

# 2019 Reports

**Announcement of Full-Year Results  
Appendix 4E  
2019 Annual Report**

PolyNovo Limited  
ABN 96 083 866 862  
22 August 2019



# Announcement of Full-Year Results

22 August 2019

FY19 was a pivotal year for the Group with sales from NovoSorb BTM increasing 435% on the prior year. Our investment in expanding the sales teams has produced significant growth not only in sales but also in the rate of customer acquisition. Surgeons continue to be impressed with the robust nature of NovoSorb BTM evident by recurring and increasing sales.

PolyNovo Limited reported revenue for year ended 30 June 2019 of \$13.683 million an increase of 128% from FY18 \$5.989 million. Sales of goods revenue was \$9.348 million up 435% from FY18 \$1.747 million. The net loss after tax of \$3.190 million for FY19 was a decrease of \$2.784 million from the prior year's \$5.974 million.

The Group loss has reduced by 46.6% on the prior year, despite operating expenses increasing as planned, due to the rising revenue generated by NovoSorb BTM sales in multiple markets. The Group expects to break even in FY20 however cash flows will continue to be reinvested to drive growth. Cash on hand at 30 June 2019 is \$13.9 million.

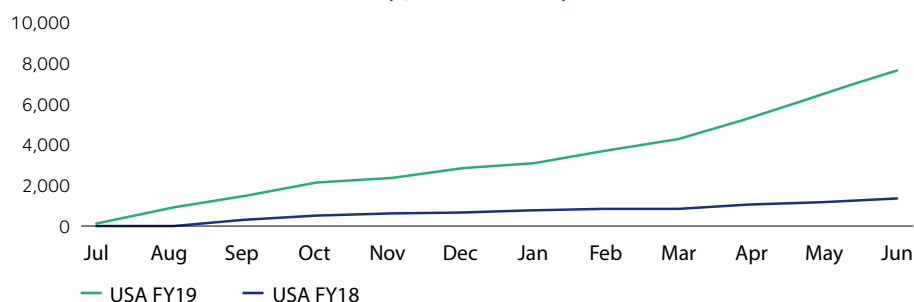
Our US sales infrastructure has expanded with the addition of new sales and marketing people. As at the end of August 2019 the PolyNovo Group has 20 sales people and 5 marketers. PolyNovo has a greater geographic reach and adjacency to our customers and an increasing customer referral network. We anticipate further sales roles to be added in the UK and Ireland and US as sales grow.

In the period we gained approval to sell NovoSorb BTM to the US Department of Defence and Veteran Affairs.

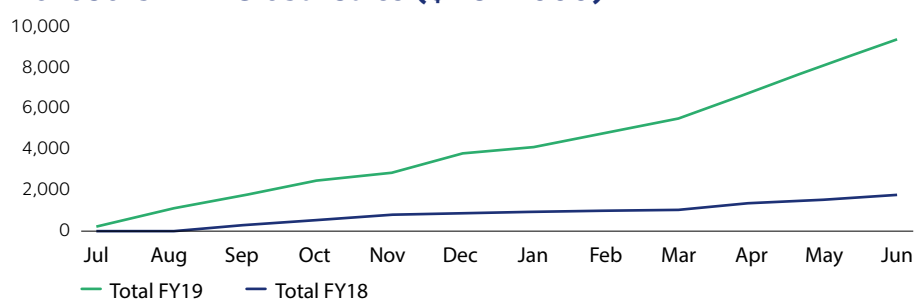
In the year ahead we expect to see accelerated revenues from our direct marketing in the US, Australia, New Zealand and UK and Ireland. India and SE Asia also represent promising opportunities. NovoSorb BTM European market entry is imminent and we have a distributor waiting for Germany.

In the past year we have entered India through a distribution arrangement with Myovatec. We announced on 8 August 2019 Regulatory approval for Singapore and in January 2019 we announced regulatory approval in Malaysia.

## NovoSorb BTM USA Sales (\$AUD '000)



## NovoSorb BTM Global Sales (\$AUD '000)



Our Australia/European burn trial has been completed and we will publish the results of this study by the end of CY 2019. Our BARDA trials are progressing well and full details can be found within the Annual Report. BARDA is committed to continuing the funding support of these trials as we move into the Pivotal phase of the program.

The new Hernia products have progressed to commercial scale up. PolyNovo purchased the adjacent factory which will enable the building of the plant and equipment for commercial manufacture of these devices. We have filed additional patents for the NovoSorb family of products.

The new breast product line is being developed in partnership with Establishment Labs. In the coming year we will monitor the evolving regulatory requirements and work towards finalising our regulatory and clinical strategies and finalise product design. The regulatory and clinical aspects of this program are the responsibility of Establishment Labs.

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

## Further information

Paul Brennan  
Chief Executive Officer  
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Chairman  
Mobile: +61 414 383 593

## About NovoSorb®

NovoSorb is a novel range of bio-resorbable polymers that can be produced in many formats including, film, fibre, foam, and coatings. NovoSorb's unique properties provide excellent biocompatibility, control over physical properties, and programmable bio-resorption profile. NovoSorb BTM is registered for use in: USA, Australia, New Zealand, South Africa, Malaysia, India, Israel and Saudi Arabia.

## About PolyNovo®

PolyNovo is an Australian based medical device company that designs, develops and manufactures dermal regeneration solutions (NovoSorb BTM) using its patented NovoSorb biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopaedic applications. For further information and market presentations see [www.polyново.com.au](http://www.polyново.com.au)

# Appendix 4E - Rule 4.3A

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

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

<b>Reporting Period:</b>	<b>Year ended 30 June 2019</b>
Previous Corresponding Period:	Year ended 30 June 2018

## 2. Results for announcement to the market

	Change from 2018			2019
2.1. Total revenue	up	128.4%	to	<b>\$13,683,323</b>
2.2. Loss after tax	down	46.6%	to	<b>(\$3,189,893)</b>
2.3. Loss after tax attributable to members	down	46.6%	to	<b>(\$3,189,893)</b>
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 2019 Annual Report.			

## 3. Net tangible assets

	<b>30 June 2019</b>	30 June 2018
Net tangible asset backing per ordinary security	<b>\$0.039</b>	\$0.042

## 4. Consolidated Statements of Comprehensive Income, Financial Position, Changes in Equity and Cash Flow are contained in the enclosed 2019 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** International Financial Reporting Standards

**9. This report is based on accounts which have been audited. The audit report, which is unmodified is contained in the enclosed 2019 Annual Report.**

Date: 22 August 2019

**Jan Gielen**  
Company Secretary

# Annual Report 2019



Improving outcomes.  
Changing lives.



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

Paul Brennan  
Chief Executive Officer

Cover: Doctor – Jeffrey E. Carter, MD; Patient – Noah Wilson  
Page 3: Patient – Malcolm Leflore  
Page 5: Patient – Noah Wilson







“

“The idea at the time was to proceed with a below knee amputation... We looked at his foot and said I don't think this is something a biologic is going to do well on. I would like to try a new form of dermal substitute... BTM.”

Dr Jeff Carter's assessment of Malcolm Leflore's injury

## Malcolm

Train crash survivor

After the train crushed his foot, Malcolm was told a below the knee amputation was the only solution. That outcome wasn't acceptable to Malcolm or his surgeon. NovoSorb BTM helped to re-cover his exposed structures so his body could heal. Today he stands tall despite the injury that knocked him down. Learn more about Malcolm.



Scan to hear my story

[i.lead.me/Leg-Trauma-Testimonial](https://i.lead.me/Leg-Trauma-Testimonial)







“

“About a month after I got out of hospital I had complete range of movement... I know if it wasn't for BTM I wouldn't be how I am today... I know that for sure.”

Noah Wilson

## Noah

### Burns survivor

Noah doesn't remember the sound of the explosion. But he does remember waking up on fire as the flames burned through his gasoline-soaked skin. Noah received full thickness burns to over half of his body potentially altering the trajectory of this young man's life. Thanks to the capable hands of his surgeon and NovoSorb BTM, Noah fully recovered and walked out of the hospital 51 days later. Learn more about his incredible story.



Scan to hear my story

[i.lead.me/Noah-Burn-Testimonial](https://i.lead.me/Noah-Burn-Testimonial)







# Global Expansion

PolyNovo had very strong initial commercial success with NovoSorb BTM and there are significant and tangible sales opportunities ahead. We are well advanced in our Hernia repair device development and anticipate US market entry in early FY21. The factory build, fit out and validation processes will be a major task for the year ahead.

The past year has been characterised by a significant organisational expansion with corresponding growth in our skills and depth of talent. This ensures we can deliver growth whilst we continue to deliver in full on time for our customers. Our sales are strong and accelerating with

FY20 set to deliver increased sales through our existing markets as well as opening new global markets. In FY20 the Company is expected to breakeven at the EBITDA line however we still plan to invest cash flows in expanding the Company and bringing forward research

and development programs that will commercialise new products. This medium-term diversification of our income streams will ensure we are able to transform from a dermal focused device company to a multi-focused medical device manufacturer and marketer.

## PolyNovo has invested in four key strategic areas

### 1. Sales Team

In the past year we have expanded the direct sales teams in Australia, New Zealand, USA and UK and Ireland. Our sales leaders in the USA business bring a high level of strategic sales planning and accountability to the team/business.

### 2. Research and Development

Team expansion has enabled considerable advancement of both Breast and Hernia devices.

Research and Development will see accelerated focus on the drug elution subcutaneous depot. These depots could improve chronic disease management and medication compliance.

### 3. Organisational Talent Building

The depth and quality of the supporting teams has been essential to service the growth of the business and capacity to generate revenue.

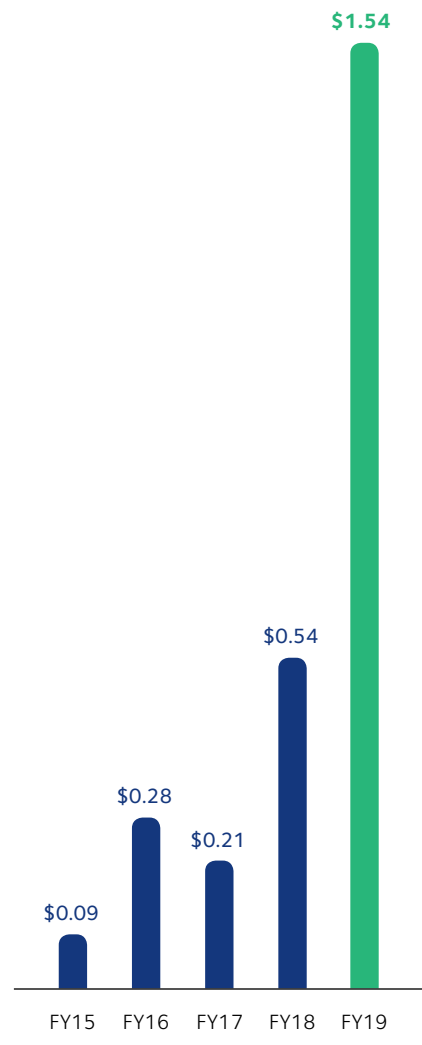
We have been able to attract excellent management talent in our Chief Financial Officer, Chief Operating Officer and Sales Managers in America. These roles enable us to provide a higher level of support to our sales and marketing teams and develop our people to assume greater role diversity as the organisation grows.

