cash). PolyNovo has submitted its application to claim eligible expenditure for 2018 R&D activities and expects to receive a 43.5% refundable tax offset of \$794,255, as disclosed in the notes to the financial statements.

Closing share price

30 June 2015	\$0.09
30 June 2016	\$0.28
30 June 2017	\$0.21
30 June 2018	\$0.54

A high of \$0.61 was reached on 25 May 2018.

Loss Per Share

In Australian dollars \$	Cents
Basic loss per share - cents	(0.95)
Diluted loss per share - cents	(0.95)

As the Group made a loss for the year ended 30 June 2018, potential ordinary shares, being options or performance rights to acquire ordinary shares, are considered non-dilutive and therefore not included in the diluted earnings per share calculation.

Dividends

No amounts have been recommended by the Directors to be paid by way of dividend during the current financial year. No cash dividends have been paid or declared by PolyNovo since the beginning of the financial year.



Indemnification and Insurance of Directors and Officers

During the year ended 30 June 2018, the Company indemnified its Directors, Company Secretary and Executive Officers in respect of any acts or omissions giving rise to a liability to another person (other than the Company or a related party) unless the liability arose out of conduct involving a lack of good faith. In addition, the Company indemnified the Directors and the Company Secretary against any liability incurred by them in their capacity as Directors or Company Secretary in successfully defending civil or criminal proceedings in relation to the Company. No monetary restriction was placed on this indemnity.

The Company has insured its Directors, Company Secretary and Executive Officers for the period under review. Under the Company's Directors' and Officers' Liability Insurance Policy, the Company shall not

release to any third party or otherwise publish details of the nature of the liabilities insured by the policy or the amount of the premium. Accordingly, the Company relies on section 300(9) of the *Corporations Act 2001* to exempt it from the requirement to disclose the nature of the liability insured against and the premium amount of the relevant policy.

Inherent Risks of Investment in Biotechnology Companies

There are many inherent risks associated with the development of pharmaceutical and medical products to a marketable stage. The clinical trial process is designed to assess the safety and efficacy of a drug or medical device prior to commercialisation and a significant proportion of drugs and medical devices fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued

patents will offer adequate protection to enable product development, the obtaining of necessary regulatory authority approvals and difficulties caused by the rapid advancements in technology.

Companies such as PolyNovo are dependent on the success of their research projects and their ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as other trading enterprises and access to capital and funding for the Group and its projects going forward cannot be guaranteed. Investment in companies specialising in research projects, such as PolyNovo, should be regarded as highly speculative. PolyNovo strongly recommends that professional investment advice be sought prior to individuals making such investments.

Forward-looking statements

Certain statements in this Annual Report contain forward-looking statements regarding the Company's business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing the Company's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of discovering, developing and commercialising drugs and medical devices that can be proven to be safe and effective for use in humans, and in the endeavour of building a business around such products and services. PolyNovo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this Annual Report. As a result readers of this report are cautioned not to rely on forward-looking statements.

Board and Committee Meetings

Details of the number of meetings of the Board of Directors and Board committees, and Directors' attendance at those meetings, during the year under review are set out in the table below.

	Full Board		Audit and Risk Committee		Remuneration Committee	
	Meetings attended	Meetings eligible to attend	Meetings attended	Meetings eligible to attend	Meetings attended	Meetings eligible to attend
Directors						
Total number of meetings held		12		2		1
Mr David Williams	12	12	-	-	1	1
Mr Bruce Rathie	12	12	2	2	-	-
Dr David McQuillan	12	12	-	-	-	-
Mr Philip Powell	12	12	2	2	-	-
Mr Max Johnston	12	12	2	2	-	-
Mr Leon Hoare	12	12	-	-	1	1

Directors' Shareholdings and Declared Interests

At 30 June 2018, the Directors of PolyNovo collectively hold 22,802,942 shares in the Company.

As at the date of this report the interests of the Directors in the Company's shares are:

Name	Shares held directly	Shares held indirectly
Directors		
Mr David Williams	-	15,902,152
Mr Bruce Rathie	-	2,737,290
Dr David McQuillan	1,000,000	-
Mr Max Johnston	-	1,611,112
Mr Philip Powell	-	1,266,667
Mr Leon Hoare	-	285,721
Total	1,000,000	21,802,942

As at 30 June 2018 and as at the date of this report, no Director has an interest in any contract or proposed contract with PolyNovo other than disclosed below or in the Groups 2018 Annual Report. Further details of the equity interests of Directors can be found in the Remuneration Report.

Auditor

Ernst & Young (EY) continues in office in accordance with section 327b(2) of the *Corporations Act 2001*.

Non-audit Services

During the year ended 30 June 2018, the amount received, or due and receivable for non-audit services provided by PolyNovo's auditor Ernst & Young were:

Tax compliance services	\$89,546
Other compliance services supporting GST and importer registrations in NZ	\$5,449

Auditor's Independence Declaration

The auditor has provided a written declaration that no professional engagement for the Group has been carried out during the financial year that would impair Ernst & Young's independence as auditor. The declaration is set out on page 24.

Corporate Governance

Overview

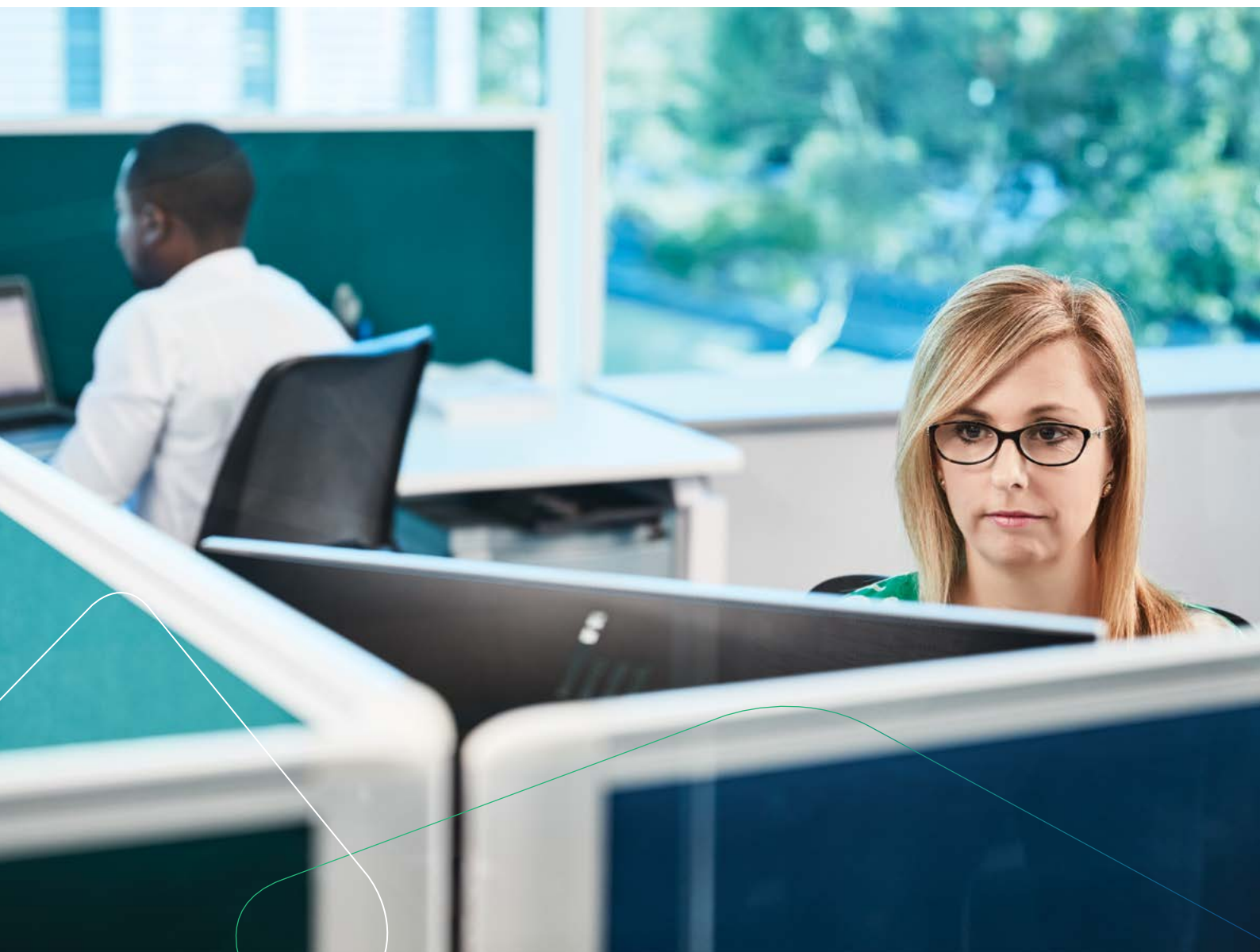
The Board of PolyNovo is responsible for the corporate governance of the Group and guides and monitors the business on behalf of its shareholders. The Board has strived to reach a balance between industry best practice and appropriate policies for PolyNovo in terms of its size, stage of development and role in the biotechnology industry. PolyNovo performed a review of its Board policies and governance practices with reference to the eight Principles of Good Corporate Governance (Principles) and the Best Practice Recommendations (Recommendations) established by the

ASX Corporate Governance Council. The Recommendations are not mandatory and cannot, in themselves, prevent corporate failure or poor corporate decision-making. They are intended to provide a reference point for companies regarding their corporate governance structures and practices.

The Directors have considered each of the core Principles and Recommendations applicable for the year ended 30 June 2018. There are instances where the Group would not benefit from compliance with the Recommendations, and in some instances

the Group has not had the resources to comply. The Recommendations that were not adopted are discussed in the Corporate Governance Statement located on the Company's website.

PolyNovo's Corporate Governance Statement, which summarises the Group's corporate governance practices and incorporates the disclosures required by the ASX Principles, can be viewed on the Company's website at www.polyново.com.au/company



Remuneration Report

The Directors' of PolyNovo present the Remuneration Report prepared in accordance with section 300A of the *Corporations Act 2001* for the Company and its controlled entities (the Group) for the year ended 30 June 2018. This Remuneration Report is audited.

This Remuneration Report forms part of the Directors' Report and includes details of the Group's remuneration strategy and arrangements for the 2018 financial year.

This report outlines the compensation arrangements for the key management personnel of PolyNovo and explains how these arrangements are linked to Company performance.

Key Management Personnel

Key management personnel are those persons who are responsible for planning, directing and controlling the activities of the Group. The Board has determined that the key management personnel of the Group are the Non-executive Directors and Senior Managers (Executives) of PolyNovo, whose details are set out below.

Non-executive Directors

- Mr David Williams – *Non-executive Chairman (appointed as Non-executive Director on 28 February 2014 and Non-executive Chairman on 13 March 2014)*
- Mr Bruce Rathie – *Non-executive Director (appointed 18 February 2010)*
- Dr David McQuillan – *Non-executive Director (appointed 6 August 2012)*
- Mr Max Johnston – *Non-executive Director (appointed 13 May 2014)*
- Mr Philip Powell – *Non-executive Director (appointed 13 May 2014)*
- Mr Leon Hoare – *Non-executive Director (appointed 27 January 2016)*

Senior Managers

- Mr Paul Brennan – *Chief Executive Officer (appointed 13 February 2015)*
- Mr Greg Lewis – *Chief Operating Officer/Chief Financial Officer/Company Secretary (appointed 24 January 2018)*
- Mr Gavin Smith – *Chief Financial Officer/Company Secretary (resigned 20 February 2018)*
- Ms Andrea Goldie – *Chief Financial Officer/Company Secretary (resigned 18 October 2017)*

Remuneration Strategy

PolyNovo has designed its compensation policies to ensure significant linkage between rewards and specific achievements that are intended to improve shareholder wealth. In assessing the link between Group performance and compensation policy, it must be recognised that biotechnology companies generally do not make a profit until a drug or device is licensed or commercialised, either of which takes a number of years.

Furthermore, the biotechnology sector as a whole is highly volatile, significantly driven by market sentiment and inherently high risk. Therefore, the direct correlation of compensation policy and key financial performance measures such as total shareholder return (TSR), net earnings per share or Company earnings, in the view of the Board, are inappropriate. As an alternative, key milestones are a more meaningful measure of performance to correlate levels of compensation. These milestones are discrete achievements that can be used to evaluate PolyNovo's progress towards commercialising its various projects.