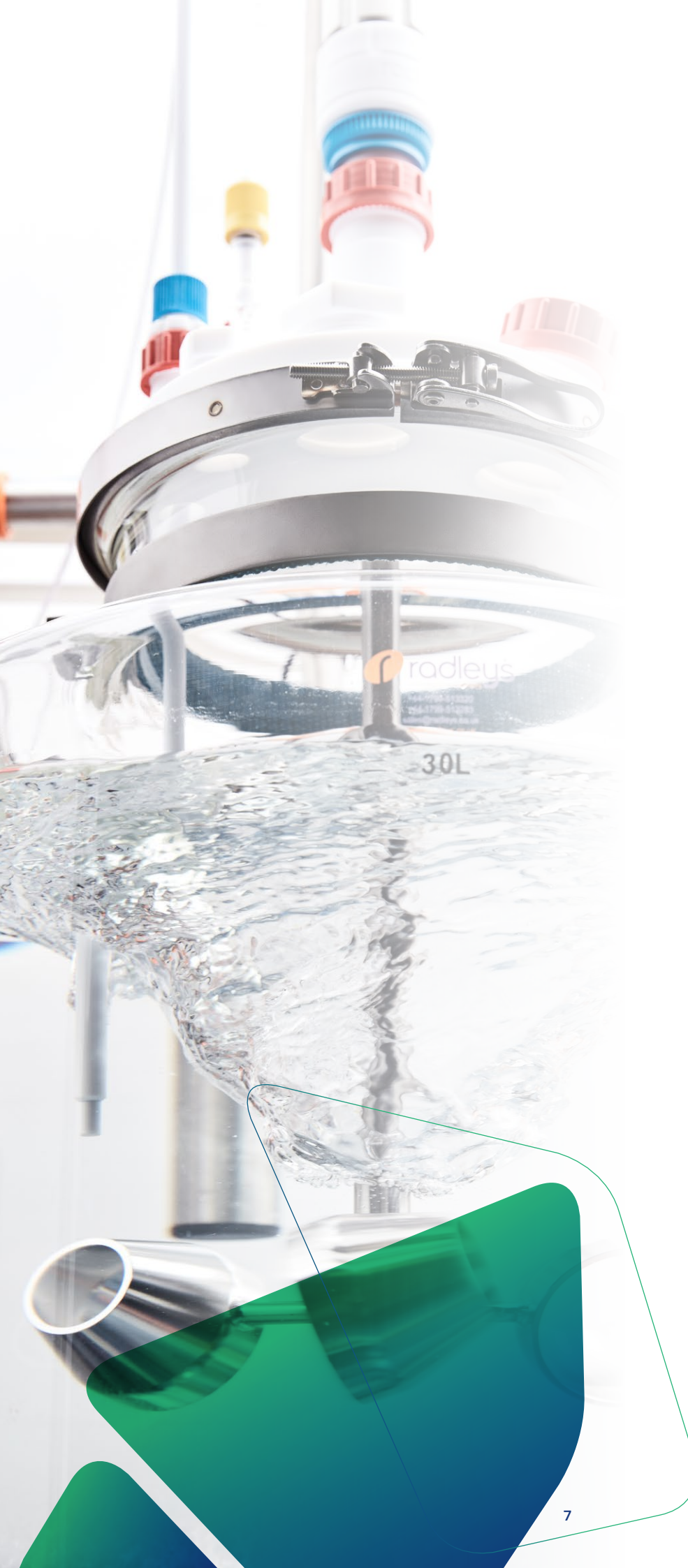
We will continue to reinvest in our sales and marketing capacity in response to growing customer demand and the introduction of our Hernia range.

### 4. Infrastructure/Capital

The purchase of the adjacent building in Port Melbourne to our Head Office and hernia/breast manufacturing equipment in preparation for commercial production of these devices. The associated office space expansion will also allow for the growth of the business teams into the coming years. PolyNovo remains debt free and these assets add to the wealth of the Company.

## Five year share price growth (as at 30 June)





## Our Performance

**\$9.3M**



Sales Revenue of NovoSorb BTM

**435%**



Growth in sales of NovoSorb BTM on prior year

**128%**



Growth in total revenue (excluding R&D tax benefit) on prior year

**\$3.2M**



Research and development costs for continued innovation

**\$4.9M**



Purchased adjacent property to meet production demands from increased sales growth and development of new products

**47**



Total headcount increased from 38 on prior period to drive and support growth

**\$13.9M**



Cash on hand

**-51%**



Decrease in net cash outflow from operating activities (from \$6.9M in FY18 to \$3.4M)





# Global Expansion continued



## Australia

We have had a very successful year with NovoSorb BTM having been used in all states and territories except the ACT. We have increased our sales team from 1 to 3 and may add further to this in the year ahead. Our marketing organisation will grow in response to geographical expansion and in development of global support programs.

The acquisition of the adjacent factory in Port Melbourne, for Hernia and Breast product manufacturing, also provides expanded office facilities and staff amenities.



## New Zealand

PolyNovo's direct sales model has proved to be an excellent choice. We have established close, direct customer relationships and we have seen the start of a change in clinical management made possible by NovoSorb BTM. Many patients are benefitting through reduced scarring, improved functional outcomes and potentially less long-term revision surgery. This is saving patients pain, cost and improving their quality of life. For the New Zealand Health System BTM is realising significant health economic benefits.



## US Market Penetration

The US market is PolyNovo's single largest market and in the past year we have established many key hospital accounts. Surgeons continue to be impressed with the robust nature of NovoSorb BTM and the ability to utilise it for indications that they normally would not use a dermal matrix/scaffold.

Our BARDA program continues with the pivotal phase of the Burns trial commencing in FY20. Our DAPA/FSS/VA contract approval offers considerable scope for sales growth and demonstrates our ability to disrupt existing market paradigms.

Our sales roles have increased to 16 and we anticipate that we will add further sales roles in FY20 as we generate further sales demand. FY20 will also be an important launch planning period for our Hernia devices.



## Europe

PolyNovo displayed NovoSorb BTM at the British Burn Association meeting held in Leeds during May 2019. We have a full marketing and sales program in place ready for sales upon receiving our CE Certification. Expansion of our direct UK and Ireland sales team will occur through FY20 as we generate sales.

Germany, Austria and Switzerland (DACH) will be distributed by our partner PMI. There are several key marketing events scheduled to promote sales in the region with FY20 looking promising.

Once we establish the UK and Ireland and DACH countries, further European countries will be examined in considering our commercial expansion options. The options include both direct and partner models.



## Expanding into the Middle East

Al Mofadaly as our distributor for Saudi Arabia is active in promoting NovoSorb BTM and have completed several cases. This market will grow sales in FY20.

Our Israel distributor AMI Technologies has been slow to initiate sales. Whilst Israel is a small market, we see this as a key market for health technology adoption and remain committed to penetrating this market.



## South Africa

Our partners in South Africa, Ascendis Medical, continue to be an excellent partner. The market however is currently limited by insurance coverage.

We have several surgeon champions for NovoSorb BTM and we see South Africa as an important long term market where NovoSorb BTM can provide significant quality of life improvement for a large population. The publication of the CE Burns trial results in late 2019, will support private health insurance reimbursement process.



# Chairman and CEO Report

Dear Shareholder,

In the past year PolyNovo demonstrated that we can grow sales of NovoSorb BTM and build a direct scalable commercial enterprise.

NovoSorb BTM is delivering outstanding clinical results with leading US, New Zealand and Australian surgeons now using the device regularly and several surgeons stating they no longer use biologic based scaffolds. Many surgeons have presented clinical papers at conferences throughout FY19 endorsing NovoSorb BTM's effectiveness and improved outcomes.

Our financial position is strong, sales revenues continue to increase and we are debt free. We are on track for the Company to potentially breakeven in FY20.

We will continue to reinvest in expanding the business to service the demands of customers and bring new products to market. FY19 has delivered significant revenues, market penetration and key opinion leader advocates supporting NovoSorb BTM. We have a strong foundation for rapid growth in the year ahead.

## Markets

### United States of America

Our sales trajectory is strong and the expansion of our sales team has enabled us to service an expanding customer base. The year ahead will see further sales team and geographic expansion.

NovoSorb BTM has been used in the US for surgical wounds, limb salvage, reconstruction, trauma, necrotising 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. Surgeons are impressed by the 'robustness' of NovoSorb BTM, its ease of use and excellent clinical outcomes.

NovoSorb BTM is becoming the standard dermal scaffold of choice in some hospitals with the word spreading that it is outperforming the established biological based products.

NovoSorb BTM is having a direct impact improving the clinical outcomes of our patients. (See patient testimonial stories within this report via the QR code links).

US key opinion leaders (KOLs) presented NovoSorb BTM cases and posters at several conferences including Boswick, North America Burns Association and American Burn Association Conferences. The growing body of published evidence on NovoSorb BTM is exciting and adding gravitas to the effectiveness of a resorbable synthetic scaffold based on NovoSorb polymer. We also had the first publications of NovoSorb BTM in the treatment of diabetic foot ulcers and venous leg ulcer chronic wounds through Wake Forest University. NovoSorb BTM demonstrated excellent wound closure.

Further clinical studies in chronic wounds will be conducted in the year ahead to build the health economic data to support reimbursement process for the non-hospital market segments. This is a 2-3 year program to achieve unique reimbursement codes for the out-patient market segment.

FY20 promises to be an exciting year for PolyNovo. We have new sales management in place and an expanded sales team in place.

### Australia and Other Markets

#### Australia and New Zealand

We have had excellent sales post Therapeutic Goods Administration (TGA) registration in August 2018. This was achieved by one salesperson and the support of our head office team. We recently expanded the sales team to three giving us the capacity to rapidly service our customers and drive market penetration.

Surgeons have addressed resurfacing of body areas for scar management, complex trauma where limbs have been degloved, burns up to 90% total body surface area (TBSA) and many other challenging large wounds. A wide range of applications and success shows the potential of NovoSorb BTM and the capacity to positively impact patients' lives.

### Israel

Our distributor in Israel has been slow to initiate sales. We are working with them to address our performance in this market.

### Saudi Arabia

Al Mofadaly are our exclusive distributor for Saudi Arabia. They have had some successful NovoSorb BTM surgeries with positive acceptance by some surgeons. This is a market with good potential in the year ahead. We will also look at entry into other markets in the Middle East during FY20.