PolyNovo's annual expenditure has predominantly been driven by research and development activities. The Group has not made a profit and therefore no dividends have been declared, nor has there been a return of capital. The Group's performance is based on its key milestones and with more of the Group's activities slanted towards the commercialisation stage, additional milestones in relation to the achievement of product sales and production targets will be added to the traditional clinical trials and licensing deals milestones. Such milestones are directly linked to performance conditions set within the short-term incentives that form a significant proportion of Senior Management compensation. The Board continues to review the Group's compensation policy to ensure competitive and appropriate rewards that endeavour to result in greater shareholder wealth.

PolyNovo's compensation policy for key management personnel is designed to provide competitive and appropriate rewards that are transparent and fully aligned to shareholder interests. In accordance with corporate governance best practice, the Company has a compensation policy for Non-executive Directors and a separate policy for Senior Managers.

Remuneration Report continued

Non-executive Director Remuneration

The compensation of Non-executive Directors is based on market practice, Directors' duties and the level of Director accountability. The compensation policy is designed to attract and retain competent and suitably qualified Non-executive Directors and aims to align Directors' interests with the interests of shareholders. Non-executive Directors are paid a set fee plus statutory superannuation, where appropriate, and are reimbursed for out-of-pocket expenses. In addition, as medium-and long-term incentives, Non-executive Directors may be invited to participate in the PolyNovo Employee Share Option Plan. Non-executive Directors are encouraged to own shares in PolyNovo.

Non-executive Directors' fees are determined within an aggregate Directors' fee pool limit, which is approved by shareholders. This limit has been set at \$400,000.

Total Non-executive Directors' fees (including superannuation but excluding share-based payments) for the year ended 30 June 2018 were \$374,742. The Directors' fees are considered within the average range for similar sized companies in the biotechnology industry and are reviewed periodically.

Executive Remuneration

PolyNovo's compensation policy for its senior managers is determined by the Board and is designed to link performance and retention strategies to ensure that:

- the balance between fixed and variable (performance) components for each position is appropriate in light of internal and external factors;
- the objectives set for each person will result in sustainable beneficial outcomes for PolyNovo;
- all variable (performance) components are appropriately linked to measurable personal, business unit or Company outcomes; and
- total compensation (the sum of fixed and variable components) for each Senior Manager is fair, reasonable and market competitive.

Generally, there are two components of Senior Management compensation, as follows:

1. Fixed annual compensation comprising salary and benefits, superannuation and non-monetary benefits.
2. Medium-and long-term incentives, through participation in the PolyNovo Employee Share Option Plan ('the Plan') with share price thresholds to be achieved.

Fixed Annual Compensation

Senior Managers are offered a market competitive base salary, which reflects their competencies, job description as well as the size of the Group. Base salaries are reviewed against market data for comparable positions. Adjustments to base salary are made based on significant role responsibility changes, pay relativities to market and relative performance in the role.

Medium and Long Term Incentives

PolyNovo's medium and long term incentive policy for Senior Managers encourages high-quality performance and long-term retention. Carefully designed and performance linked equity incentive plans are widely recognised as an effective way of providing performance incentives.

Service Contracts

Chief Executive Officer – PolyNovo Limited

Mr Paul Brennan was appointed Chief Executive Officer of PolyNovo Limited on 13 February 2015.

The key terms of his contract are as follows:

- A salary of \$270,000 per annum inclusive of superannuation.
- a long term incentive plan in the form of equity interest. Details of the options package and the fair value of options and other compensation are included in the 'CEO Performance Incentives' section of the Remuneration Report and in Tables A, B, C and D below;
- no fixed employment term; and
- the Group may terminate the employment contract by providing three months' notice or payment in lieu of notice. In the event of resignation, a notice period of three months is required.

Company Secretary and Chief Operating & Financial Officer (COO/CFO)

Mr Greg Lewis was appointed COO, CFO and Company Secretary on 24 January 2018. The terms of his contract are as follows:

- a salary of \$174,100 per annum;
- a car allowance of \$26,900 per annum;
- superannuation of 9.50% (on salary only);
- a long term incentive plan in the form of equity interest. Details of the options package and the fair value of options and other compensation are included in the 'COO/CFO Performance Incentives' section of the Remuneration Report and in Tables A, B, C and D below;
- no fixed employment term; and
- the Group may terminate the employment contract by providing one months' notice or payment in lieu of notice. In the event of resignation, a notice period of one month is required.

CEO Performance Incentives

The performance evaluation of the Chief Executive Officer is conducted by the Board.

On 6 August 2015, PolyNovo issued an options package comprising three tranches of 4,185,095 share options (a total of 12,555,285 options), to the CEO, Mr Paul Brennan.

The vesting hurdle for the options is linked to the PolyNovo volume weighted average market price. The vesting hurdles for each tranche are as follows:

- \$0.18 per share for tranche 1;
- \$0.25 per share for tranche 2; and
- \$0.35 per share for tranche 3.

The share price must be sustained over a period of at least 90 consecutive calendar days. Any vested options are exercisable at 9 cents and may be exercised within 90 days of vesting. The options package had an expiry date of 5 August 2018.

The first tranche of options vested and were exercised in April 2016. The second tranche of options vested and were exercised in two transactions – 3,368,200 shares on October 2016 and 816,895 shares in December 2016. The third tranche of options vested and were exercised in May 2018 and remain in escrow until May 2019.

All shares issued under the incentive scheme are escrowed for a period of 12 months commencing on the date of issue. The Board approved a waiver to this policy for the 816,895 shares issued in December 2016, which Mr Brennan donated to Giant Steps with 300,000 of these shares to not be subject to the 12-month escrow period.

The expense relating to the incentive scheme shares during the financial year was \$55,803.

COO/CFO Performance Incentives

The performance evaluation of the Chief Operating Officer & Chief Financial Officer is conducted by the Board.

On 23 November 2017, PolyNovo issued an options package comprising 1,000,000 options to the COO/CFO, Mr Greg Lewis.

The vesting hurdle for the options is linked to PolyNovo's financial performance and its volume weighted average market price. The vesting hurdles are as follows:

- First hurdle – sales of \$12 million from the time of employment; and
- Second hurdle – a share price of 50 cents must be sustained over a period of at least 90 consecutive calendar days.

The first hurdle of \$12 million in sales, must occur before 28 February 2019. The options package will expire on 30 June 2019 (ignoring termination or cessation of employment).

The exercise price is 35 cents per option.

All shares issued under the incentive scheme are escrowed as to 50% for a period of 12 months and the remaining 50% for a period of 24 months commencing on the date of issue.

The fair value of the options relating to the incentive scheme shares was \$94,000. Management assessed the probability of achieving the first hurdle to be 10% and therefore the current period expense of \$2,827 was recognised.

Remuneration Report continued

Remuneration of Key Management Personnel

Details of the remuneration for key management personnel for the years ended 30 June 2018 and 30 June 2017 are set out in Table A below.

Table A		Short term			Post employ- ment	Leave allow- ances ¹	Share-based payments		Total \$	% per- for- mance based
		Cash salary & fees \$	Cash bonus \$	Consul- ing fees ³ \$	Superan- nuation \$	Annual and long service \$	Termina- tion benefits ² \$	Options and perfor- mance rights \$		
Directors										
Mr David Williams (Chairman/Non-executive Director)	2018	75,000	-	-	7,125	-	-	-	82,125	-
	2017	75,000	-	-	7,125	-	-	-	82,125	-
Mr Bruce Rathie (Non-executive Director)	2018	45,000	-	-	4,275	-	-	-	49,275	-
	2017	45,000	-	-	4,275	-	-	-	49,275	-
Dr David McQuillan (Non-executive Director)	2018	45,000	-	50,517	-	-	-	-	95,517	-
	2017	45,000	-	-	-	-	-	-	45,000	-
Mr Max Johnston (Non-executive Director)	2018	45,000	-	-	4,275	-	-	-	49,275	-
	2017	45,000	-	-	4,275	-	-	-	49,275	-
Mr Philip Powell (Non-executive Director)	2018	45,000	-	-	4,275	-	-	-	49,275	-
	2017	45,000	-	-	4,275	-	-	-	49,275	-
Mr Leon Hoare (Non-executive Director)	2018	45,000	-	-	4,275	-	-	-	49,275	-
	2017	45,000	-	-	4,275	-	-	109,000	158,275	-
Subtotal compensation for Directors	2018	300,000	-	50,517	24,225	-	-	-	374,742	-
	2017	300,000	-	-	24,225	-	-	109,000	433,225	-
Key management personnel										
Mr Paul Brennan (CEO)	2018	246,575	-	-	23,425	21,291	-	55,803	347,094	16%
	2017	246,575	24,658	-	25,767	12,253	-	177,225	486,478	41%
Mr Greg Lewis (CFO/Company Secretary)	2018	88,388	-	-	7,971	6,221	-	2,827	105,408	3%
	2017	-	-	-	-	-	-	-	-	-
Ms Andrea Goldie (CFO/Company Secretary)	2018	-	-	-	-	-	68,458	-	68,458	-
	2017	116,667	-	-	11,083	(5,470)	-	-	122,280	-
Mr Gavin Smith (Interim CFO/Company Secretary)	2018	52,534	-	82,680	4,991	-	-	-	140,205	-
	2017	-	-	100,132	-	-	-	-	100,132	-
Subtotal compensation for other key management personnel	2018	387,497	-	82,680	36,387	27,512	68,458	58,630	661,164	9%
	2017	363,242	24,658	100,132	36,850	6,783	-	177,225	708,890	28%
Total compensation for all key management personnel	2018	687,497	-	133,197	60,612	27,512	68,458	58,630	1,035,906	6%
	2017	663,242	24,658	100,132	61,075	6,783	-	286,225	1,142,115	27%

1. Leave allowances: annual and long service: Reflects the employees' entitlement for the 2018 financial year.

2. Ms Andrea Goldie: termination benefits: Due to a company position restructure, Ms Goldie received a redundancy payment reflective of her years of employment.

3. Mr David McQuillan: consulting fees: Services provided in relation to product development for the hernia project.

Options Granted as Part of Remuneration

During the year ended 30 June 2018, 1,000,000 options (2017: 1,000,000) were granted, no options were cancelled (2017: nil), and no options were forfeited (2017: nil). These options were issued pursuant to the PolyNovo Employee Share Option Plan.

Details of the share-based payment component included in total remuneration in Table B are set out below.

2018 financial year	Grant date	Grant number	Average fair value per option at grant date \$	Fair value of options granted during the year \$	Value of options forfeited/lapsed during the year \$	Value of options exercised during the year \$	Number of shares issued upon exercise of options	Value of shares received upon exercise of options \$	Value of options yet to be exercised \$	Fair value of options included in remuneration during the year \$	% compensation consisting of options during the year
Mr David Williams											
Options	19-May-14	2,500,000	\$0.03300	-	-	\$82,500	2,500,000	\$537,500	-	-	-
Mr Bruce Rathie											
Options	17-Nov-14	500,000	\$0.04300	-	-	\$21,500	500,000	\$180,000	-	-	-
Dr David McQuillan											
Options	17-Nov-14	500,000	\$0.04300	-	-	\$21,500	500,000	\$170,000	-	-	-
Mr Philip Powell											
Options	17-Nov-14	500,000	\$0.04300	-	-	\$21,500	500,000	\$100,000	-	-	-
Options	17-Nov-14	500,000	\$0.05400	-	-	\$27,000	500,000	\$152,500	-	-	-
Mr Max Johnston											
Options	17-Nov-14	500,000	\$0.04300	-	-	\$21,500	500,000	\$152,500	-	-	-
Options	17-Nov-14	500,000	\$0.05400	-	-	\$27,000	500,000	\$152,500	-	-	-
Mr Leon Hoare											
Options	18-Nov-16	500,000	\$0.12000	-	-	-	-	-	-	-	-
Options	18-Nov-16	500,000	\$0.09800	-	-	-	-	-	-	-	-
Mr Paul Brennan											
Options	6-Aug-15	4,185,095	\$0.03692	-	-	\$154,514	4,185,095	\$2,155,324	-	\$55,803	16%
Mr Greg Lewis											
Options	23-Nov-17	1,000,000	\$0.09400	\$94,000	-	-	-	-	\$91,173	\$2,827	3%
Total		11,685,095		\$94,000	-	\$377,014	9,685,095	\$3,600,324	\$91,173	\$58,630	-

Options granted in year ended 30 June 2018

The fair value of options granted during the year, as included in Table B, was determined using a Monte Carlo simulation based pricing model due to it analysing options where the exercise condition is dependent on outcomes associated with factors other than or in addition to, the share price. The fair value of options granted during the year was \$94,000. However, management has determined at balance date, the likelihood of achieving the first vesting hurdle of \$12 million in sales by 28 February 2019 to be 10%. As a result, the fair value of the options expensed and included in remuneration is \$2,827.