### India

We had a very successful launch in New Delhi, Dec 18, and our first order from our distributor Myovatec has been supplied. There are several surgeons in India with Australian experience of BTM so the surgeon to surgeon support network is well established. India is a growth market and we are looking for solid growth in this market during FY20.

### 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 full year post-implant follow up of the last patient is in progress to close out the first phase of this trial. The six US trial 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.

The next phase of the trial program will be the 'pivotal phase' which BARDA has indicated will be funded through an extension of the existing contract and further funds committed. We are in the process of US FDA protocol submission/approval and this process will determine the final budget. Further announcements on these milestones will be made in the coming months. We anticipate beginning patient recruitment before the end of 2019.

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

The CE Mark burn trial results will be published late CY19. The initial results show excellent "take" of BTM and all Australian sites involved in the trial are using NovoSorb BTM post trial. We achieved TGA approval through the innovative technology pathway. PolyNovo was the first company to do so and the first approval for use not tied to a defined list of indications rather for use wherever there has been significant dermal loss regardless of cause.

PolyNovo's Conformity Assessment submission has been impacted by Brexit workflow demands on the regulatory authority however our submission and site audits are complete and we await the issue of our certification.

We employed our first UK and Ireland sales person in September 2018 to begin the pre-sales work in advance of the CE Mark certification. This has been an excellent investment with several major NHS Trusts indicating they are ready to evaluate NovoSorb BTM. Our DACH region distributor has been trained and we have visited many of their key surgeons and hospitals in preparation of the launch. We expect the UK and Ireland and DACH regions to realise sales soon after CE approval is received, which is expected in early FY20.

## Hernia

Our Hernia devices will be in two formats to address the specific needs of surgeons repairing hernias in different abdominal



wall tissue planes. Our panel of surgeon advisors insights have informed the design to address the unmet clinical needs. The NovoSorb polymer is a significant advancement on current technologies in use.

The manufacturing process for hernia will bring some efficiency benefits to NovoSorb BTM making positive impact towards our gross margins. New manufacturing machines have been ordered and delivery will be circa February 2020. We anticipate filing for US FDA 510(k) towards the end of FY20.

## Breast

Product development with Establishment Labs continues with initial product concepts performing well in laboratory testing. The regulatory environment for breast products has heightened the need for devices to demonstrate safety and efficacy. Our NovoSorb polymer offers many advantages however the path forward may require the development of new test protocols and evidence to support applications. We are proactive in our approach and will monitor the evolving regulatory requirements.

## Beta-Cell Diabetes application

Beta-Cell (a non-related commercial entity) has successfully conducted swine studies demonstrating Islet cells live and function well within a NovoSorb BTM dermal implant. Further work is now in progress using stem cell derived islet cells verses cadaver donor cells. Human trials are anticipated in 2020.

## Manufacturing

Our current cleanroom production facility has been fully audit inspected by US FDA, Australian TGA and EU TUV-SUD. We are a fully accredited medical device manufacturing facility with significant production capacity for NovoSorb BTM. Following the acquisition of the adjacent facility to our head office, we will be commissioning an additional production facility for the production of hernia and breast devices in FY20. This facility will also add to our polymer and foam production capacities and bring further cost reductions to NovoSorb BTM.

## Summary

- Significant expansion of sales of BTM in the US, Australia and New Zealand.
- Expansion of sale territories in FY20.
- Exciting new product pipeline in breast and hernia.
- Increasing manufacturing capacity in FY20.

**David Williams**  
Chairman

**Paul Brennan**  
Chief Executive Officer



# Directors' 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 2019 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 35 years' experience working with and advising ASX-listed companies in the food, medical device and pharmaceutical sectors.

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, FGIA)*

#### 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 Corporate Counsel to Bell Resources Limited in its early years. He then studied for his MBA in Geneva and embarked on his 15 year investment banking career. When Head of the Industrial Franchise Group at Salomon Smith Barney he led Salomon's roles in the Federal Government's privatisation of Qantas, Commonwealth Bank (CBA3) and Telstra (T1). He now has over 17 years' experience as a full time professional Non-executive Director. He is currently Chairman of Capricorn Mutual Limited and a Non-executive Director of Capricorn Society Limited and Australian Meat Processors Limited. In the medical device space, he was previously Chairman of ASX listed 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), BARD1 Life Sciences Ltd (ASX:BD1) and was a former Non-executive Director of Enero 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), BARD1 Life Sciences Ltd (ASX:BD1) and RMA Global Ltd (ASX:RMY). He is also an alternate Director of the Nature's Dairy Australia group.



## Directors' Report continued



### **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 (all divisions) 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) businesses 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.



### **Mr Jan Gielen**

*(CA, Bachelor Bus (Acc))*

#### **Chief Financial Officer and Company Secretary**

Mr Gielen joined PolyNovo on 12 December 2018. Mr Gielen holds a Bachelor of Business (Accounting) degree from Monash University, is a member of the Institute of Chartered Accountants and commenced his career with Pitcher Partners. Since then Mr Gielen has held senior finance roles for various businesses across a range of industries such as retail, ICT, logistics (3PL) & medical, both locally and internationally. Mr Gielen has extensive experience in CFO and Finance Director roles for fast growing PE and VC backed businesses and played an important part in expanding these businesses globally, both from a financial and operational perspective. Mr Gielen had a long involvement from inception with ICIX, a leading SaaS platform supporting global retailers and manufacturers where he served as Finance Director in Silicon Valley. Mr Gielen's most recent role was CFO of CardioScan for 6 years, Australia's largest cardiac reporting provider, which during his tenure the business expanded to HK, Singapore & North America.



### **Mr Ashok Srinivasan**

*(BEng (Mechanical),  
MSc (Industrial Eng)*

#### **Chief Operating Officer**

Mr Srinivasan joined PolyNovo on 6 May 2019. Mr Srinivasan holds Engineering qualifications and a Master of Science in Manufacturing and Industrial Engineering. He began his career almost 25 years ago in Indiana, before being invited in 2003 to spearhead a joint venture with Biomet Inc (USA) in Jinhua, China. He was responsible for starting a green-field plant manufacturing orthopaedic surgical instruments and orthopaedic implants for the US and EU markets. This plant employed more than 300 people.

From 2008 to 2013 Mr Srinivasan was Vice President of Biomet's Asia Pacific Operations in Shanghai. He then moved to Europe as Vice President of European Operations including responsibility for its Global Supply Chain and Distribution Centre in the Netherlands.

In 2015, Mr Srinivasan left Biomet to return to the US as Chief Operating Officer of Meral/ GHI Inc, a supplements company in Anaheim, California, before moving to Melbourne in January 2019.



### **Mr Greg Lewis**

*(MBA, FPIPA, MAICD)*

#### **COO, CFO and Company Secretary**

Mr Lewis was appointed CFO, COO and Company Secretary on 24 January 2018 and left the Group on 7 December 2018.



# Directors' 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 2019, PolyNovo Limited had six wholly owned subsidiaries: PolyNovo Biomaterials Pty Limited, NovoSkin Pty Ltd, NovoWound Pty Ltd, PolyNovo NZ, PolyNovo UK, 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 and PolyNovo UK will be both the employing and sales entity for UK and Ireland. PolyNovo NZ is the registered entity for the New Zealand business.

### 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 bio reabsorb in a defined fashion in-situ to harmless by-products. NovoSorb has significant advantages over competitor bioabsorbable polymers in terms of its design flexibility and biocompatibility. PolyNovo can manufacture

NovoSorb polymer devices with the ability to elute drugs, antimicrobials as well as be expressed in a variety of physical formats including:

- Films
- Foam
- Coatings/sprays
- Fibres
- Plastic structures
- Biologic carrier

NovoSorb is currently covered by 47 patents all fully owned by PolyNovo. PolyNovo has no royalty or licence obligations to any other parties nor any debt finance.

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

### 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 Australia, USA, New Zealand, South Africa, India, Saudi Arabia, and Israel. New markets in FY20 will be UK, Ireland, Germany, Austria, Switzerland, Singapore and Malaysia. Further markets may be added to this list.

Key attributes of the NovoSorb technology include an unparalleled range of mechanical properties and bio reabsorption times, excellent biocompatibility and safety profile and harmless degradants.

Publications and videos relating to NovoSorb BTM applications can be found on our website: [www.polyново.com.au](http://www.polyново.com.au).

In the past year we have seen a significant number of podium presentations, clinical posters and peer reviewed publications of NovoSorb BTM. Its role as a clinical agent of change is being demonstrated through the diverse and challenging clinical applications.

### NovoSorb BTM indication for full thickness burns

NovoSorb BTM is an innovative treatment for any loss of the dermis. NovoSorb BTM is indicated for full thickness/ third degree burns in markets outside of the USA.

Full thickness burns treatment for US FDA regulatory 'claim' requires additional clinical evidence generation (trials). These trials are in progress and funded by BARDA.

The pathway for US FDA 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.

Australia: Head Office Team celebrating the milestones of achieving \$1 share price and over \$1 million in global sales in a month.





US: Sales and Marketing Team.

## 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 and the pivotal trial. Patient recruitment in the feasibility phase has closed and the results of this study are due to be published in FY20.

The pivotal trial will be funded by BARDA through an extension of the existing contract. The final value for the Pivotal trial will be announced once the protocol has been finalised and approved by the US FDA. This is anticipated for late September 2019.

Successful completion of the pivotal trial will 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 finalised list of trial hospitals/ institutions will be published via an ASX announcement later in the year.

In addition, PolyNovo is on track to complete the swine toxicology study mapping the full degradation pathway of the NovoSorb BTM during FY20. The data generated in this study will support our PMA application and add to the body of evidence demonstrating the mode of action of NovoSorb BTM.

## CE Mark Certification

PolyNovo is currently awaiting CE Mark approval of NovoSorb BTM with all documents submitted and TUV-SUD site audit completed. This certification enables sales throughout Europe and supportive evidence for most of South East Asia.

## TGA approval

PolyNovo announced in August 2018 that it achieved Therapeutic Goods Administration of Australia approval as a class III medical device through the 'Priority Review Designation' pathway. We are proud to be the first company to achieve approval via this pathway.

Dr Marcus Wagstaff is acting as PolyNovo Medical Director overseeing the clinical conduct of PolyNovo trials and providing valuable clinical support for our global medical teams.

## Hernia Repair

PolyNovo is currently building the factory and equipment for the manufacture of NovoSorb hernia products. Our first market will be the USA in FY21. We have acquired the adjacent factory to our Head Office this year to enable manufacturing of these hernia products. The facility expansion builds significant earning capacity and diversification of our market segments.

## Breast Device Developments

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 and marketing activities related to this product range. PolyNovo will undertake all the development and manufacturing processes with the products sold under the Motiva brands globally by Establishment Labs.

The past year has seen various laboratory tests, product design inputs and early manufacturing scale up being completed.