Options granted in year ended 30 June 2017

The fair value of options granted during the year, as included in Table B, was determined using a binomial option pricing model due to the immediate vesting conditions attached to these options. The fair value of options included in remuneration during the year was \$109,000 and represents 100% allocation to the year ended 30 June 2017 due to the immediate vesting conditions.

Remuneration Report continued

Options Granted as Part of Remuneration continued

Options expiry dates

Participant	Date
Mr Leon Hoare	1 February 2019
Mr Greg Lewis	30 June 2019

Key Management Personnel Disclosures

Movements in shares of the Company

The movement during the reporting period in the number of shares in the Company held either directly or indirectly by each of the key management personnel, including their related parties, is set out in the table below:

Table C	Balance at 1 July 2017	Granted as compensation	On exercise of options	Net change other	Balance at 30 June 2018	Balance at end of year - directly held	Balance at end of year - indirectly held
Directors							
Mr David Williams	8,100,000	-	2,500,000	5,302,152	15,902,152	-	15,902,152
Mr Bruce Rathie	2,100,000	-	500,000	137,290	2,737,290	-	2,737,290
Dr David McQuillan	500,000	-	500,000	-	1,000,000	1,000,000	-
Mr Max Johnston	611,112	-	1,000,000	-	1,611,112	-	1,611,112
Mr Philip Powell	211,112	-	1,000,000	55,555	1,266,667	-	1,266,667
Mr Leon Hoare	170,166	-	-	115,555	285,721	-	285,721
Other key management personnel							
Mr Paul Brennan	7,820,447	-	4,185,095	-	12,005,542	162,577	11,842,965
Ms Andrea Goldie	225,905	-	-	-	225,905	-	225,905
Mr Gavin Smith	250,000	-	-	-	250,000	-	250,000

Options and performance rights of key management personnel

The option holdings of key management personnel for the year ended 30 June 2018 are set out in the following table.

Table D	Balance at 1 July 2017	Granted as compensation	Options exercised	Net change other	Balance at 30 June 2018	Total vested at end of year	Total exercisable at end of year	Total not exercisable at end of year	Total vested during year
Directors									
Mr David Williams	2,500,000	-	2,500,000	-	-	-	-	-	-
Mr Bruce Rathie	500,000	-	500,000	-	-	-	-	-	-
Dr David McQuillan	500,000	-	500,000	-	-	-	-	-	-
Mr Max Johnston	1,000,000	-	1,000,000	-	-	-	-	-	-
Mr Philip Powell	1,000,000	-	1,000,000	-	-	-	-	-	-
Mr Leon Hoare	1,000,000	-	-	-	1,000,000	-	1,000,000	-	-
Other key management personnel									
Mr Paul Brennan	4,185,095	-	4,185,095	-	-	-	-	-	4,185,095
Mr Greg Lewis	-	1,000,000	-	-	1,000,000	-	-	1,000,000	-
Total	10,685,095	1,000,000	9,685,095	-	2,000,000	-	1,000,000	1,000,000	4,185,095

Loans to Key Management Personnel

No loans have been made to Directors of PolyNovo or to any other key management personnel, including their personally related entities.

Other Key Management Personnel Transactions

Kidder Williams Limited, an advisory firm specialising in capital raising, assisted PolyNovo during the process of capital raising in September and October 2017 when PolyNovo raised a total of \$23.05m from a placement to sophisticated investors followed by a Share Purchase Plan. PolyNovo paid \$818,276 plus GST to Kidder Williams Limited for its services. Kidder Williams Limited is a company associated with the Chairman of the Board of PolyNovo, Mr David Williams, as Mr David Williams is the owner and Managing Director of Kidder Williams Limited.

This Directors' Report, incorporating the Corporate Governance Statement and Remuneration Report, has been signed in accordance with a Resolution of the Directors made on 16 August 2018.



Mr David Williams
Chairman
16 August 2018

Auditor's Independence Declaration



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Auditor's independence declaration to the Directors of PolyNovo Limited

As lead auditor for the audit of PolyNovo Limited for the financial year ended 30 June 2018, I declare to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- b) no contraventions of any applicable code of professional conduct in relation to the audit.

This declaration is in respect of PolyNovo Limited and the entities it controlled during the financial year.

Ernst + Young

Ernst & Young

Joanne Lonergan
Partner
16 August 2018

Consolidated Statement of Comprehensive Income

For the year ended 30 June 2018

	Notes	30 June 2018 \$	30 June 2017 \$
Revenue			
Sale of goods		1,747,102	136,896
Sale of materials		10,228	25,000
Licences revenue		130,109	-
Royalty revenue		-	2,014
BARDA revenue	4(b)	3,827,016	3,456,216
Finance revenue	4(a)	275,303	138,906
Total revenue		5,989,758	3,759,032
Research and development tax benefit	4(f)	839,397	833,174
Change in inventories of finished goods and work in progress	9	(632,859)	937,228
Raw materials and consumables used		-	(51,619)
Operating Leases		(190,768)	(359,420)
Employee-related expenses	4(c)	(5,656,333)	(4,488,816)
Research and development expenses		(3,806,108)	(3,136,002)
Depreciation and amortisation expense	4(d)	(181,890)	(246,971)
Corporate, administrative and overhead expenses	4(e)	(2,335,329)	(2,252,620)
Net loss for the period before tax		(5,974,132)	(5,006,014)
Income tax benefit	5	-	-
Net loss for the period after tax		(5,974,132)	(5,006,014)
Other comprehensive income			
Loss on translation of foreign operation	16(b)	(159,300)	-
Total comprehensive income/(loss) for the period		(6,133,432)	(5,006,014)
Loss for the period is attributable to:			
Owners of the parent		(5,974,132)	(5,006,014)
		(5,974,132)	(5,006,014)
Total comprehensive loss for the period attributable to:			
Owners of the parent		(6,133,432)	(5,006,014)
Loss attributable to members of the parent		(6,133,432)	(5,006,014)
Loss per share			
Basic loss per share – cents	7	(0.95) cents	(0.89) cents
Diluted loss per share – cents	7	(0.95) cents	(0.89) cents

The accompanying notes form part of these financial statements.

Consolidated Statement of Financial Position

As at 30 June 2018

	Notes	30 June 2018 \$	30 June 2017 \$
Current assets			
Cash and cash equivalents	8	3,147,081	5,496,609
Inventories	9	1,083,586	981,112
Receivables	10	2,679,675	1,369,535
Prepayments		164,766	62,006
Other financial assets	22	19,050,000	50,000
Total current assets		26,125,108	7,959,262
Non-current assets			
Property, plant and equipment	12	1,139,665	1,452,354
Intangible assets	13	2,395,864	2,519,788
Other assets	11	161,288	124,460
Total non-current assets		3,696,817	4,096,602
Total assets		29,821,925	12,055,864
Current liabilities			
Trade and other payables	14	942,719	892,737
Provisions	15(a)	275,698	176,874
Total current liabilities		1,218,417	1,069,611
Non-current liabilities			
Provisions	15(b)	29,287	14,623
Deferred rent liability		115,251	158,764
Total non-current liabilities		144,538	173,387
Total liabilities		1,362,955	1,242,998
Net assets		28,458,970	10,812,866
Equity			
Contributed equity	16(a)	138,120,502	114,476,370
Reserves	16(b)	(6,392,311)	(6,368,415)
Accumulated losses	16(c)	(103,269,221)	(97,295,089)
Parent interests		28,458,970	10,812,866
Total equity		28,458,970	10,812,866

The accompanying notes form part of these financial statements.

Consolidated Statement of Changes in Equity

For the year ended 30 June 2018

	Contributed equity \$	Other reserves \$	Acquisition of non- controlling interest reserves \$	Retained earnings \$	Owners of the parent \$	Total \$
As at 30 June 2016	114,099,712	2,595,045	(9,293,956)	(92,289,075)	15,111,726	15,111,726
Loss for the period	-	-	-	(5,006,014)	(5,006,014)	(5,006,014)
Issue of shares on exercise of options	376,658	-	-	-	376,658	376,658
Share-based payments	-	330,496	-	-	330,496	330,496
As at 30 June 2017	114,476,370	2,925,541	(9,293,956)	(97,295,089)	10,812,866	10,812,866
Loss for the period	-	-	-	(5,974,132)	(5,974,132)	(5,974,132)
Issue of shares on exercise of options	1,416,659	-	-	-	1,416,659	1,416,659
Issue of shares on capital raise (see Note16)	22,227,473	-	-	-	22,227,473	22,227,473
Translation of foreign operation	-	(159,300)	-	-	(159,300)	(159,300)
Share-based payments	-	135,404	-	-	135,404	135,404
As at 30 June 2018	138,120,502	2,901,645	(9,293,956)	(103,269,221)	28,458,970	28,458,970

The accompanying notes form part of these financial statements.

Consolidated Cash Flow Statement

For the year ended 30 June 2018

	Notes	30 June 2018 \$	30 June 2017 \$
Cash flows from operating activities			
Receipts from customers		1,467,117	167,136
Receipts from BARDA reimbursements and advances		3,016,578	3,674,028
Receipts of research and development income tax credit		878,268	783,356
Receipts from royalty revenue		2,699	3,234
Receipts from licence revenue		130,109	-
Payments to suppliers and employees		(12,372,732)	(9,789,287)
Net cash outflows from operating activities	8	(6,877,961)	(5,161,533)
Cash flows from investing activities			
Interest received		36,753	208,967
Payments for purchase of property, plant and equipment		(219,979)	(581,745)
Proceeds from sales of available-for-sale financial assets		-	-
Term deposits classified as other assets		(19,000,000)	-
Net cash outflows used in investing activities		(19,183,226)	(372,778)
Cash flows from financing activities			
Net cash flows from financing activities			
Proceeds from the issue of share capital (net of costs)	16(a)	22,227,473	-
Proceeds from the exercise of options		1,416,659	376,659
Cash flows from financing activities		23,644,132	376,659
Net (decrease)/increase in cash and cash equivalents		(2,417,055)	(5,157,652)
Cash and cash equivalents at beginning of period		5,496,609	10,746,691
Effects of exchange rate changes on cash and cash equivalent		67,527	(92,430)
Cash and cash equivalents at end of period	8	3,147,081	5,496,609

The accompanying notes form part of these financial statements.

Notes to the Financial Statements

For the year ended 30 June 2018

1. Corporate Information

The Financial Report of PolyNovo Limited (the Company) and its controlled entities (the Group) for the year ended 30 June 2018 was authorised for issue in accordance with a resolution of the Directors on 16 August 2018.

PolyNovo Limited, a for-profit entity, is a Company incorporated in Australia, whose shares are publicly traded on ASX Limited (ASX code: PNV).

The Company operates predominantly in the medical device and healthcare industry and has operations in Australia and the USA.

2. Summary of Significant Accounting Policies

(a) Basis of preparation

The Financial Report is a general-purpose Financial Report, which has been prepared in accordance with the requirements of the *Corporations Act 2001*, applicable Accounting Standards and other mandatory professional reporting requirements.

The Financial Report has been prepared on a historical cost basis. The Financial Report is presented in Australian dollars.

The financial statements have been prepared in compliance with Legislative Instrument 2016/191 'ASIC Corporations (Rounding in Financial/Directors' Reports)' and rounded to the nearest dollar.

The financial statements of the Group have been prepared on a going concern basis. The Group's operations are subject to major risks due primarily to the nature of the research, development and commercialisation to be undertaken. These risks may materially impact the financial performance and position of the Group, including the value of recorded assets and the future value of its shares, options and performance rights. The financial statements take no account of the consequences, if any, of the effects of unsuccessful research, development and commercialisation of the Group's projects.

(b) Statement of compliance

The Financial Report complies with Australian Accounting Standards as issued by the Australian Accounting Standards Board and International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

The Group has adopted all applicable new and amended Australian Accounting Standards and AASB Interpretations that apply as of 1 July 2017. Those Australian Accounting Standards and Interpretations that have recently been issued or amended but are not yet effective, have not been adopted. Details of the new and amended Standards adopted, along with a summary of the new and amended Standards that are not yet effective, are set out below.

(c) Changes in accounting policy, disclosures, standards and interpretations

The Group has adopted the following new and amended Australian Accounting Standards and AASB Interpretations as of 1 July 2017.

- AASB 2017–2 Amendments to Australian Accounting Standards – Further Annual Improvements 2014–2016 Cycle
- AASB 2016–2 Amendments to Australian Accounting Standards – Disclosure Initiative: Amendments to AASB 107
- AASB 2016–1 Amendments to Australian Accounting Standards – Recognition of Deferred Tax Assets for Unrealised Losses

The above new and amended Australian Accounting Standards and AASB Interpretation did not have any material impact on the accounting policies, financial position or performance of the Group.

The following new Australian Accounting Standards have been issued by the AASB but are not yet effective for the period ended 30 June 2018. They have not been adopted by the Group for the year ended 30 June 2018.

- AASB 9 Financial instruments: this replaces AASB 139. AASB 9 is effective for annual periods beginning on or after 1 January 2018.
- AASB 15 Revenue from Contracts with Customers: this replaces the existing revenue recognition standards. AASB 15 is effective for annual reporting periods commencing on or after 1 January 2018.
- AASB 16 Leases: supersedes AASB 117. AASB 16 will be effective for annual periods beginning on or after 1 January 2019.
- AASB 2015–3 Amendments to Australian Accounting Standards arising from the Withdrawal of AASB 1031 Materiality.

Notes to the Financial Statements continued

For the year ended 30 June 2018

2. Summary of Significant Accounting Policies continued

(c) Changes in accounting policy, disclosures, standards and interpretations continued

A preliminary update covering the potential impact from the adoption of each standard follows:

- AASB 9 – The Group does not anticipate significant issues on adoption based on existing financial instruments.
- AASB 15 – The Group's treatment for customer contract arrangements will be assessed as the revenue-related arrangements are entered into. Initial assessment of existing contracts has not indicated any material change to recognition of revenue, but our analysis is ongoing.
- AASB 16 – The Group's current operating lease at its Port Melbourne headquarters will be assessed. There will be an impact on the Group's Balance Sheet and Income Statement. The Group does not anticipate significant issues on adoption based on existing lease arrangements.

In addition, there are no other new amendments to existing standards (issued but not yet effective) expected to result in significant changes to the Company's accounting policies in the future.

(d) Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 30 June 2018. The Group controls an investee if and only if the Group has:

- power over the investee (that is, rights that give it the ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

When the Group has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- the contractual arrangement with the other vote holders of the investee;
- rights arising from other contractual arrangements; and
- the Group's voting rights and potential voting rights.

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate a change in one or more of the three elements of control. Consolidation of a subsidiary commences when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. The assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the Statement of Comprehensive Income from the date the Group gains control until the date the Group ceases to control the subsidiary.

Items of profit or loss and each component of other comprehensive income (OCI) are attributed to the equity holders of the parent Company and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it:

- de-recognises the assets (including goodwill) and liabilities of the subsidiary;
- de-recognises the carrying amount of any non-controlling interests;
- de-recognises the cumulative translation differences recorded in equity;
- recognises the fair value of the consideration received;
- recognises the fair value of any investment retained;
- recognises any surplus or deficit in profit or loss; and
- reclassifies the parent's share of components previously recognised in OCI to profit or loss or retained earnings, as appropriate, as would be required if the Group had directly disposed of the related assets or liabilities.

(e) Business combinations

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred measured at acquisition date fair value and the amount of any non-controlling interests in the acquiree. For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree at fair value or at the proportionate share of the acquiree's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative expenses.

If the business combination is achieved in stages, any previously held equity interest is re-measured at its acquisition date fair value and any resulting gain or loss is recognised in profit or loss. It is then considered in the determination of goodwill.

(f) Intangible assets

Intangible assets acquired separately or in a business combination are initially measured at cost. The cost of an intangible asset acquired in a business combination is its fair value as at the date of acquisition. The intangible assets carried by the Group, being intellectual property assets had an initial indefinite useful life on acquisition. In the current period, and following the first commercial sales of NovoSorb BTM, amortisation has been recognised across the finite life of the intangible assets. See Note 13 for further detail.

Internally generated intangible assets are not capitalised and expenditure is recognised in the Statement of Comprehensive Income (profit or loss) in the year in which the expenditure is incurred.

(g) Impairment of intangible and other assets

Intangible assets that have an indefinite useful life are not subject to amortisation. They are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets including definite lived intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

The Group conducts an annual internal review of asset values, which is used as a source of information to assess for any indicators of impairment. External factors, such as changes in expected future processes, technology and economic conditions, are also monitored to assess for indicators of impairment. If any indication of impairment exists, an estimate of the asset's recoverable amount is calculated.

(h) Share-based payments

The Group provides benefits to employees in the form of share-based payment transactions, whereby employees render services in exchange for shares or rights over shares.

The PolyNovo Employee Share Option Plan was in place for the year ended 30 June 2018. Information relating to this Plan is set out in Note 6 and in the Remuneration Report section of the Directors' Report.

The cost of share-based payments under the terms of the Share Option Plan is measured by reference to the fair value of options at the date at which they are granted. The fair value of options granted is determined by using the Monte Carlo simulation model or the binomial option valuation model. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in the Remuneration Report, and/or Note 6. All option arrangements are settled in equity.

The fair value of options is recognised as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognised over the option period. The employee benefit expense recognised each period takes into account the most recent estimate of the number of options that are expected to vest.

(i) Plant and equipment

Plant and equipment is stated at cost less accumulated depreciation and any impairment in value. Depreciation is calculated on a straight-line basis over the estimated useful life of the asset as follows:

Office equipment	3 to 10 years
Laboratory plant and equipment	3 to 13.33 years
Leasehold improvements	6.67 to 12 years

Notes to the Financial Statements continued

For the year ended 30 June 2018

2. Summary of Significant Accounting Policies continued

(j) Plant and equipment impairment

Impairment

The carrying values of plant and equipment are reviewed for impairment at each reporting date, when events or changes in circumstances indicate that the carrying value may be impaired. An asset is impaired when its carrying value exceeds its estimated recoverable amount. In this instance, the asset is written down to its recoverable amount and the impairment loss recognised in the Statement of Comprehensive Income.

For impairment testing purposes, the recoverable amount of an asset is estimated as the higher of its fair value less cost of disposal and its 'value-in-use'. Value-in-use is calculated by discounting, the estimated future cash flows derived from use of the asset, using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

Disposal

Plant and equipment is de-recognised upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on de-recognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the item) is recognised in the Statement of Comprehensive Income.

(k) Research and development costs

Research and development costs are expensed as incurred. An intangible asset arising from development expenditure on an individual project is recognised only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available-for-use or sale. No development expenditure has been capitalised.

(l) Investments

Available-for-sale investments

After initial recognition, investments classified as available-for-sale are measured at fair value. For investments that are actively traded in organised financial markets, fair value is determined by reference to Stock Exchange quoted market bid prices at the close of business on balance date. Gains or losses on available-for-sale investments are recognised as a separate component of equity until the investment is disposed of. At this point, the cumulative gain or loss previously reported in Other Comprehensive Income (equity) is included in the Statement of Comprehensive Income (profit and loss).

The Group had no available-for-sale investments as at 30 June 2018.

(m) Cash and cash equivalents

Cash at bank and short-term deposits are stated at nominal value.

(n) Employee leave benefits

Liabilities for wages, salaries and annual leave expected to be settled within 12 months of the reporting date and pro-rata long service leave for employees with over seven years of service, are recognised in current liabilities. Wages, salaries, annual leave and long service leave are measured at the amounts expected to be paid when the liabilities are settled.

Liabilities for pro-rata long service leave for employees with less than seven years of service are recognised in non-current liabilities and are measured as the present value of the expected future payments to be made.

(o) Operating leases

The minimum lease payments of operating leases, where the lessor retains substantially all of the risks and benefits of ownership of the leased items, are recognised as an expense in the Statement of Comprehensive Income on a straight-line basis over the lease term.

(p) Revenue recognition

Revenue is recognised when it is probable that future economic benefits will flow to the entity and the revenue can be reliably measured.

Revenue from the sale of goods is measured at fair value of consideration received or receivable. Revenue is recognised when the amount of revenue can be reliably measured and it is probable that the future economic benefits will flow to PolyNovo Limited and the significant risks and rewards of ownership of the goods have passed to the buyer.

The amount of revenue arising on the BARDA contract is determined by the BARDA agreement between PolyNovo and BARDA. Revenue is measured in accordance with the criteria set out in the contract and is assessed based on employee timesheets, sub-contractor invoices, direct BARDA expenses and other indirect rates as defined in the contract or otherwise agreed with BARDA. The BARDA contract is a cost plus fixed fee contract of a reimbursement nature and has a pre agreed contract period and contract value. The customer, being the US Government, has low or no credit risk.

Revenue from licences is recognised in line with the terms of the agreement.

Interest revenue is recognised when the Group has the right to receive the interest payment. Interest receivable, and GST recoverable are recorded at amortised cost. Due to the short-term nature of these receivables amortised cost equates to face value.

(q) Inventory

Inventory is measured at cost for raw materials and packaging materials. A standard cost has been derived for finished goods and semi-finished goods. The standard cost includes an allocation of materials, direct labour and manufacturing overheads. The value of finished goods and semi-finished goods may include an allocation of manufacturing variances incurred during the period if it is determined that the relevant production remains in inventory at balance date.

(r) Government grants

Government grants are recognised at their fair value when the grant is received and all attaching conditions have been complied with. Research and development income tax revenue is recognised when there is reasonable assurance of receipt.

(s) Trade and other payables

Trade and other payables are carried at amortised cost. They represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid. The amounts are unsecured and are normally settled on 30-day terms. Due to the short-term nature of these payables amortised cost equates to fair value.

(t) Income tax

Deferred income tax is provided on all temporary differences at balance date, calculated as the difference between the tax cost base of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax assets are recognised for all deductible temporary differences to the extent that it is probable that taxable profit will be available against which the deductible temporary differences can be utilised. The same criteria apply for recognition of tax assets relating to unused tax losses.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) effective at balance date.

Income taxes relating to items recognised directly in equity are recognised in Other Comprehensive Income (equity) and not in the Statement of Comprehensive Income (profit and loss).

Notes to the Financial Statements continued

For the year ended 30 June 2018

2. Summary of Significant Accounting Policies continued

(u) Significant accounting, estimates and assumptions

Deferred tax liability

The deferred tax liability (DTL) arising from the carrying value of PolyNovo's intangible assets is offset by deferred tax assets (DTAs) recognised for unused tax losses, where the continuity of ownership test is satisfied. Significant management judgement is required to determine the amount of the DTA that can be used to offset the impact of the DTL. Further details on deferred taxes are disclosed in Note 5.

Share-based payments

Estimating fair value for share-based payment transactions requires selection of the most appropriate valuation model, which in turn is dependent on the terms and conditions of the share-based payment granted. Determination of the most appropriate inputs to the valuation model, including the expected life of the share option, volatility and dividend yield, is also required. The models and related assumptions used for estimating the fair value of share-based payment transactions are disclosed in Note 6 and in the Remuneration Report.

Impairment of intangibles

Impairment exists when the carrying value of an asset exceeds its recoverable amount. PolyNovo considers indicators of impairment and if an indicator exists, will determine the recoverable amount of the intangible asset. An estimate is provided on the useful life of the current intangible asset based on the existing patent period. The assessment for the current period is further explained in Note 13.

(v) Goods and services tax (GST)

Revenues, expenses and assets are recognised net of GST except:

- where the GST incurred on purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognised as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables, which are stated with the amount of GST (if any) included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the Statement of Financial Position. Cash flows are included in the Cash Flow Statement on a gross basis (that is, including GST) and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority are classified as operating cash flows. Commitments and contingencies are disclosed exclusive of the amount of GST recoverable from, or payable to, the taxation authority.