## NovoSorb Dermal Beta Cell Implant

PolyNovo is collaborating with Beta Cell Technologies Pty Ltd, on a research project exploring the potential of integrated NovoSorb BTM to host pancreatic islets in the skin. It is anticipated that human trials will begin in the next year.

Initial swine studies are being repeated utilising stem cell derived Islet cells within a dermal depot of NovoSorb BTM. The next phase will be to conduct human trials in 2020. PolyNovo will supply NovoSorb BTM in specific sizes and specifications for the trials with the long-term view to establishing commercial sales for this indication and treatment.

BetaCell with funding supported by the Juvenile Diabetes Research Foundation (JDRF, US) will manage the trial program.

## **NovoSorb Drug Elution Depot (pellet)**

PolyNovo produced polymers with up to 45% of the weight being a bound drug. Our initial work is focused on low temperature extrusion for optimal drug stabilisation. Further development will continue in the coming year with the aim to develop a comprehensive technical dossier in preparation of clinical trials. PolyNovo is likely to license this technology to a pharmaceutical partner once we have established robust evidence to support the mode of action and stability of drug elution rates.

## **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. Our current focus is on areas of greater financial returns for the Company.

## **Capital investment**

PolyNovo is currently commissioning the fit out of our Hernia and Breast factory in Port Melbourne. We anticipate having this facility fully commissioned in FY20. Various production machines have been ordered with delivery of these machines scheduled through to February 2020.

Waste reduction initiatives:

- Our total facility has moved to LED lighting
- implemented a waste tracking program
- actively recycle
- uses environmental accredited waste disposal contractors
- looking to install solar panels on the new factory facility.

PolyNovo is investing in the upgrade of our Enterprise Resource Planning system and Client Relationship Management tool to actively manage the business and customer needs across multiple countries. The ERP system will be complete by the publication of this report.

PolyNovo is investing in the upgrade of our Enterprise Resource Planning system and Client Relationship Management tool to actively manage the business and customer needs across multiple countries. The ERP system will be complete by the publication of this report.

In FY20 we will also migrate our Quality Management System from paper based to electronic processes. This will improve data tracking, add pace to our ability to adopt change and improvements and reduce our environmental impact.

## **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 2019.

## **Strategic Overview and Likely Developments**

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

- accelerate of commercial NovoSorb BTM sales in the existing markets of US, Australia, New Zealand, South Africa, India, Saudi Arabia and Israel.
- Drive new sales revenue from entry to UK and Ireland, Germany and Austria and Switzerland (DACH), Singapore and Malaysia and select areas of Europe and SE Asia
- finalise commercial partnerships for the BTM product in markets where regulatory approval can be achieved within the year
- publish CE Mark burn trial medical report
- file hernia 510(k) application with US FDA
- 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
- commence pivotal burn trial in US with BARDA funding support
- Partner with The Alfred Hospital and Monash University in the development of cultured epithelial cells utilising a NovoSorb foam substrate
- Continue the partnership with Skin TE on their Cultured Skin Composite utilising NovoSorb foam substrate within a bioreactor.

## **Significant Events after the Balance 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.

Announcements released by the Company after the balance date include:

- 1 August 2019 – Trading Update and Sales Run Rate.
- 8 August 2019 – Singapore Regulatory Approval.





## Financial results

PolyNovo Limited reported revenue for the year ended 30 June 2019 of \$13,683,323 an increase of \$7,693,565 from the prior year's \$5,989,758. The net loss after tax of \$3,189,893 for FY19 was a decrease of \$2,784,239 from the prior year's \$5,974,132. A number of factors contributed to the improvement on the prior year's result as follows:

- Revenue from the sale of commercial products for FY19 increased by 435% to \$9,348,226 from the prior year's \$1,747,102
- Revenue from BARDA for FY19 increased by 5% to \$4,000,994 from the prior year's \$3,827,016
- Employee related expenses increased by 51% to \$8,549,240 as PolyNovo increased headcount to drive marketing, sales and meet the resource requirements to service our growing customer base and clinical programs.
- Included in revenue is interest income for FY19 of \$334,103 which is \$58,800 higher than prior year's \$275,303.
- Depreciation and amortisation increased by \$127,710 attributable to 12 months amortisation of intangible assets.

## R&D Tax Incentives

During the 2019 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 2018, the Company applied to claim eligible FY18 R&D expenditure and early the following month received a 43.5% refundable tax offset of \$794,256 (cash). PolyNovo has submitted its application to the Department of Industry, Innovation and Science to claim eligible expenditure for 2019 R&D activities and expects to receive a 43.5% refundable tax offset of \$694,602, as disclosed in the notes to the financial statements.

### Closing share price

30 June 2016	\$0.28
30 June 2017	\$0.21
30 June 2018	\$0.54
<b>30 June 2019</b>	<b>\$1.54</b>

A high of \$1.56 was reached on 24 June 2019.

## Loss Per Share

In Australian dollars \$	Cents
Basic loss per share – cents	(0.48)
Diluted loss per share – cents	(0.48)

As the Group made a loss for the year ended 30 June 2019, 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 2019, 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.

## Indemnification of Auditors

To the extent permitted by law, the Company has agreed to indemnify its auditors, Ernst & Young Australia, as part of the terms of its engagement agreement against claim by third parties arising from the audit (for an unspecified amount). No payment has been made to indemnify Ernst & Young Australia during or since the financial year.

## 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.

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

## 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.

Directors	Role	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
Total number of meetings held		12		2		1	
Mr David Williams	Non-Executive Director	10	12	-	-	1	1
Mr Bruce Rathie	Non-Executive Director	12	12	2	2	-	-
Dr David McQuillan	Non-Executive Director	12	12	-	-	-	-
Mr Philip Powell*	Non-Executive Director	12	12	2	2	-	-
Mr Max Johnston	Non-Executive Director	12	12	2	2	-	-
Mr Leon Hoare**	Non-Executive Director	12	12	-	-	1	1

\* Mr Philip Powell is Chair of the Audit Committee.

\*\* Mr Leon Hoare is Chair of the Remuneration Committee.

## Directors' Shareholdings and Declared Interests

At 30 June 2019, the Directors of PolyNovo collectively hold 25,850,187 shares in the Company.

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

Name Directors	Shares held directly	Shares held indirectly
Mr David Williams	-	16,778,305
Mr Bruce Rathie	-	3,555,555
Dr David McQuillan	1,162,000	39,718
Mr Max Johnston	-	1,711,111
Mr Philip Powell	-	1,266,667
Mr Leon Hoare	-	1,336,831
Total	1,162,000	24,688,187

As at 30 June 2019 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 2019 Annual Report. Further details of the equity interests of Directors can be found in the Remuneration Report.



# Directors' Report continued

## 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 2019, the amount received, or due and receivable for non-audit services provided by PolyNovo's auditor Ernst & Young were:

Tax compliance services	111,422
Advice on mileage and petrol reimbursements in the USA	6,958
Other compliance services supporting GST and importer registrations in NZ	950

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## 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 31.



# 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 2019. 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](http://www.polyново.com.au/company)



# Remuneration Report – Audited

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 2019. 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 2019 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. The following are considered to be Key Management Personnel during the period unless otherwise stated.

### 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 Jan Gielen – Chief Financial Officer/Company Secretary (appointed 12 December 2018)
- Mr Ashok Srinivasan – Chief Operating Officer (appointed 6 May 2019)
- Mr Greg Lewis – Chief Operating Officer/Chief Financial Officer/Company Secretary (resigned 7 December 2018)

## 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.



## 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 and consulting fees) for the year ended 30 June 2019 were \$369,227. 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

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 \$300,000 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.

# Remuneration Report continued

## Company Secretary and Chief Financial Officer (CFO)

Mr Jan Gielen was appointed CFO and Company Secretary on 12 December 2018. The terms of his contract are as follows:

- a salary of \$182,648 per annum;
- superannuation of 9.50%;
- 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 '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 three months' notice or payment in lieu of notice. In the event of resignation, a notice period of three months is required.

## Company Secretary, Chief Operating Officer (COO) and Chief Financial Officer (CFO)

On 7 November 2018, Mr Greg Lewis resigned as Company Secretary, COO and CFO and was replaced by Mr Jan Gielen.

## Chief Operating Officer (COO)

Mr Ashok Srinivasan was appointed COO on 6 May 2019. The terms of his contract are as follows:

- a salary of \$180,000 per annum;
- superannuation of 9.50% (on salary only);
- a bonus incentive of up to 20% of salary after 12 months service, dependent upon performance against objectives and targets, including detailed KPIs;
- a long term incentive plan in the form of equity interest, the details of which are yet to be agreed.
- 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 were 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 \$0.09 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 remained 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 \$0 as the options vested in previous periods.

## CFO Performance Incentives

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

On 6 March 2019, PolyNovo issued an options package comprising three tranches totaling 1,000,000 options to the CFO, Mr Jan Gielen. Details of the three tranches are set out below.

The vesting hurdle for the options is linked to Mr Gielen's length of employment and the PolyNovo volume weighted average market price. The vesting hurdles are as follows:

- First hurdle – 12 months of employment with the Company; and
- Second hurdle – a share price of 90 cents must be sustained over a period of at least 90 consecutive calendar days.

Once vested, the options can be exercised in three tranches as follows:

- Tranche 1: 300,000 options – not to be exercised before 31 December 2020 and not later than 30 June 2021;
- Tranche 2: 300,000 options – not to be exercised before 31 December 2021 and not later than 30 June 2022; and
- Tranche 3: 400,000 options – not to be exercised before 31 December 2022 and not later than 30 June 2023.

The options whether they have vested or not will be cancelled on the date of termination or cessation of employment.

The exercise price is \$0.60 per option tranche.

All shares issued under the incentive scheme are escrowed for a period of 12 months from date of issue. Sixty percent (60%) of the shares issued on the exercise of options are restricted shares subject to rule 9 of the Employee Option Plan for a period of 12 months from the date of issue.

The fair value of the options relating to the incentive scheme shares was \$321,700. The expense relating to the incentive scheme shares during the financial year was \$56,913.

## Former CFO Incentives

As disclosed, Mr Greg Lewis resigned from the group on 7 November 2018 and left the Group on 7 December 2018. Mr Lewis participated in the Company share options scheme. On departure from the Company on 7 December 2018, 1,000,000 share options were forfeited. No share based payment expense has been recognised during the current financial period.



# Remuneration Report continued

## Remuneration of Key Management Personnel

Details of the remuneration for key management personnel for the years ended 30 June 2019 and 30 June 2018 are set out in Table A below.

		Short term			Post employment	Leave allowances <sup>1</sup>	Termination benefits <sup>2</sup>	Share-based payments	Total	% performance based
		Cash salary & fees	Cash bonus	Consulting fees <sup>3</sup>	Superannuation	Annual and long service		Options and performance rights		
Table A		\$	\$	\$	\$	\$	\$	\$	\$	
<b>Non-Directors</b>										
Mr David Williams (Chairman/Non-executive Director)	2019	81,850	-	-	7,776	-	-	-	89,626	-
	2018	75,000	-	-	7,125	-	-	-	82,125	-
Mr Bruce Rathie (Non-executive Director)	2019	51,850	-	-	4,926	-	-	-	56,776	-
	2018	45,000	-	-	4,275	-	-	-	49,275	-
Dr David McQuillan (Non-executive Director)	2019	52,500	-	69,912	-	-	-	-	122,412	-
	2018	45,000	-	50,517	-	-	-	-	95,517	-
Mr Max Johnston (Non-executive Director)	2019	51,850	-	-	4,926	-	-	-	56,776	-
	2018	45,000	-	-	4,275	-	-	-	49,275	-
Mr Philip Powell (Non-executive Director)	2019	51,850	-	-	4,926	-	-	-	56,776	-
	2018	45,000	-	-	4,275	-	-	-	49,275	-
Mr Leon Hoare (Non-executive Director)	2019	51,850	-	-	4,926	-	-	-	56,776	-
	2018	45,000	-	-	4,275	-	-	-	49,275	-
<b>Subtotal compensation for Non-Executive Directors</b>	<b>2019</b>	<b>341,750</b>	<b>-</b>	<b>69,912</b>	<b>27,480</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>439,142</b>	<b>-</b>
	<b>2018</b>	<b>300,000</b>	<b>-</b>	<b>50,517</b>	<b>24,225</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>374,742</b>	<b>-</b>
<b>Key management personnel</b>										
Mr Paul Brennan (CEO)	2019	264,840	-	-	25,160	25,871	-	-	315,871	-
	2018	246,575	-	-	23,425	21,291	-	55,803	347,094	16%
Mr Jan Gielen (CFO/Company Secretary)	2019	101,627	-	-	9,655	8,275	-	56,913	176,470	32%
	2018	-	-	-	-	-	-	-	-	-
Mr Ashok Srinivasan (COO)	2019	26,862	-	-	2,552	2,272	-	-	31,686	-
	2018	-	-	-	-	-	-	-	-	-
Mr Greg Lewis (CFO/Company Secretary)	2019	83,144	-	-	7,259	6,334	-	(2,827)	93,910	-
	2018	88,388	-	-	7,971	6,221	-	2,827	105,407	3%
Ms Andrea Goldie (CFO/Company Secretary)	2019	-	-	-	-	-	-	-	-	-
	2018	-	-	-	-	-	68,458	-	68,458	-
Mr Gavin Smith (Interim CFO/Company Secretary)	2019	-	-	-	-	-	-	-	-	-
	2018	52,534	-	82,680	4,991	-	-	-	140,205	-
<b>Subtotal compensation for other key management personnel</b>	<b>2019</b>	<b>476,473</b>	<b>-</b>	<b>-</b>	<b>44,626</b>	<b>42,752</b>	<b>-</b>	<b>54,086</b>	<b>617,937</b>	<b>9%</b>
	<b>2018</b>	<b>387,497</b>	<b>-</b>	<b>82,680</b>	<b>36,387</b>	<b>27,512</b>	<b>68,458</b>	<b>58,630</b>	<b>661,164</b>	<b>9%</b>
<b>Total compensation for all key management personnel</b>	<b>2019</b>	<b>818,223</b>	<b>-</b>	<b>69,912</b>	<b>72,106</b>	<b>42,752</b>	<b>-</b>	<b>54,086</b>	<b>1,057,079</b>	<b>5%</b>
	<b>2018</b>	<b>687,497</b>	<b>-</b>	<b>133,197</b>	<b>60,612</b>	<b>27,512</b>	<b>68,458</b>	<b>58,630</b>	<b>1,035,906</b>	<b>6%</b>

1. Leave allowances: annual and long service: Reflects the employees' entitlement for the 2019 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. The consulting fees are excluded from the aggregate Directors' fee pool limit.

## Options Granted as Part of Remuneration

During the year ended 30 June 2019, 1,000,000 options (2018: 1,000,000) were granted, no options were cancelled (2018: nil), and 1,000,000 options were forfeited (2018: 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.

2019 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 \$ of options	Number of shares issued upon exercise	Value of shares received upon exercise \$	Value of options exercised yet to be included in remuneration during the year \$	Fair value of options included in remuneration during the year \$	% compensation consisting of options during the year
<b>Mr Leon Hoare</b>											
Options	18-Nov-16	500,000	\$0.12000	-	-	165,000	500,000	302,500	-	-	-
Options	18-Nov-16	500,000	\$0.09800	-	-	125,000	500,000	302,500	-	-	-
<b>Mr Jan Gielen</b>											
Options	6-Mar-19	300,000	\$0.23600	70,800	-	-	-	-	70,800	18,880	13%
Options	6-Mar-19	300,000	\$0.31100	93,300	-	-	-	-	93,300	16,736	11%
Options	6-Mar-19	400,000	\$0.39400	157,600	-	-	-	-	157,600	21,297	14%
<b>Mr Greg Lewis</b>											
Options	20-Nov-17	1,000,000	\$0.09400	-	94,000	-	-	-	-	-	-
<b>Total</b>		<b>3,000,000</b>		<b>321,700</b>	<b>94,000</b>	<b>290,000</b>	<b>1,000,000</b>	<b>605,000</b>	<b>321,700</b>	<b>56,913</b>	<b>-</b>

### Options granted in year ended 30 June 2019

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 included in remuneration during the year was \$56,913. This represents 32% allocation to the year ended 30 June 2019 as the options have not yet vested.

### 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 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. No expense has been recognised in the period as the share option was forfeited on resignation of the former COO/CFO, Greg Lewis.

### Options expiry dates

Participant	Date
<b>Mr Jan Gielen</b>	
• Tranche 1	30 June 2021
• Tranche 2	30 June 2022
• Tranche 3	30 June 2023

Other terms of the share options include:

- Vesting hurdles – 12 months of employment with the Company and a share price of 90 cents must be sustained over a period of at least 90 consecutive calendar days.
- Exercise price – \$0.60 per option tranche.
- Escrow period – 12 months from date of issue with sixty percent (60%) of the shares issued on the exercise of options are restricted shares subject to rule 9 of the Employee Option Plan for a period of 12 months from the date of issue.

# Remuneration Report continued

## 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 2018	Granted as compen- sation	On exercise of options	Net change other <sup>1</sup>	Balance at 30 June 2019	Balance at end of year – directly held	Balance at end of year – indirectly held
<b>Directors</b>							
Mr David Williams	15,980,457	-	-	797,848	<b>16,778,305</b>	-	16,778,305
Mr Bruce Rathie	2,737,290	-	-	818,265	<b>3,555,555</b>	-	3,555,555
Dr David McQuillan	1,038,518	-	-	163,200	<b>1,201,718</b>	1,162,000	39,718
Mr Max Johnston	1,711,111	-	-	-	<b>1,711,111</b>	-	1,711,111
Mr Philip Powell	1,266,667	-	-	-	<b>1,266,667</b>	-	1,266,667
Mr Leon Hoare	336,831	-	1,000,000	-	1,336,831	-	1,336,831
<b>Other key management personnel</b>							
Mr Paul Brennan	10,955,542	-	-	(722,115)	10,233,427	5,915,872	4,317,555

1. 'Net Change Other' reflects shares privately acquired or disposed during the period.

### Options and performance rights of key management personnel

The option holdings of key management personnel for the year ended 30 June 2019 are set out in the following table.

Table D	Balance at 1 July 2018	Granted as compen- sation	Options exercised	Net change other	Balance at 30 June 2019	Total vested at end of year	Total exercisable at end of year	Total not exercisable at end of year	Total vested during year
<b>Directors</b>									
Mr Leon Hoare	1,000,000	-	1,000,000	-	-	-	-	-	-
<b>Other key management personnel</b>									
Mr Jan Gielen	-	1,000,000	-	-	<b>1,000,000</b>	-	-	1,000,000	-
Mr Greg Lewis	1,000,000	-	-	(1,000,000)*	-	-	-	-	-
<b>Total</b>	<b>2,000,000</b>	<b>1,000,000</b>	<b>1,000,000</b>	<b>(1,000,000)</b>	<b>1,000,000</b>	-	-	<b>1,000,000</b>	-

\* The net change reflects share options forfeited in the period by the former CFO.

### 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

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

This Directors' Report, incorporating the Corporate Governance Statement and Remuneration Report, has been signed in accordance with a Resolution of the Directors made on 22 August 2019.



**Mr David Williams**  
Chairman  
22 August 2019



# 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 the financial report of PolyNovo Limited for the financial year ended 30 June 2019, 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.

A handwritten signature in black ink that reads 'Ernst + Young'.

Ernst & Young

A handwritten signature in black ink that reads 'Joanne Lonergan'.

Joanne Lonergan  
Partner  
22 August 2019

# Consolidated Statement of Comprehensive Income

For the year ended 30 June 2019

	Notes	30 June 2019 \$	30 June 2018 \$
<b>Revenue from contracts with customers</b>	4(a)	13,349,220	5,714,455
<b>Other income</b>			
Research and development tax benefit	4(f)	694,602	839,397
Interest income	4(b)	334,103	275,303
<b>Total revenue</b>		<b>14,377,925</b>	<b>6,829,155</b>
Changes in inventories of finished goods and work in progress		(1,294,146)	(632,859)
Operating Leases		(193,597)	(190,768)
Employee-related expenses	4(c)	(8,549,240)	(5,656,333)
Research and development expenses		(3,248,426)	(3,806,108)
Depreciation and amortisation expense	4(d)	(309,600)	(181,890)
Corporate, administrative and overhead expenses	4(e)	(3,972,809)	(2,335,329)
<b>Net loss for the period before tax</b>		<b>(3,189,893)</b>	<b>(5,974,132)</b>
Income tax benefit	5	-	-
<b>Net loss for the period after tax</b>		<b>(3,189,893)</b>	<b>(5,974,132)</b>
<b>Other comprehensive income</b>			
Loss on translation of foreign operation	16(b)	(216,639)	(159,300)
<b>Total comprehensive income/(loss) for the period</b>		<b>(3,406,532)</b>	<b>(6,133,432)</b>
<b>Loss for the period is attributable to:</b>			
Owners of the parent		(3,189,893)	(5,974,132)
		(3,189,893)	(5,974,132)
<b>Total comprehensive loss for the period attributable to:</b>			
Owners of the parent		(3,406,532)	(6,133,432)
Loss attributable to members of the parent		(3,406,532)	(6,133,432)
<b>Loss per share</b>			
Basic loss per share – cents	7	(0.48) cents	(0.95) cents
Diluted loss per share – cents	7	(0.48) cents	(0.95) cents

The accompanying notes form part of these financial statements.