(w) Earnings per share (EPS)

Basic EPS is calculated as the net profit/(loss) attributable to shareholders, adjusted to exclude costs of servicing equity (other than dividends), divided by the weighted average number of ordinary shares.

Diluted EPS is calculated as the net profit/(loss) attributable to members, adjusted for:

- the costs of servicing equity (other than dividends);
- the after-tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognised as expenses; and
- other non-discretionary changes in revenues or expenses during the period that would result from the dilution of potential ordinary shares.

The resultant net profit/(loss) is divided by the weighted average number of ordinary shares and dilutive potential ordinary shares.

(x) Contributed equity

Ordinary shares are classified as equity and recognised at the fair value of the consideration received by the Company. Any transaction costs arising on the issue of ordinary shares are recognised directly in equity as a reduction of the share proceeds received.

(y) Foreign currency translation

The functional currency of each of the entities in the Group must reflect the primary economic environment in which the entity operates. Accordingly, the relevant functional currencies are Australian dollars for Australian entities and US dollars for the US entity. Foreign currency items are translated to Australian currency on the following basis.

- Transactions are converted at exchange rates approximating those in effect at the date of the transaction.
- On consolidation, the assets and liabilities of the foreign operation are translated into Australian dollars at the rate of exchange prevailing at the reporting date except for retained earnings which is translated at a historic rate of exchange pertaining to the relevant financial year. The Statement of Comprehensive Income is translated at an average exchange rate over the financial year.
- The exchange difference arising on translation for consolidation are recognised in the balance sheet as a foreign currency translation reserve. On disposal of a foreign operation, the reserve is reclassified to profit or loss.

(z) Comparatives

Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosures.

(aa) Security deposits

Security deposits are recorded at amortised cost in the Statement of Financial Position.

3. Segment Information

Operating segment

PolyNovo has only one operating segment, being the development of the NovoSorb® technology for use in a range of biodegradable medical devices.

The chief operating decision-maker is the Chief Executive Officer of PolyNovo Limited.

The chief operating decision-maker reviews the results of the business on a single entity basis. For financial results refer to the Statement of Comprehensive Income and Statement of Financial Position.

The chief operating decision-maker monitors the operating results of the Group for the purpose of making decisions about resource allocation in order to progress the commercialisation of the PolyNovo technology.

Sales revenue

	30 June 2018 \$	30 June 2017 \$
Geographical areas		
United States of America	5,337,850	3,456,216
Australia and New Zealand	651,908	302,815
	5,989,758	3,759,032

Non-current assets

	30 June 2018 \$	30 June 2017 \$
Geographical areas		
United States of America	33,779	-

Notes to the Financial Statements continued

For the year ended 30 June 2018

4. Revenues and Expenses

(a) Finance revenue

	30 June 2018 \$	30 June 2017 \$
Term deposit interest	236,557	121,029
Bank account interest	38,746	17,766
Interest income – other	-	111
	275,303	138,906

(b) BARDA revenue

Revenue from contract with BARDA	3,827,016	3,456,216
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The contract with the Biomedical Advanced Research and Development Authority (BARDA) is a cost plus fixed fee reimbursement contract that was awarded on 28 September 2015. The contract is to fund the full cycle of clinical trial activities relating to commercialisation of the Company's BTM in deep tissue burns.

(c) Employee-related expenses

	30 June 2018 \$	30 June 2017 \$
Wages and salaries	(4,002,385)	(2,932,348)
Superannuation	(267,013)	(233,945)
Share-based payments (expense)(see Note 6)	(135,404)	(330,496)
Other	(1,251,531)	(992,027)
	(5,656,333)	(4,488,816)

(d) Depreciation and amortisation expense

	30 June 2018 \$	30 June 2017 \$
Depreciation – property, plant and equipment	(57,966)	(246,971)
Amortisation – intangible assets	(123,924)	-

Depreciation of property, plant and equipment is also included in the cost of inventory.

(e) Corporate, administrative and overhead expenses

Insurances	(338,094)	(185,563)
Accounting and audit fees	(199,396)	(259,526)
Investor relations and share registry expenses	(157,797)	(131,475)
Consultants and contractors	(436,240)	(526,466)
Travel	(747,035)	(403,228)
Marketing costs	(186,474)	(167,213)
Communication expenses	(110,772)	(117,119)
Other	(159,521)	(462,030)
	(2,335,329)	(2,252,620)

(f) Research and development tax benefit

Research and development tax benefit income of \$839,397 (2017: \$833,174) was recognised as other income in the Statement of Comprehensive Income. \$794,255 (2017: \$833,124) is receivable, as recognised in the Statement of Financial Position, with respect to the year ended 30 June 2018.

Notes to the Financial Statements continued

For the year ended 30 June 2018

5. Income Tax

(a) Income tax benefit/(income tax expense)

	30 June 2018 \$	30 June 2017 \$
<i>Current income tax</i>		
Current income tax charge	-	-
<i>Deferred income tax</i>		
Relating to origination and reversal of temporary differences	-	-
Income tax benefit/(income tax expense)	-	-
Income tax recognised directly in equity		
Deferred tax expense	-	-
Available-for-sale asset	-	-
Reconciliation of income tax expense to prima facie tax payable		
Net loss before income tax expense	5,974,132	5,006,014
Prima facie tax calculated at 27.5% (2017: 27.5%)	(1,642,886)	(1,376,654)
Tax effect of amounts which are not included in accounting loss:		
Research and development	502,115	526,689
Non-assessable R&D income tax credit	(230,834)	(229,110)
Tax effect of amounts which are not deductible:		
Share-based payments	37,236	90,887
	(1,334,369)	(988,188)
Current year tax losses not brought to account	1,597,423	1,115,737
Current year temporary differences not brought to account	(263,053)	(127,549)
Income tax benefit/(income tax expense)	-	-

(b) Deferred tax assets and liabilities

	30 June 2018 \$	30 June 2017 \$
Deferred tax assets	411,203	302,303
Deferred tax liabilities	(411,203)	(302,303)
Net deferred tax assets/(liabilities)	-	-
Deferred tax balances reflects temporary differences attributable to:		
Amounts recognised in profit and loss		
Recognised tax losses	147,266	77,243
Recognised on temporary differences	263,937	225,060
Amount recognised due to acquisition of PolyNovo	(411,203)	(302,303)
Net deferred tax assets/(liabilities)	-	-
Movement in temporary differences during the year:		
Balance as of 1 July	-	-
Credit to profit and Loss	-	-
Charged to equity	-	-
Net deferred tax assets/(liabilities) as 30 June	-	-

(c) Deferred tax assets not brought to account

Unrecognised, unconfirmed tax losses for which no deferred tax asset has been recognised	91,718,206	87,701,802
Deductible temporary differences – no deferred tax asset has been recognised	956,558	463,815
	92,674,764	88,165,617
Potential tax benefit at 27.5%	25,485,560	24,245,545

The availability of the tax losses in future periods is uncertain and will be dependent on the Group satisfying strict requirements with respect to continuity of ownership and the same business test, imposed by income tax legislation. The recoupment of available tax losses as at 30 June 2018 is contingent upon the following:

- the Group deriving future assessable income of a nature and of an amount sufficient to enable the benefit from the losses to be realised;
- the conditions for deductibility imposed by tax legislation continuing to be complied with; and
- there being no changes in tax legislation that would adversely affect the Group from realising the benefit from the losses.

Given the Group's history of recent losses (with the exceptions of the benefit noted in (d) below) the Group has not recognised a deferred tax asset with regard to unused tax losses, as it has not been determined that the Group will generate sufficient taxable profit against which the unused tax losses can be utilised.

In a prior year, consideration was given to PolyNovo's ability to satisfy the tax loss recoupment tests for losses incurred in 2003 and earlier income years. Based on re-assessment, tax losses of approximately \$26 million were forfeited.

(d) Income tax benefit

The income tax benefit arises due to the recording of deferred tax assets that are available in the current year to offset against deferred tax liabilities from temporary differences.

Notes to the Financial Statements continued

For the year ended 30 June 2018

6. Share-Based Payments

(a) Employee share-based payment plans

The Company provides benefits to employees and Non-executive Directors in the form of share-based payment transactions, whereby employees and Non-executive Directors render services in exchange for shares or rights over shares.

The expense recognised in the Statement of Comprehensive Income for the years ended 30 June 2018 and 30 June 2017 were \$135,404 and \$330,496 respectively.

(b) Share-based payments for the year ended 30 June 2018

During the 2018 financial year, 1,000,000 options were issued and 4,185,095 were exercised. Details of the share options granted pursuant to the terms of the PolyNovo Employee Share Option Plan (ESOP) are as follows:

- On 23 November 2017, the Company granted employee share options to Mr Greg Lewis. He was granted 1,000,000 options exercisable at \$0.35. The options vest first upon a sales target of \$12 million being achieved by 28 February 2019 and then upon a share price of \$0.50 being sustained over a period of 90 consecutive calendar days. The options package will expire on 30 June 2019. The expense relating to the options package during the year was \$2,827. Management assessed the probability of achieving the first hurdle to be 10%.

The expense relating to the incentive scheme shares recognised in the Statement of Comprehensive Income during the 2018 financial year was \$135,404.

	Balance at 1 July 2017	Granted as compen- sation	Options exercised	Net change other (forfeited, lapsed, expired)	Balance at 30 June 2018	Total vested at end of year	Total exercisable at end of year	Total not exercisable at end of year	Total vested during year	Share- based payments expense \$
2018										
Directors										
Mr Leon Hoare	1,000,000	-	-	-	1,000,000	1,000,000	1,000,000	-	-	-
Other key management personnel										
Mr Paul Brennan	4,185,095	-	(4,185,095)	-	-	-	-	-	(4,185,095)	\$55,803
Mr Greg Lewis	-	1,000,000	-	-	1,000,000	-	-	1,000,000	-	\$2,827
Other employees	2,000,000	-	-	-	2,000,000	-	-	2,000,000	-	\$79,601
Total	7,185,095	1,000,000	(4,185,095)	-	4,000,000	1,000,000	1,000,000	3,000,000	(4,185,095)	\$138,231

The fair value of options granted during 2018, as included in the above table, were determined using a Monte Carlo simulation-based model. A Monte Carlo simulation-based model simulates the path of the share price according to a probability distribution assumption. After a large number of simulations, the arithmetic average of the outcomes, discounted to the valuation date, is calculated to represent the option value. This model can accommodate complex exercise conditions when the number of options exercised depends on some function of the whole path followed by the share price.

Options issued during the period

Grant date	Number of options	Exercise Price	Vesting hurdle	Risk-free interest rate	Volatility	Expiry	Dividend yield	Average fair value per option
23 November 2017	1,000,000	\$0.35	\$12 million in sales and 3 months share price exceeds \$0.50	1.78%	49.52%	30-Jun-19	-	\$0.094

(c) Share-based payments for the year ended 30 June 2017

During the 2017 financial year, 3,000,000 options were issued and 4,185,095 were exercised. Details of the share options granted pursuant to the terms of the PolyNovo Employee Share Option Plan (ESOP) are as follows:

- On 18 November 2016, following members' approval at the Company's Annual General Meeting, an options package comprising 500,000 options exercisable at \$0.25 and 500,000 options exercisable at \$0.33 were issued to Mr Leon Hoare, a Non-executive Director. The options vested immediately on issue and expire on 1 February 2019.
- On 9 December 2016, the Company issued employee share options to two employees. Each employee was granted 1,000,000 options on identical terms that will become immediately exercisable at \$0.33 only when the share price of PolyNovo Limited is above \$0.50 for more than three months. The options vest as soon as the vesting hurdles are achieved and are exercisable within three months of vesting. The options expire on 31 December 2018.

The expense relating to the incentive scheme shares recognised in the Statement of Comprehensive Income during the 2017 financial year was \$330,496.