# Consolidated Statement of Financial Position

As at 30 June 2019

	Notes	30 June 2019 \$	30 June 2018 \$
<b>Current assets</b>			
Cash and cash equivalents	8	13,920,695	3,147,081
Inventories	9	1,215,450	1,083,586
Receivables and contract assets	10	4,405,047	2,679,675
Prepayments		310,321	164,766
Other financial assets	22	50,000	19,050,000
<b>Total current assets</b>		<b>19,901,513</b>	<b>26,125,108</b>
<b>Non-current assets</b>			
Property, plant and equipment	12	6,008,219	1,139,665
Intangible assets	13	2,148,016	2,395,864
Other assets	11	170,767	161,288
<b>Total non-current assets</b>		<b>8,327,002</b>	<b>3,696,817</b>
<b>Total assets</b>		<b>28,228,515</b>	<b>29,821,925</b>
<b>Current liabilities</b>			
Trade and other payables	14	1,751,829	942,719
Provisions	15(a)	312,172	275,698
<b>Total current liabilities</b>		<b>2,064,001</b>	<b>1,218,417</b>
<b>Non-current liabilities</b>			
Provisions	15(b)	47,738	29,287
Deferred rent liability		17,297	115,251
<b>Total non-current liabilities</b>		<b>65,035</b>	<b>144,538</b>
<b>Total liabilities</b>		<b>2,129,036</b>	<b>1,362,955</b>
<b>Net assets</b>		<b>26,099,479</b>	<b>28,458,970</b>
<b>Equity</b>			
Contributed equity	16(a)	139,070,502	138,120,502
Reserves	16(b)	(6,511,909)	(6,392,311)
Accumulated losses	16(c)	(106,459,114)	(103,269,221)
<b>Parent interests</b>		<b>26,099,479</b>	<b>28,458,970</b>
<b>Total equity</b>		<b>26,099,479</b>	<b>28,458,970</b>

The accompanying notes form part of these financial statements.



# Consolidated Statement of Changes in Equity

For the year ended 30 June 2019

	Contributed equity \$	Other reserves \$	Acquisition of non- controlling interest reserves \$	Retained earnings \$	Owners of the parent \$	Total \$
<b>As at 30 June 2017</b>	<b>114,476,370</b>	<b>2,925,541</b>	<b>(9,293,956)</b>	<b>(97,295,089)</b>	<b>10,812,866</b>	<b>10,812,866</b>
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	22,227,473	-	-	-	22,227,473	22,227,473
Share-based payments	-	135,404	-	-	135,404	135,404
Translation of foreign operation	-	(159,300)	-	-	(159,300)	(159,300)
<b>As at 30 June 2018</b>	<b>138,120,502</b>	<b>2,901,645</b>	<b>(9,293,956)</b>	<b>(103,269,221)</b>	<b>28,458,970</b>	<b>28,458,970</b>
Loss for the period	-	-	-	(3,189,893)	(3,189,893)	(3,189,893)
Issue of shares on exercise of options	950,000	-	-	-	950,000	950,000
Share-based payments	-	97,041	-	-	97,041	97,041
Translation of foreign operation	-	(216,639)	-	-	(216,639)	(216,639)
<b>As at 30 June 2019</b>	<b>139,070,502</b>	<b>2,782,047</b>	<b>(9,293,956)</b>	<b>(106,459,114)</b>	<b>26,099,479</b>	<b>26,099,479</b>

The accompanying notes form part of these financial statements.

# Consolidated Cash Flow Statement

For the year ended 30 June 2019

	Notes	30 June 2019 \$	30 June 2018 \$
<b>Cash flows from operating activities</b>			
Receipts from customers		7,768,050	1,467,117
Receipts from BARDA reimbursements		4,323,872	3,016,578
Receipts of research and development income tax credit		794,256	878,268
Receipts from royalty revenue		245	2,699
Receipts from licence revenue		-	130,109
Payments to suppliers and employees		(16,256,156)	(12,372,732)
<b>Net cash outflows from operating activities</b>	8	<b>(3,369,733)</b>	<b>(6,877,961)</b>
<b>Cash flows from investing activities</b>			
Interest received		581,566	36,753
Payments for purchase of property, plant and equipment		(6,520,204)	(219,979)
Term deposits classified as other assets		-	(19,000,000)
Transferred to cash and cash equivalents		19,000,000	-
<b>Net cash outflows used in investing activities</b>		<b>13,061,362</b>	<b>(19,183,226)</b>
<b>Cash flows from financing activities</b>			
<b>Net cash flows from financing activities</b>			
Proceeds from the issue of share capital (net of costs)	16(a)	-	22,227,473
Proceeds from the exercise of options		950,000	1,416,659
<b>Cash flows from financing activities</b>		<b>950,000</b>	<b>23,644,132</b>
Net increase/(decrease) in cash and cash equivalents		10,641,629	(2,417,055)
<b>Cash and cash equivalents at beginning of period</b>		<b>3,147,081</b>	<b>5,496,609</b>
Effects of exchange rate changes on cash and cash equivalent		131,985	67,527
<b>Cash and cash equivalents at end of period</b>	8	<b>13,920,695</b>	<b>3,147,081</b>

The accompanying notes form part of these financial statements.

# Notes to the Financial Statements

For the year ended 30 June 2019

## 1. Corporate Information

The Financial Report of PolyNovo Limited (the Company) and its controlled entities (the Group) for the year ended 30 June 2019 was authorised for issue in accordance with a resolution of the Directors on 22 August 2019.

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, New Zealand, United Kingdom 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 2018. 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 2018.

- AASB 9 Financial Instruments (AASB 9)
- AASB 15 Revenue from Contracts with Customers (AASB 15)

#### AASB 15 Revenue from contracts with customers

As from 1 July 2018, the Group has adopted AASB 15 Revenue from Contracts with Customers in respect to Revenue Recognition. The Group recognises revenue in accordance with the core principles of AASB 15 Revenue from Contracts with Customers. AASB 15 replaces all existing revenue requirements in Australian Accounting Standards (AASB 111 Constructions Contracts, AASB 118 Revenue) and applies to all revenue arising from contracts with customers.

The new standard establishes a five-step model to account for revenue arising from contracts with customers. Under AASB 15 Revenue from contracts with customers, revenue is recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The Group complies with AASB 15 Revenue from contracts with customers in that contract income is only recognised as revenue as or when performance obligations pursuant to that contract are satisfied by the Group. The standard also specifies the accounting for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract.

The Group has applied the modified retrospective method of adoption and has elected to apply that method to all contracts that were not completed at the date of initial application. The impact of these new standards has been assessed by management and determined the application of the new standards does not have a material impact on the previous period financial statements therefore there will not be any disclosures that outline any impact to the comparative period and there will not be a cumulative catch-up adjustment that will be recognised in the statement of change in equity for the year ending 30 June 2019. Under this method of initial application, disclosures for the comparative period in the notes to the financial report remain under the previous revenue recognition accounting requirements applicable to that period.



The Group has identified the following main categories of revenue:

#### *Commercial product sales*

The group revenue primarily consists of the sale of its NovoSorb BTM product. Revenue is recorded when the customer takes possession of the product. All contracts with customers are standardised and satisfy the criteria of transaction approval, identification of each party's rights, payment terms, commercial substance, and probable collection based on the customer's ability and intention to pay. Revenue is recognised at a point in time when control over the product transfers to the customer, which is assessed to be at the time of receipt of goods by the customer.

#### *Distribution sales*

The group sells its BTM product in certain overseas territories via a distributor model. The sales are made direct to a distributor being the customer of PolyNovo Limited, with the distributor permitted to resell the BTM product to an end user. The group has assessed these arrangements to consider that control passes to the distributor at the point the distributor takes possession of the product. The group consider themselves to be acting as principal in the sale of goods to distributors and recognise revenue on a gross basis.

All contracts with distributors are standardised, and satisfy the criteria of transaction approval, identification of each party's rights, payment terms, commercial substance, and probable collection based on the customer's ability and intention to pay. Revenue is recognised at a point in time when control over the product transfers to the distributor as the customer, which is assessed to be at the time of receipt of goods by the customer.

#### *BARDA revenue*

The BARDA arrangement requires the group to provide to BARDA a solution for severe thermal burns, with the performance obligation as defined in the terms of the arrangement being to perform research and development for specific clinical and trial tasks to support the product development of Biodegradable Temporal Matrix ('BTM') for severe thermal burns. Judgement has been applied to consider that the license of intellectual property and research and development activities are not distinct. Revenue is recognised over time based on input measures of specified costs, with the performance obligations being achieved through delivery to BARDA of the contracted clinical studies and trial tasks to support the development the BTM product for severe thermal burns.

BARDA is considered a customer in accordance with AASB 15 as the nature of services performed by PolyNovo are considered part of the group's licence of intellectual property and normal research and development operating activities and in exchange, consideration is to be paid as the group progresses with its research and development of a mass scalable severe thermal burns product.

#### *Licence revenue*

The Group entered into a fixed term licence arrangement with a customer to provide use of to specific intellectual property owned by the group to permit certain research and development activity to be performed by the customer with the objective to develop new commercial products. The arrangement's performance condition is satisfied on delivery of the licence, with no further requirements to enhance the intellectual property. The revenue recognised reflects the consideration to which the Group expects to be entitled to for transfer of the licence, and is recognised on a point in time basis, based on control of the licence being transferred and there being no further ongoing obligations required over the licence term.

The Group is entitled to further revenue from the delivery of the licence upon the customer's achievement of certain milestones. However, given there is uncertainty as to whether these milestones will be achieved, revenue is currently constrained and will be recognised when uncertainty is resolved.

#### *Contract Balances*

##### *Contract asset*

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If the Group performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognised for the earned consideration that is conditional. As at 30 June 2019, the Group has disclosed in Note 4(a) contract assets. The Group did not recognise any contract liabilities as at 30 June 2019.

##### *Trade receivables*

A receivable represents the Group's right to an amount of consideration that is unconditional (i.e. only the passage of time is required before payment of the consideration is due).

# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 2. Summary of Significant Accounting Policies continued

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

#### AASB 9 Financial Instruments

AASB 9 replaced AASB 139: Financial Instruments: Recognition and Measurement ('AASB 139') for the period beginning on 1 July 2018, bringing together all three aspects of the accounting for financial instruments: classification and measurement; impairment; and hedge accounting. There was no material transition impact, with \$27,076 recognised in the period related to expected credit losses.

#### *Classification and measurement*

Except for certain trade receivables, under AASB 9, the group initially measures a financial asset at its fair value.

Under AASB 9, financial assets are subsequently measured at fair value through profit or loss (FVPL), amortised cost, or fair value through other comprehensive income (FVOCI). The classification is based on two criteria: The Group's business model for managing the assets; and whether the instruments' contractual cash flows represent 'solely payments of principal and interest' on the principal amount outstanding (the 'SPPI criterion').

The accounting for the Group's financial liabilities remains largely the same as it was under AASB 139.

#### *Impairment*

The adoption of AASB 9 has included a review of the Group's accounting for impairment losses for financial assets by replacing AASB 139's incurred loss approach with a forward looking expected credit loss ('ECL') approach. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive. The shortfall is then discounted at an approximation to the asset's original effective interest rate. For trade and other receivables, the Group has applied the standard's simplified approach and has calculated ECLs based on lifetime expected credit losses. The Group has established a provision matrix that is based on the Group's historical credit loss experience, adjusted for forward looking factors specific to the debtors and the economic environment.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group uses a provision matrix to calculate ECLs for trade receivables and contract assets. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns.

The provision matrix is initially based on the Group's historical observed default rates. The Group calibrates the matrix to adjust the historical credit loss experience. The provision rates are based on days past due to grouping of various customer segments with similar loss patterns which is by geographical region and customer type. The calculation reflects the reasonable supportable information available that at the reporting date including customer credit reports to assess customer credit quality, customer historical defaults, current conditions and forecasts of future economic conditions. At every reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analysed. Generally, trade receivables are written off if past due for more than one year. The total expected credit loss is disclosed in note 10.

The assessment of the correlation between historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and of forecast economic conditions. The Group's historical credit loss experience and forecast of economic conditions may also not be representative of customer's actual default in the future. The Group has applied AASB retrospectively with the initial application date being 1 July 2018.

The following new Australia Accounting Standards have been issued by the AASB but are not yet effective for the period ended 30 June 2019.

#### AASB 16 Leases

- The Group is required to adopt AASB 16 Leases from 1 July 2019. AASB 16 Leases supersedes AASB 117 *Leases*, Interpretation IFRIC 4 *Determining whether an arrangement contains a lease*, Interpretation 115 *Operating Leases – Incentives* and Interpretation 127 *Evaluating the Substance of Transactions Involving the Legal Form of a Lease*.
- The Group will recognise right-of-use assets and lease liabilities for its current operating lease at its Port Melbourne headquarters in Australia and San Diego premises in the US. The nature of the expense related to those leases will now change because the Group will recognise a depreciation charge for the right-to-use assets and interest expense on lease liabilities instead of rent expense. The Group continues to consider other leases such as office and other equipment. There will be an impact on the Group's Balance Sheet and Income Statement to reflect this accounting with the transitional impact currently being finalised.

#### **(d) Basis of consolidation**

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 30 June 2019. 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 prior period, and following the first commercial sales of NovoSorb BTM, amortisation was 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.



# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 2. Summary of Significant Accounting Policies continued

### (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 impairment assessment 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 which is based on – 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.

### (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 2019. 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 vesting 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:

Property	40 years
Office equipment	3 to 10 years
Laboratory plant and equipment	3 to 13.33 years
Leasehold improvements	3 to 10 years

### (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) Cash and cash equivalents**

Cash at bank and short-term deposits are stated at nominal value. Cash at bank and short-term deposits are amounts with a maturity of three months or less. If greater than three months, these amounts are recognised within 'other financial assets'.

### **(m) 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.

### **(n) 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.

### **(o) Interest income**

Interest income is recognised when the Group has the right to receive the interest payment using the effective interest rate method.

### **(p) 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.

### **(q) 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.

### **(r) 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.

### **(s) 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 2019

## 2. Summary of Significant Accounting Policies continued

### (t) 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.

### (u) 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.

### (v) 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.

### (w) 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.

## (x) 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.

## (y) 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

### Business Segment

PolyNovo has only one business 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.

During the period, sales to BARDA in the United States of America, represented 30% of total sales revenue from contracts with customers.

	30 June 2019 \$	30 June 2018 \$
<b>Revenue from contracts with customers</b>		
<b>Geographical areas</b>		
United States of America	11,729,101	5,207,741
Australia and New Zealand	1,572,088	376,605
Rest of World	48,031	130,109
	<b>13,349,220</b>	<b>5,714,455</b>

	30 June 2019 \$	30 June 2018 \$
<b>Non-current assets</b>		
<b>Geographical areas</b>		
United States of America	72,907	33,779
Australia and New Zealand	8,254,095	3,663,038
	<b>8,327,002</b>	<b>3,696,817</b>



# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 4. Revenues and Expenses

### (a) Revenue from Contracts with Customers

Below is set out the disaggregation of group revenue from contracts with customers.

	30 June 2019 \$	30 June 2018 \$
Commercial product sales	9,348,226	1,747,102
Sale of materials	-	10,228
Licenses revenue	-	130,109
BARDA revenue	4,000,994	3,827,016
	<b>13,349,220</b>	<b>5,714,455</b>

The comparative period has not been restated on adoption of AASB 15 because this is not done under the modified retrospective approach.

### (b) Finance revenue (net)

	30 June 2019 \$	30 June 2018 \$
Term deposit interest	341,392	236,557
Bank account interest	-	38,746
Other	(7,289)	-
	<b>334,103</b>	<b>275,303</b>

### (c) Employee-related expenses

	30 June 2019 \$	30 June 2018 \$
Wages and salaries (including sales commission)	(6,494,587)	(4,002,385)
Superannuation	(355,097)	(267,013)
Share-based payments (expense)(see Note 6)	(97,040)	(135,404)
Other	(1,602,516)	(1,251,531)
	<b>(8,549,240)</b>	<b>(5,656,333)</b>

Included in other employee related expenses are directors' fees of \$369,230 (2018:\$324,225) and payroll taxes of \$300,985 (2018: \$214,556).

### (d) Depreciation and amortisation expense

	30 June 2019 \$	30 June 2018 \$
Depreciation – property, plant and equipment	(61,752)	(57,966)
Amortisation – intangible assets	(247,848)	(123,924)
	<b>(309,600)</b>	<b>(181,890)</b>

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

## (e) Corporate, administrative and overhead expenses

	30 June 2019 \$	30 June 2018 \$
Insurances	(613,934)	(338,094)
Accounting and audit fees	(365,531)	(199,396)
Investor relations and share registry expenses	(203,618)	(157,797)
Consultants and contractors	(300,520)	(436,240)
Travel	(1,321,801)	(747,035)
Marketing costs	(828,463)	(268,733)
Communication expenses	(82,251)	(110,772)
Foreign exchange gain	345,216	233,766
Other	(601,907)	(311,028)
	<b>(3,972,809)</b>	<b>(2,335,329)</b>

Included in other administrative expenses are software licences \$150,484 (2018: \$31,177) and 3PL fees \$114,019 (2018: \$80,555).

## (f) Research and development tax benefit

Research and development tax benefit income of \$694,602 (2018: \$839,397) was recognised as other income in the Statement of Comprehensive Income. \$694,602 (2018: \$794,255) is receivable, as recognised in the Statement of Financial Position, with respect to the year ended 30 June 2019.

## 5. Income Tax

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

	30 June 2019 \$	30 June 2018 \$
<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)	-	-
<b>Income tax recognised directly in equity</b>		
Deferred tax expense	-	-
Available-for-sale asset	-	-
<b>Reconciliation of income tax expense to prima facie tax payable</b>		
Net loss before income tax expense	<b>3,189,893</b>	5,974,132
Prima facie tax calculated at 27.5% (2018: 27.5%)	<b>(877,220)</b>	(1,642,886)
Tax effect of amounts which are not included in accounting loss:		
Research and development	<b>439,116</b>	502,115
Non-assessable R&D income tax credit	<b>(191,016)</b>	(230,834)
Tax effect of amounts which are not deductible:		
Share-based payments	<b>26,686</b>	37,236
	<b>(602,434)</b>	(1,334,369)
Current year tax losses not brought to account	<b>778,965</b>	1,597,423
Current year temporary differences not brought to account	<b>(176,531)</b>	(263,053)
Income tax benefit/(income tax expense)	-	-

# Notes to the Financial Statements continued

## For the year ended 30 June 2019

### 5. Income Tax continued

#### (b) Deferred tax assets and liabilities

	30 June 2019 \$	30 June 2018 \$
Deferred tax assets	435,521	411,203
Deferred tax liabilities	(435,521)	(411,203)
Net deferred tax assets/(liabilities)	-	-
<b>Deferred tax balances reflects temporary differences attributable to:</b>		
Amounts recognised in profit and loss		
Recognised tax losses	201,724	147,266
Recognised on temporary differences	233,797	263,937
Amount recognised due to acquisition of PolyNovo	(435,521)	(411,203)
Net deferred tax assets/(liabilities)	-	-
<b>Movement in temporary differences during the year:</b>		
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

	30 June 2019 \$	30 June 2018 \$
Unrecognised, unconfirmed tax losses for which no deferred tax asset has been recognised	92,462,871	91,718,206
Deductible temporary differences – no deferred tax asset has been recognised	641,934	956,558
	93,104,805	92,674,764
Potential tax benefit at 27.5%	25,603,821	25,485,560

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 2019 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 net 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.

## 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 2019 and 30 June 2018 were \$97,040 and \$138,231 respectively.

### (b) Share-based payments for the year ended 30 June 2019

During the 2019 financial year, 1,000,000 options were issued and 3,000,000 were exercised. Details of the share options granted pursuant to the terms of the PolyNovo Employee Share Option Plan (ESOP) are as follows:

- On 6 March 2019, the Company granted employee share options to Mr Jan Gielen. He was granted 1,000,000 options exercisable at \$0.60. The options vest upon 12 months of employment with the Company and a share price of \$0.90 being sustained over a period of 90 consecutive calendar days. Once vested, the options can be exercised as follows:
  - Tranche 1: not to be exercised before 31 December 2020 and not later than 30 June 2021.
  - Tranche 2: not to be exercised before 31 December 2021 and not later than 30 June 2022.
  - Tranche 3: not to be exercised before 31 December 2022 and not later than 30 June 2023.

If not exercised the options become void. The options package will expire on 30 June 2023. The expense relating to the options package during the year was \$56,913. Should the CFO leave employment prior to the exercise date, the share options will be forfeited and option expenses will be reversed.

The weighted average share price of the options exercised in the period was \$0.32.

The expense relating to the incentive scheme shares recognised in the Statement of Comprehensive Income during the 2019 financial year was \$97,041.

	Balance at 1 July 2018	Granted as compensation	Options exercised	Net change other (forfeited, lapsed, expired)*	Balance at 30 June 2019	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 pay- ments expense \$
<b>Directors</b>										
Mr Leon Hoare	1,000,000	-	1,000,000	-	-	-	-	-	-	-
<b>Other key management personnel</b>										
Mr Jan Gielen	-	1,000,000	-	-	1,000,000	-	-	1,000,000	-	56,913
Mr Greg Lewis	1,000,000	-	-	(1,000,000)	-	-	-	-	-	-
Other employees	2,000,000	-	2,000,000	-	-	-	-	(2,000,000)		40,128
<b>Total</b>	<b>4,000,000</b>	<b>1,000,000</b>	<b>3,000,000</b>	<b>(1,000,000)</b>	<b>1,000,000</b>	<b>-</b>	<b>-</b>	<b>1,000,000</b>	<b>(2,000,000)</b>	<b>97,041</b>

\* The net change reflects share options forfeited in the period by the former CFO.