	Balance at 1 July 2016	Granted as compensation	Options exercised	Net change other (forfeited, lapsed, expired)	Balance at 30 June 2017	Total vested at end of year	Total exercisable at end of year	Total not exercisable at end of year	Total vested during year	Share-based payments expense \$
2017										
Directors										
Mr Leon Hoare	-	1,000,000	-	-	1,000,000	1,000,000	1,000,000	-	1,000,000	\$109,000
Other key management personnel										
Mr Paul Brennan	8,370,190	-	(4,185,095)	-	4,185,095	-	-	4,185,095	-	\$177,225
Other employees	-	2,000,000	-	-	2,000,000	-	-	2,000,000	-	\$44,271
Total	8,370,190	3,000,000	(4,185,095)	-	7,185,095	1,000,000	1,000,000	6,185,095	1,000,000	\$330,496

The fair value of options granted during the year to Mr Leon Hoare, as included in the above table, was determined using a binomial option pricing model due to the immediate vesting conditions attached to these options.

The fair value of options granted during the year, as included in the above table, was determined using a Monte Carlo simulation-based model. A binomial simulation-based model simulates the path of the share price according to a probability distribution assumption. After a large number of simulations, the arithmetic average of the outcomes, discounted to the valuation date, is calculated to represent the option value. This model can accommodate complex exercise conditions when the number of options exercised depends on some function of the whole path followed by the share price.

Notes to the Financial Statements continued

For the year ended 30 June 2018

7. Earnings Per Share (EPS)

Basic EPS amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on the conversion of all the dilutive potential ordinary shares into ordinary shares.

Basic EPS:

30 June 2018	(0.95) cents per share
30 June 2017	(0.89) cents per share

Diluted EPS:

30 June 2018	(0.95) cents per share
30 June 2017	(0.89) cents per share

	30 June 2018	30 June 2017
The following reflects the income and share data used in the calculation of basic and diluted EPS:		
Net loss used in calculating basic and diluted EPS attributable to equity holders of the parent entity	(\$5,974,132)	(\$5,006,014)
Weighted average number of ordinary shares on issue used in the calculation of basic EPS	627,887,135	561,760,275
Potential weighted average number of ordinary shares on issue plus all unexercised share options used in the calculation of diluted EPS	630,887,135	574,445,360

There were no transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of completion of these financial statements.

8. Cash and Cash Equivalents

Reconciliation of cash at the end of the year

	30 June 2018 \$	30 June 2017 \$
Cash at bank ⁽ⁱ⁾	3,147,081	5,496,609
Cash and cash equivalents are denominated in:		
Australian dollars	1,435,669	3,599,272
US dollars	1,694,839	1,897,337
NZ dollars	16,573	
	3,147,081	5,496,609

(i) Cash at bank earns interest at floating rates based on daily bank deposit rates.

For the purpose of the Consolidated Cash Flow Statement cash and cash equivalents comprises cash at bank and investments in short-term deposits as listed above. The Group has no borrowings.

Reconciliation of net loss after income tax to net cash flow from operating activities

	30 June 2018 \$	30 June 2017 \$
Net Loss	(5,974,132)	(5,006,014)
Adjustments for non-cash items:		
Depreciation and amortisation	542,933	246,971
Share-based payment expense	135,404	330,496
Interest	(272,066)	(138,906)
Unrealised foreign exchange rate differences	(226,828)	92,430
Change in assets and liabilities during the financial year:		
(Increase)/decrease in prepayments	(102,759)	(23,335)
(Increase)/decrease in trade receivables	(984,141)	212,488
(Increase)/decrease in inventory	(102,474)	(981,112)
(Increase)/decrease in other assets	(127,514)	(49,568)
Increase/(decrease) in payables	(84,399)	(112,513)
Increase/(decrease) in provisions	113,488	60,263
Increase/(decrease) in other liabilities	204,527	207,267
Net cash outflows from operating activities	(6,877,961)	(5,161,533)

9. Inventories

Inventories comprise of the following:

	30 June 2018 \$	30 June 2017 \$
Finished goods	927,292	381,027
Provision for finished goods	(3,596)	-
	927,292	381,027
Work in progress	112,374	556,201
	1,039,666	937,228
Raw materials and other (at cost)	43,920	43,884
	1,083,586	981,112

The total of inventory is held at lower of cost or net realisable value (NRV).

During the period, the Group has written off finished goods and work in progress for a total of \$474,008 as a result of a review of volume sales demand, product expiry dates and new packaging requirements.

10. Receivables (Current)

	30 June 2018 \$	30 June 2017 \$
Trade receivables and accrued income	1,598,574	485,589
R&D tax concession	794,255	833,126
Interest receivable	235,313	-
GST recoverable	26,833	49,836
Sundry receivables	24,700	984
	2,679,675	1,369,535

Trade receivables and accrued income relates to invoices to customers for sale of goods and PolyNovo's BARDA project representing invoiced and uninvoiced services for labour and sub-contractor expenses.

Notes to the Financial Statements continued

For the year ended 30 June 2018

11. Other Assets (Non-Current)

Non-current

	30 June 2018 \$	30 June 2017 \$
Security deposit	161,288	124,460

The non-current security deposit relates to PolyNovo's long-term lease of premises in Port Melbourne.

12. Plant and Equipment

	30 June 2018 \$	30 June 2017 \$
Office equipment		
(i) Cost		
Opening balance	428,502	281,979
Additions	81,231	146,523
Closing balance	509,733	428,502
(ii) Accumulated depreciation		
Opening balance	(270,236)	(221,218)
Depreciation for the year	(57,967)	(49,018)
Closing balance	(328,203)	(270,236)
Net book value – office equipment	181,530	158,266

	30 June 2018 \$	30 June 2017 \$
Laboratory plant and equipment		
(i) Cost		
Opening balance	1,363,120	1,275,090
Additions	23,181	88,030
Closing balance	1,386,301	1,363,120
(ii) Accumulated depreciation		
Opening balance	(1,024,069)	(955,698)
Depreciation for the year	(77,373)	(68,371)
Closing balance	(1,101,442)	(1,024,069)
Net book value – laboratory plant and equipment	284,859	339,051

	30 June 2018 \$	30 June 2017 \$
Leasehold improvements		
(i) Cost		
Opening balance	1,934,652	1,461,848
Additions	1,908	472,804
Closing balance	1,936,560	1,934,652
(ii) Accumulated depreciation		
Opening balance	(979,615)	(849,325)
Depreciation for the year	(283,669)	(130,290)
Closing balance	(1,263,284)	(979,615)
Net book value – leasehold improvements	673,276	955,037
Net book value – plant and equipment	1,139,665	1,452,354

13. Intangible Assets

Intangible assets, comprising intellectual property, were acquired through the business combination with PolyNovo Biomaterials Pty Ltd on 17 December 2008. The acquired intangible assets were initially recognised at fair value and were assessed to be indefinite lived assets subject to an impairment test on an annual basis or when there was an indication of impairment. The indefinite intangible assets relate to the acquired NovoSorb® technology.

Following the consistent commercial sales of NovoSorb® BTM in the current period, amortisation has commenced over the remaining finite life through to March 2028 being the remaining patent life period over which economic benefits will be consumed. This has been considered to be a change in the accounting estimate. No indicators of impairment related to the NovoSorb® technology have been identified as at 30 June 2018.

	30 June 2018 \$	30 June 2017 \$
Intangibles		
(i) Cost		
Opening balance	2,519,788	2,519,788
Additions	-	-
Impairment	-	-
Closing balance	2,519,788	2,519,788
(ii) Accumulated amortisation		
Opening balance	-	-
Amortisation for the year	(123,924)	-
Closing balance	(123,924)	-
Net book value – leasehold improvements	2,395,864	2,519,788

Notes to the Financial Statements continued

For the year ended 30 June 2018

13. Intangible Assets continued

As at 30 June 2017, the impairment assessment considered the following:

- No reasonable possible changes in the assumptions were identified which could cause an impairment of the identified intangible assets except for a failure in clinical trials. Due to the nature of the business, the cash flows were assessed on a short-term 12-month basis with assumptions applied to future model to assess the recoverable amount of identified intangibles.
- The recoverable amount has been determined using a value-in-use method.
- The Directors considered an external valuation report and it was the opinion of the Directors that PolyNovo's intangible assets were not impaired as at 30 June 2017.

	30 June 2017
Growth rate	2%
After-tax discount rate	20%
Pre-tax discount rate	not applicable
Royalty on sales	5% to 8%
Market penetration	5% to 7.5%

Growth rate: derived from published data on growth prospects and historical growth of products being sold into those conditions.

Royalty on sales: based on available industry data.

Market penetration: a best estimate, taking into consideration the quality of proposed products relative to competitive offerings, where competitors exist, number of competitive products and what commercial partners would expect to justify further investment in development.

Consideration was also given to recent transactions in the field of each project and the market capitalisation of ASX-listed companies with similar technology.

As part of the initial acquisition accounting a deferred tax liability was recognised in respect of these intangibles as the carrying values are expected to be recovered through use.

14. Trade and Other Payables

	30 June 2018 \$	30 June 2017 \$
Trade creditors and payables	223,355	421,414
Other payables	719,364	471,323
Total trade and other payables	942,719	892,737

Trade payables are non-interest bearing and are normally settled on 30-day terms.

15. Provisions

(a) Current provisions

	30 June 2018 \$	30 June 2017 \$
Annual leave	216,165	122,194
Long service leave	59,533	54,680
Total current provisions	275,698	176,874

(b) Non-current provisions

Long service leave	29,287	14,623
Total non-current provisions	29,287	14,623

16. Contributed Equity and Reserves

(a) Movement in contributed equity

	30 June 2018 \$	30 June 2017 \$
Contributed equity at beginning of year	114,476,370	114,099,712
Shares issued: capital raising	23,045,749	-
Costs of share issue	(818,276)	-
Exercise of options	1,416,659	376,658
Contributed equity at end of year	138,120,502	114,476,370

	Number of Shares	
On issue at start of year	563,049,010	558,863,915
Shares issued: capital raising	85,353,939	-
Exercise of options	9,685,095	4,185,095
On issue at end of year	658,088,044	563,049,010

(b) Reserves

	30 June 2018 \$	30 June 2017 \$
Share-based payments reserve (i)	3,060,945	2,925,541
Foreign currency translation reserve (ii)	(159,300)	-
Acquisition of non-controlling interest reserve (iii)	(9,293,956)	(9,293,956)
Balance at end of period	(6,392,311)	(6,368,415)

(i) Share-based payments reserve

Balance at beginning of period	2,925,541	2,595,045
Share-based payments movement	135,404	330,496
Balance at end of period	3,060,945	2,925,541

This reserve represents the nominal consideration paid for subscriber or employee options and the fair value of options and performance rights.

	30 June 2018 \$	30 June 2017 \$
(ii) Foreign currency translation reserve		
Opening balance	-	-
Translation of foreign currency operations	(159,300)	-
Balance at end of period	(159,300)	-

This reserve represents on consolidation, the translation of the foreign operation into Australian dollars. The exchange difference is recognised in the balance sheet as a reserve. Please refer to Note 2(y) for further information.

Notes to the Financial Statements continued

For the year ended 30 June 2018

16. Contributed Equity and Reserves continued

(b) Reserves continued

	30 June 2018 \$	30 June 2017 \$
(iii) Acquisition of non-controlling interest reserve		
Opening balance	(9,293,956)	(9,293,956)
Balance at end of year	(9,293,956)	(9,293,956)

This reserve represents the premium paid by PolyNovo Limited for the non-controlling interest in subsidiary entities PolyNovo Biomaterials Pty Ltd, NovoSkin Pty Ltd and NovoWound Pty Ltd.

(c) Accumulated losses

	30 June 2018 \$	30 June 2017 \$
Accumulated losses at beginning of year	(97,295,089)	(92,289,075)
Net loss attributable to members of the parent	(5,974,132)	(5,006,014)
Accumulated losses at end of financial year	(103,269,221)	(97,295,089)

17. Commitments and Contingencies

Operating lease commitments

The Group has entered into commercial office and laboratory leases. These leases have an initial term of 12 years, from 2008 to 2020, with a further five-year option. Future minimum rentals payable under the non-cancellable operating leases are as follows:

	30 June 2018 \$	30 June 2017 \$
Not later than one year	298,022	286,560
Later than one year, but not later than five years	256,576	554,598
	554,598	841,158

Contingencies

The Directors are not aware of any other contingent liabilities or contingent assets at 30 June 2018. There has been no change in this assessment up to the date of this report.

18. Related Party Disclosures

Related party transactions are disclosed under key management personnel (Note 23).

19. Events after the Balance Sheet Date

The Directors are not aware of any other matters or circumstances since the end of the financial year other than those described above, nor otherwise dealt with in this report, which have significantly affected, or may significantly affect the operations of the Group, the results of those operations or the state of affairs of the Group in subsequent financial years.

20. Auditor's Remuneration

The auditor of PolyNovo Limited is Ernst & Young. The amounts received or due and receivable by Ernst & Young for audit and other services were as follows:

	30 June 2018 \$	30 June 2017 \$
An audit or review of the Financial Reports of the entity:		
- Half-year and full-year audits	110,722	107,470
Other services in relation to the entity:		
- Tax compliance services	89,546	42,283
- Other compliance services supporting GST and importer registrations into NZ	5,449	-
- Other compliance services supporting start-up of US operations	-	77,401
Total auditor's remuneration	205,717	227,154

The Directors are satisfied that the provision of non-audit services during the current period is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001*. The nature and scope of each type of non-audit service provided means that auditor's independence was not compromised.

21. Parent Entity Information

	30 June 2018 \$	30 June 2017 \$
Current assets	45,863,400	21,586,481
Total assets	51,900,336	27,629,604
Current liabilities	213,298	134,254
Total liabilities	213,298	134,254
Issued capital	138,120,502	114,476,370
Retained earnings	(83,530,190)	(83,942,341)
Total reserves	(2,903,274)	(3,038,679)
Total shareholders' equity	51,687,038	27,495,350
Loss of the parent entity	(420,975)	(618,259)
Total comprehensive loss of the parent entity	(420,975)	(618,259)

Details of operating leases entered into by PolyNovo Limited are provided in Note 17.

22. Financial Risk Management Objectives and Policies

(a) Financial instruments

The Group's financial instruments comprise cash and cash equivalents, trade and other receivables, trade and other payables, other financial assets and available-for-sale financial assets.

	30 June 2018 \$	30 June 2017 \$
Cash and cash equivalents	3,147,081	5,496,609
Trade and other receivables	2,679,675	1,369,535
Other financial assets (classified as held to maturity) ^{1,2}	19,050,000	50,000
Trade and other payables	942,719	892,737

1. At 30 June 2018 and 30 June 2017, the carrying value of these held-to-maturity assets approximated fair value.

2. At 30 June 2018, funds received from the capital raising in October 2017 had been transferred to a short-term deposit with a term of 180 days and an interest rate of 2.54% p.a. payable on maturity being 3rd July 2018.

Notes to the Financial Statements continued

For the year ended 30 June 2018

22. Financial Risk Management Objectives and Policies continued

(b) Risk management policy

The Group has a formal risk management policy and framework. The Group's approach to risk management involves identifying, assessing and managing risk, including consideration of identified risks, in the context of the Group's values, objectives and strategies. The Board is responsible for overseeing the implementation of the risk management system and reviews and assesses the effectiveness of the Group's implementation of that system.

The Group seeks to ensure that its exposure to risks that are likely to impact its financial performance, continued growth and survival are minimised in a cost-effective manner.

(c) Significant accounting policies

Details of the significant accounting policies and methodologies adopted in respect of each class of financial asset, financial liability and equity instrument are disclosed in Note 2.

Details in relation to interest revenue earned on holdings of cash and cash equivalents are disclosed in Note 8.

(d) Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern and to maintain an optimal capital structure so as to maximise shareholder value. In order to maintain an optimal capital structure, the Group may issue new shares or reduce its capital, subject to the provisions of the Company's Constitution and any relevant regulatory requirements. The capital structure of the Group consists of equity attributed to equity holders of the Group comprising contributed equity, reserves and accumulated losses as disclosed in Note 16. The Board monitors the need to raise additional equity from the equity markets based on its ongoing review of PolyNovo's actual and forecast cash flows, which are provided by management.

(e) Financial risk management

The key financial risks the Group is exposed to through its operations are:

- interest rate risk;
- credit risk;
- liquidity risk; and
- foreign currency risk.

Interest rate risk

Interest rate risk arises when the value of a financial instrument fluctuates as a result of changes in market interest rates.

The Group is exposed to interest rate risks in relation to its holdings in cash and cash equivalents. The objective of managing interest rate risk is to minimise the Group's exposure to fluctuations in interest rates. To manage this risk, the Group locks a portion of the Group's cash and cash equivalents into term deposits. The required maturity period of term deposits is determined based on the Group's cash flow forecast with particular focus on the timing of cash requirements. In addition, the Group considers the lower interest rate received on cash held in the Group's operating account compared to placing funds on term deposit. Account is also taken of the costs associated with early withdrawal of a term deposit should access to cash and cash equivalents be required.

The Group's exposure to interest rate risk and the interest rates (current at the end of each year) on the Group's financial assets and financial liabilities as at 30 June 2018, along with prior year comparatives, was as follows:

	Weighted average effective interest rate	Floating interest rate \$	Fixed interest rate 0 to 90 days \$	Fixed interest rate 91 to 365 days \$	Fixed interest rate 1 to 5 years \$	Fixed interest rate over 5 years \$	Non- interest bearing \$	Total \$
2018								
Financial assets:								
Cash and cash equivalents	1.23%	3,147,081	-	-	-	-	-	3,147,081
Other financial assets	2.54%	-	19,000,000	50,000	-	-	-	19,050,000
Receivables	-	-	-	-	-	-	2,679,675	2,679,675
Total financial assets	-	3,147,081	19,000,000	50,000	-	-	2,679,675	24,876,756
Financial liabilities:								
Trade and other payables	-	-	-	-	-	-	942,719	942,719
Total financial liabilities:	-	-	-	-	-	-	942,719	942,719
	Weighted average effective interest rate	Floating interest rate \$	Fixed interest rate 0 to 90 days \$	Fixed interest rate 91 to 365 days \$	Fixed interest rate 1 to 5 years \$	Fixed interest rate over 5 years \$	Non- interest bearing \$	Total \$
2017								
Financial assets:								
Cash and cash equivalents	0.6%	5,496,609	-	-	-	-	-	5,496,609
Other financial assets	2.49%	-	-	50,000	-	-	-	50,000
Receivables	-	-	-	-	-	-	1,369,535	1,369,535
Total financial assets		5,496,609	-	50,000	-	-	1,369,535	6,916,144
Financial liabilities:								
Trade and other payables	-	-	-	-	-	-	892,737	892,737
Total financial liabilities:	-	-	-	-	-	-	892,737	892,737

There has been no change to the Group's exposure to interest rate risk, other than the fact that cash holdings are higher than at the previous year's end. As noted above, cash is invested in term deposits of varying maturity terms to maximise interest income as well as to meet the timing of operational cash flow requirements. All term deposits are with the NAB, to ensure market interest rates are achieved without compromising the security of funds on deposit. There is interest receivable of \$235,313 related to the term deposit at 30 June 2018.

The Group had a large component of cash invested in fixed term deposits well into the 2017 financial year and as the various fixed terms expired, the funds have not been reinvested in the expectation that cash is required to fund current operations and the expected build in trade receivables commensurate with the anticipated increase in commercial product sales to hospitals and distributors. However, in the 2018 financial year, the Company received \$22.2 million (net of costs) from a capital raising and \$1.4 million from the exercise of employee share options. In January 2018, \$19 million in cash was invested into a fixed term deposit for 180 days at 2.54% with interest paid at the end of the term being 3rd July 2018.

Notes to the Financial Statements continued

For the year ended 30 June 2018

22. Financial Risk Management Objectives and Policies continued

(e) Financial risk management continued

Interest rate risk continued

The analysis below details the impact on the Group's loss after tax and equity if the interest rate associated with the closing balance of financial assets was to fluctuate by the margins below, assuming all other variables had remained constant:

	Loss (higher)/lower Equity higher/(lower) 2018 \$	Loss (higher)/lower Equity higher/(lower) 2017 \$
+ 1% (100 basis points)	190,659	55,470
- 1% (100 basis points)	(190,659)	(55,470)

Credit risk

Credit risk arises when a counterparty defaults on its contractual obligations, resulting in a financial loss to the Group.

The Group is exposed to credit risk via its cash and cash equivalents and receivables. To reduce risk exposure in relation to its holdings of cash and cash equivalents, they are placed on deposit with the Group's main bankers, the National Australia Bank (S&P Rating AA/A-1+, Moody's rating Aa1/P-1). A change to the Group's bankers requires Board approval.

In previous years the Group has had minimal trade and other receivables, with the majority of its cash being provided via shareholder investment.

In 2018, the receivables balance at 30 June 2018 includes \$1,287,712 owing by BARDA, a US government agency. BARDA is contractually obliged to reimburse the Group for services provided and is considered to be a low credit risk customer.

In 2018, the receivables balance at 30 June 2018 includes \$310,862 owing by customers. Trade receivables are expected to grow significantly as commercial product sales to hospitals and distributors increase. The ageing analysis of trade and other receivables is as follows.

	0-30 days \$	30-60 days \$	60-90 days \$	90+ day \$	Total \$
2018					
Trade and other receivables	1,606,847	95,793	42,706	140,074	1,885,420
2017					
Trade and other receivables	262,809	273,600	-	-	536,409

Liquidity risk

Liquidity risk arises if the Group encounters difficulty in raising funds to meet its financial liabilities.

The Group is exposed to liquidity risk via its trade and other payables. Responsibility for managing liquidity risk rests with the Board, who regularly review liquidity risk by monitoring the undiscounted cash flow forecasts and actual cash flows provided to them by management. This process is undertaken to ensure that the Group continues to be able to meet its debts as and when they fall due. Contracts are not entered into unless the Board is satisfied that there is sufficient cash flow to fund the additional commitment. The Board determines when reviewing the undiscounted cash flow forecasts whether the Group needs to raise additional working capital from its existing shareholders, the equity capital markets or other available external sources. The Board may also review the timing of internal programs if necessary to moderate cash requirements.

A maturity analysis of trade and other payables, based on contractual terms, is set out below:

	0-30 days \$	30-60 days \$	60-90 days \$	90+ day \$	Total \$
2018					
Trade and other payables	942,226	74	34	385	942,719
2017					
Trade and other payables	865,289	12,253	187	15,008	892,737

Foreign currency risk

Foreign currency risk arises when foreign currency exchange rates fluctuate against the Australian dollar, resulting in a foreign currency exchange loss or gain to the Group.

The Group is exposed to foreign currency risk via its cash and cash equivalents, trade receivables and trade payables as part of its normal business.

The Group incurs foreign currency expenses predominantly in USD. To reduce foreign currency risk exposure, the Group maintains an amount of cash and cash equivalents in USD. The Group receives payment from its overseas customer (BARDA) in USD and pays USD trade payables from its USD funds. NZD denominated payable balances carry some foreign currency risk, however these payable balances are typically low in value (nil balance at 30 June 2018) and are therefore considered to expose the Group to minimal risk.

The holdings of cash and cash equivalents, trade receivables and trade payables analysed by nominated currency at 30 June 2018, along with prior year comparatives, were as follows.

	Denominated in AUD \$	Denominated in USD \$	Denominated in NZD \$	Total \$
2018				
Financial assets				
Cash and cash equivalents	1,435,669	1,694,839	16,573	3,147,081
Receivables	1,180,497	1,488,392	10,786	2,679,675
Total financial assets	2,616,166	3,183,231	27,359	5,826,756
Financial liabilities				
Trade and other payables	495,462	446,468	789	942,719
Total financial liabilities	495,462	446,468	789	942,719

A hypothetical 10% strengthening in the exchange rate of the Australian dollar against the US dollar (as at 30 June 2018) with all other variables held constant would have a \$191,402 unfavourable effect on the loss and equity for the 2018 financial year.

	Denominated in AUD \$	Denominated in USD \$	Denominated in EUR \$	Denominated GBP \$	Total \$
2017					
Financial assets					
Cash and cash equivalents	3,599,272	1,897,337	-	-	5,496,609
Receivables	883,946	485,589	-	-	1,369,535
Total financial assets	4,483,218	2,382,926	-	-	6,866,144
Financial liabilities					
Trade and other payables	572,069	318,180	760	1,728	892,737
Total financial liabilities	572,069	318,180	760	1,728	892,737

A hypothetical 10% strengthening in the exchange rate of the Australian dollar against the US dollar (as at 30 June 2017) with all other variables held constant would have a \$243,860 unfavourable effect on the loss and equity for the 2017 financial year.

Notes to the Financial Statements continued

For the year ended 30 June 2018

23. Key Management Personnel Disclosures

The key management personnel compensation disclosures required by the *Corporations Act 2001* are provided in the Remuneration Report in the Directors' Report.

(a) Details of key management personnel

The key management personnel of the Group are those persons having the authority and responsibility for planning, directing and controlling the activities of the Group, directly or indirectly, during the 2018 and 2017 financial years. Unless otherwise indicated they were key management personnel during the whole of the financial years.

PolyNovo's key management personnel are its Directors' and members of the Senior Management team. Details of each Director and Senior Executive, who are classified as key management personnel, are provided in the Remuneration Report.

(b) Compensation by category: key management personnel

	30 June 2018 \$	30 June 2017 \$
Short term	820,694	788,032
Post-employment – superannuation	60,611	61,075
Leave allowances	27,513	6,783
Share-based payments	58,630	286,225
Termination benefits	68,458	-
	1,035,906	1,142,115

(c) Interests held by key management personnel

Share options held by key management personnel to purchase ordinary shares have the following expiry dates and exercise prices:

Issue date	Expiry date	Exercise price	2018 number outstanding	2017 number outstanding
2014	03/07/17	\$0.20	-	2,500,000
2014	17/11/17	\$0.14	-	1,000,000
2014	17/11/17	\$0.20	-	2,000,000
2015	05/08/18	\$0.09	-	4,185,095
2016	01/02/19	\$0.25	500,000	500,000
2016	01/02/19	\$0.33	500,000	500,000
2017	30/06/19	\$0.35	1,000,000	-
			2,000,000	10,685,095

(d) Loans to key management personnel

No loans have been made to Directors of PolyNovo or to any other key management personnel, including their personally related entities.

(e) Other transactions with Directors

No other transactions between the Group and any of the Directors of PolyNovo or any other key management personnel have been identified.

There were transactions with Directors during the year ended 30 June 2018 as follows:

- Kidder Williams Ltd, an entity associated with Mr David Williams, received payments in the amount of \$691,372. These payments were in respect to consulting services provided to PolyNovo Limited in relation to a capital raising. The transaction was entered into at arm's length and under normal commercial terms.

No other transactions between the Group and any of the Directors of PolyNovo or any other key management personnel have been identified.

24. Controlled Entities

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy in Note 2:

		Percentage owned	
		30 June 2018 %	30 June 2017 %
Country of incorporation			
Company:			
PolyNovo Limited	Australia	100%	100%
Subsidiaries of PolyNovo Limited:			
PolyNovo North America LLC	United States	100%	100%
PolyNovo Biomaterials Pty Ltd	Australia	100%	100%
NovoSkin Pty Ltd	Australia	100%	100%
NovoWound Pty Ltd	Australia	100%	100%

PolyNovo Limited (ABN 96 083 866 862)

Directors' Declaration

For the year ended 30 June 2018

In accordance with a resolution of the Directors of PolyNovo Limited, I state that:

1. In the opinion of the Directors:

- (a) The Financial Report and the Remuneration Report included in the Directors' Report, of the Company and of the Group are in accordance with the *Corporations Act 2001*, including:
 - (i) giving a true and fair view of the Company and the Group's financial position as at 30 June 2018 and of their performance for the year ended on that date;
 - (ii) complying with Australian Accounting Standards and *Corporations Regulations 2001*; and
 - (iii) complying with International Financial Reporting Standards as issued by the International Accounting Standards Board.
- (b) There are reasonable grounds to believe that the Company and the Group will be able to pay their debts as and when they become due and payable.

2. This declaration has been made after receiving the declarations required to be made to Directors in accordance with section 295A of the *Corporations Act 2001* for the financial period ended 30 June 2018.

On behalf of the Board,



Mr David Williams
Chairman
16 August 2018

Independent Auditor's Report

For the year ended 30 June 2018



Ernst & Young
8 Exhibition Street
Melbourne VIC 3000 Australia
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Independent Auditor's Report to the Members of PolyNovo Limited

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of PolyNovo Limited (the Company) and its subsidiaries (collectively the Group), which comprises the consolidated statement of financial position as at 30 June 2018, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes to the financial statements, including a summary of significant accounting policies, and the directors declaration.

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

- a) giving a true and fair view of the consolidated financial position of the Group as at 30 June 2018 and of its consolidated financial performance for the year ended on that date; and
- b) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for Opinion

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

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

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial report of the current year. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

Independent Auditor’s Report continued

For the year ended 30 June 2018



We have fulfilled the responsibilities described in the *Auditor’s Responsibilities for the Audit of the Financial Report* section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial report. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial report.

Inventory existence and valuation

Why significant	How our audit addressed the key audit matter
<p>At 30 June 2018, the Group held inventory of \$1.1 million on the statement of financial position, which comprised raw materials, work in progress and finished product.</p> <p>The existence and valuation of inventory was a key audit matter given the significance of the inventory balance at 30 June 2018 and the judgement required in determining the initial cost of the inventory and whether it is recorded at the lower of cost and net realisable value. The net realisable value of the inventory is assessed considering inventory sales and forecast usage and expiry dates of product.</p> <p>At 30 June 2018, the Company had material inventories held at a central warehouse in Australia and by a third party logistics provider in the US.</p>	<p>We assessed the inventory counts that occurred at the Australian warehouse and in the US that determine the quantity of inventory on hand at year end.</p> <p>We selected a sample of inventory items to assess whether cost, including allocations of labour and manufacturing overheads was appropriately calculated.</p> <p>We assessed management’s consideration of the level of inventory on hand in light of sales forecasts and considering expiry dates as it impacted on inventory provisioning.</p> <p>We analysed inventory gross margins in assessing whether inventory was carried at the lower of cost and net realisable value.</p> <p>We reviewed the inventory provision at year end to determine whether it was determined in accordance with the company’s policy.</p> <p>We considered whether the accounting policy as disclosed in note 2(q) to the financial statements resulted in inventory being carried at the lower cost and net realisable value.</p>

Accounting for share based payment arrangements

Why significant

During the year the Group issued options to the Chief Financial & Operating Officer under a share based payment arrangement. The share based payment arrangement included both market based and non-market based vesting conditions.

This is in addition to existing share based payment arrangements with the Chief Executive Officer and other employees.

Details of these share based payment arrangements are disclosed in Note 6 of the financial report.

There is judgement involved in determining the fair value of share based payment arrangements and the subsequent recording of the fair value as an expense over the estimated vesting period. As a result, the audit of the share based payment arrangements was considered a key audit matter.

In determining the value of the new arrangement the Group used the services of a third party valuation specialist.

How our audit addressed the key audit matter

In performing our procedures we assessed the terms of the share based payment arrangements issued during the period to the Chief Financial & Operating Officer.

We involved our valuation specialists to assess the appropriateness of the valuation methodology used and key input assumptions such as volatility rates and expected life.

We assessed the Group's judgement in relation to the probability of achieving the non-market based vesting condition and the subsequent expense recorded in the consolidated statement of comprehensive income.

We also considered the appropriateness of the previously estimated vesting periods for the existing share based payment arrangements.

We considered the disclosure in Note 6 in relation to the share based payment arrangements.

Information Other than the Financial Report and Auditor's Report Thereon

The directors are responsible for the other information. The other information comprises the information included in the Company's 2018 Annual Report, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon, with the exception of the Remuneration Report and our related assurance opinion.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.



Responsibilities of the Directors for the Financial Report

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

Auditor's Responsibilities for the Audit of the Financial Report

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

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

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

- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the financial report. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

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

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

Report on the Audit of the Remuneration Report

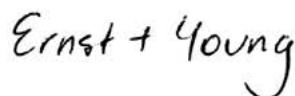
Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 17 to 23 of the directors' report for the year ended 30 June 2018.

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

Responsibilities

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.



Ernst & Young



Joanne Lonergan
Partner
Melbourne
16 August 2018

Additional Information Required by ASX

For the year ended 30 June 2018

Additional information required by the Australian Securities Exchange is as follows:

Ordinary Shares

As at 7 August 2018 there were 658,088,044 ordinary shares on issue held by 7,049 shareholders. Each ordinary share carries one vote per share.

Top 20 Shareholders as at 7 August 2018

Shareholder	No. of shares	%
HSBC Custody Nominees (Australia) Limited	41,805,387	6.35
Citicorp Nominees Pty Limited	38,523,183	5.85
The Trust Company (Australia) Limited <Mof A/C>	21,707,819	3.30
Moggs Creek Pty Ltd <Moggs Creek Super A/C>	15,246,597	2.32
Dr John Edward Greenwood <The Greenwood Family A/C>	13,457,864	2.04
National Nominees Limited	11,357,639	1.73
Lateral Innovations Pty Ltd <Trust A/C>	10,924,103	1.66
Monash Investment Holdings Pty Ltd	9,607,520	1.46
Sandhurst Trustees Ltd <Jmfg Consol A/C>	8,544,270	1.30
Mr Anthony Shane Kittel + Mrs Michele Therese Kittel <Kittel Family Super A/C>	7,712,889	1.17
Brispot Nominees Pty Ltd <House Head Nominee A/C>	7,120,818	1.08
J P Morgan Nominees Australia Limited	6,280,981	0.95
J A B Investments (SA) Pty Ltd <J A B A/C>	5,055,555	0.77
Mrs Suzanne Kenley	4,700,000	0.71
Dr Gavin James Shepherd + Mrs Catherine Jane Shepherd <Shepherd Investment A/C>	4,624,219	0.70
Mr Laurent Fossaert	4,475,694	0.68
BNP Paribas Nominees Pty Ltd <IB AU Noms Retailclient DRP>	4,242,817	0.64
Ms Simone Maree Beks	4,185,095	0.64
Mr Paul Gerard Brennan	4,185,095	0.64
CSIRO	4,081,250	0.62
Total	227,838,795	34.62

Unquoted Securities

Options over unissued shares

As at 30 June 2018, a total of 3,000,000 options over ordinary shares are on issue held by three individual holders. There are 1,000,000 options on issue to Directors as at the date of this report. Options do not carry a right to vote.

PolyNovo issued 1,000,000 options during the year ended 30 June 2018. Details of the options issued to one individual are included in Note 6.

The range of shareholders based on number of shares held as at 7 August 2018 is as follows:

Range of units	No. of holders	No. of shares
1 – 1000	807	486,815
1,001 – 5,000	1,857	5,421,585
5,001 – 10,000	1,063	8,794,757
10,001 – 100,000	2,482	91,692,962
100,001 and over	840	551,691,925
Number of holders with less than a marketable parcel	516	195,815

Voting Rights

Clauses 45 to 54 of the Company's Constitution stipulate the voting rights of members. In summary but without prejudice to the provisions of the Constitution, every member present in person or by representative, proxy or attorney shall have one vote on a show of hands and on a poll have one vote for each share held by the member.

Substantial Shareholders

Name of shareholding	No. of shares
HSBC Custody Nominees (Australia) Limited	41,805,387
Citicorp Nominees Pty Limited	38,523,183

Quotation of the Company's Shares

PolyNovo has been granted official quotation for its shares on the Australian Securities Exchange (ASX Code: PNV).

Corporate Directory

ABN 96 083 866 862

Non-executive Chairman

Mr David Williams

Non-executive Directors

Mr Bruce Rathie
Dr David McQuillan
Mr Philip Powell
Mr Max Johnston
Mr Leon Hoare

Chief Executive Officer

Mr Paul Brennan

Company Secretary

Mr Greg Lewis

Registered Office

Unit 2/320 Lorimer Street
Port Melbourne
Victoria 3207

T (03) 8681 4050

F (03) 8681 4099

Share Registry

Computershare Investor Services Pty Ltd
Yarra Falls
452 Johnston Street
Abbotsford, Victoria 3067
T 1300 850 505

Auditors

Ernst & Young
8 Exhibition St
Melbourne Victoria

Website

www.polynovo.com.au

Australian Securities Exchange

PolyNovo shares are quoted on ASX Limited
(ASX Code: PNV)



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