The fair value of options granted during 2019, 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.

Mr Lewis options were forfeited upon cessation of his employment on 7 December 2018.

### 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
6 March 2019	1,000,000	\$0.60	12 months service period and 3 months share price exceeds \$0.90	T1 1.67%	45.9%	30-Jun-21	-	\$0.236
				T2 1.60%	54.8%	30-Jun-22	-	\$0.311
				T3 1.65%	59.7%	30-Jun-23	-	\$0.394

\* Each tranche must be exercised by the expiry date and 31 December of the preceding year otherwise they become void.



# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 6. Share-Based Payments continued

### (b) Share-based payments for the year ended 30 June 2019 continued

Options issued during the period continued

Key valuation assumptions for the Employee Share Options:

Parameters	Assumptions
Valuation date	Grant Date
Share price	Closing share price as at the valuation Date – Source: Bloomberg.
Expected life	Assumed Share Appreciation Rights will be exercised at the first opportunity i.e. as early as possible.
Risk-free interest rate	The risk free interest rates are derived from the Australian Government Bonds as at Valuation Date. The terms to maturity have been selected to align with the expected life of the options.
Dividend yield	The dividend yield is the rate of dividend expressed as a continually compounded percentage of the share price. In determining an appropriate dividend yield, forecasted dividend information provided by the management of Polynovo Limited has been relied upon.
Expected volatility	A share's volatility measure captures the characteristics of fluctuations in the share's price.  The value of options is extremely sensitive to the volatility measure and as a result great care should be taken in determining the appropriate volatility percentage. To accurately value options, a volatility measure should be selected that is most likely to represent the future volatility of the shares during the life of the options: the implied volatility.  Accordingly, in determining the expected volatility, the historical market volatility has been taken into account.
Other	Other assumptions that have not been incorporated into our valuation model include:  (i) any change of control events and reorganisation of capital during the relevant performance periods or service periods.  (ii) any dilution effect from the issue of options noting that they will not likely have a material impact on the Polynovo Limited security price.

During the period, one further option arrangement was issued to an employee who subsequently left the group in the same period. The options did not vest during this period and were forfeited on resignation from the Group. As a consequence of the options being forfeited, no option expense was recorded with respect to this arrangement.

### (c) 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, the former CFO. 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 expired on 30 June 2019. The expense relating to the option package during the year was \$2,827. Management assessed the probability of achieving the first hurdle to be 10%. Mr Lewis ceased employment with the Company on 7 December 2018 and consequently forfeited his options package.

The expense relating to the incentive scheme shares recognised in the Statement of Comprehensive Income during the 2018 financial year was \$138,231.

	Balance at 1 July 2017	Granted as compensation	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 \$
<b>Directors</b>										
Mr Leon Hoare	1,000,000	-	-	1,000,000	1,000,000	1,000,000	-	-	-	
<b>Other key management personnel</b>										
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	-	
<b>Other employees</b>										
	2,000,000	-	-	-	2,000,000	-	-	2,000,000	-	79,601
<b>Total</b>	<b>7,185,095</b>	<b>1,000,000</b>	<b>(4,185,095)</b>	<b>-</b>	<b>4,000,000</b>	<b>1,000,000</b>	<b>1,000,000</b>	<b>3,000,000</b>	<b>(4,185,095)</b>	<b>\$138,231</b>

The fair value of options granted during 2018, as included in the above table, was 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.

## 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 2019	(0.48) cents per share	30 June 2018	(0.95) cents per share
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### Diluted EPS:

30 June 2019	(0.48) cents per share	30 June 2018	(0.95) cents per share
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	30 June 2019 \$	30 June 2018 \$
<b>The following reflects the income and share data used in the calculation of basic and diluted EPS:</b>		
Net loss used in calculating basic and diluted EPS attributable to equity holders of the parent entity	(3,189,893)	(5,974,132)
Weighted average number of ordinary shares on issue used in the calculation of basic EPS	659,663,386	627,887,135
Potential weighted average number of ordinary shares on issue plus all unexercised share options used in the calculation of diluted EPS	660,663,386	630,887,135

At 30 June 2019 there existed share options that if vested, would result in the issue of additional ordinary shares over the period to FY2023. In the current period, these potential ordinary shares are considered antidilutive as their conversion to ordinary shares would reduce the loss per share. Accordingly, they have been excluded from the dilutive earnings per share calculation. There were no further 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 2019 \$	30 June 2018 \$
Cash at bank <sup>(i)</sup>	13,920,695	3,147,081
Cash and cash equivalents are denominated in:		
Australian dollars	10,464,990	1,435,669
US dollars	3,233,959	1,694,839
NZ dollars	221,746	16,573
	13,920,695	3,147,081

(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.

# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 8. Cash and Cash Equivalents continued

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

	30 June 2019 \$	30 June 2018 \$
Net Loss	(3,189,893)	(5,974,132)
Adjustments for non-cash items:		
Depreciation and amortisation	691,033	542,933
Share-based payment expense	97,041	135,404
Interest	(247,463)	(272,066)
Unrealised foreign exchange rate differences	(348,625)	(226,828)
Change in assets and liabilities during the financial year:		
(Increase)/decrease in prepayments	(145,556)	(102,759)
(Increase)/decrease in trade receivables	(1,007,641)	(984,141)
(Increase)/decrease in inventory	(962,522)	(102,474)
(Increase)/decrease in other assets	(131,864)	(127,514)
Increase/(decrease) in payables	1,567,567	(84,399)
Increase/(decrease) in provisions	54,925	113,488
Increase/(decrease) in other liabilities	253,265	204,527
Net cash outflows from operating activities	(3,369,733)	(6,877,961)

## 9. Inventories

Inventories comprise of the following:

	30 June 2019 \$	30 June 2018 \$
Finished goods	947,926	930,888
Provision for finished goods	-	(3,596)
	947,926	927,292
Work in progress	218,719	112,374
	1,166,645	1,039,666
Raw materials and other (at cost)	48,805	43,920
	1,215,450	1,083,586

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 \$340,269 as a result of product expiry dates. The expired inventory was written off in the month of January 2019, being the balance of the excess stock manufactured in the lead up to commercial sales in the US market in 2017.

## 10. Receivables and contract assets (Current)

	30 June 2019 \$	30 June 2018 \$
Trade receivables	2,483,424	1,469,730
Contract assets	442,405	128,844
R&D tax concession	694,602	794,255
Interest receivable	-	235,313
GST recoverable	43,755	26,833
Sundry receivables	740,861	24,700
	4,405,047	2,679,675

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

Sundry receivables includes \$724,966 representing non-refundable deposits for manufacturing equipment purchased from suppliers. The significant changes in the balances of trade receivables and the information about the credit exposures are disclosed in Note 22(e).

## Contract assets

Contract assets are initially recognised for revenue earned from the provision of research and development services as receipt of consideration is conditional on the acceptance by the customer. Upon completion of the milestone and acceptance by the customer, the amounts recognised as contract assets are reclassified to trade receivables.

As at 30 June 2019, the Group has contract assets of \$448,457 (2018: \$128,844). Amounts are invoiced in the month following satisfaction of the performance obligation. There are no significant expected credit losses related to the contract assets.

The Group has an agreement with BARDA to provide research and development services, which will run for 8 years. Under this agreement \$3,593,072 revenue is expected to be recognised within the remaining life of the agreement which will be across the contract period through to its termination date in August 2020.

Based on the business failure rates by class of customers and Dun & Bradstreet credit score the Expected Credit Losses relating to trade receivables and contract assets the Group has recognised \$27,076 as at 30 June 2019. No trade receivables or contract assets were written off during the period (2018: \$nil).

As described in note 2(c), the Group uses a provision matrix to measure its expected credit loss. Set out below is information about the credit risk exposure on the Group's trade receivables and contract assets using a provision matrix as at 30 June 2019:

	Trade Receivables			Total \$
	May 30–60 Days \$	Apr 60–90 Days \$	Mar+ 90+ Days \$	
Expected credit loss rate	0.9%	3.2%	16.1%	
Estimated total gross carrying amount at default	313,350	66,675	136,678	2,483,424
Expected credit loss	2,936	2,165	21,974	27,076

Contract assets and trade receivables due in less than 30 days and other financial assets have an expected credit loss which are not significant.

## 11. Other Assets (Non-Current)

### Non-current

	30 June 2019 \$	30 June 2018 \$
Security deposit	170,767	161,288

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

## 12. Property, Plant and Equipment

	30 June 2019 \$	30 June 2018 \$
<b>Property</b>		
(i) Cost		
Opening balance	-	-
Additions	4,894,863	-
Closing balance	4,894,863	-



# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 12. Property, Plant and Equipment continued

	30 June 2019 \$	30 June 2018 \$
<b>(ii) Accumulated depreciation</b>		
Opening balance	-	-
Depreciation for the year	-	-
<b>Closing balance</b>	-	-
<b>Net book value – property</b>	<b>4,894,863</b>	-

During the period, the group acquired the freehold property of a property in Port Melbourne for total cost \$4,894,863 inclusive of non-refundable purchase taxes. Depreciation on the building has not commenced as it is currently being fitted out and is not available for use.

	30 June 2019 \$	30 June 2018 \$
<b>Office equipment</b>		
<b>(i) Cost</b>		
Opening balance	509,733	428,502
Additions	54,991	81,231
Disposals	(2,017)	-
<b>Closing balance</b>	<b>562,707</b>	509,733
<b>(ii) Accumulated depreciation</b>		
Opening balance	(328,203)	(270,236)
Depreciation for the year	(60,052)	(57,967)
<b>Closing balance</b>	<b>(388,255)</b>	(328,203)
<b>Net book value – office equipment</b>	<b>174,452</b>	181,530

	30 June 2019 \$	30 June 2018 \$
<b>Laboratory plant and equipment</b>		
<b>(i) Cost</b>		
Opening balance	1,386,301	1,363,120
Additions	295,607	23,181
<b>Closing balance</b>	<b>1,681,908</b>	1,386,301
<b>(ii) Accumulated depreciation</b>		
Opening balance	(1,101,441)	(1,024,069)
Depreciation for the year	(82,032)	(77,373)
<b>Closing balance</b>	<b>(1,183,473)</b>	(1,101,442)
<b>Net book value – laboratory plant and equipment</b>	<b>498,435</b>	284,859

	30 June 2019 \$	30 June 2018 \$
<b>Leasehold improvements</b>		
<b>(i) Cost</b>		
Opening balance	1,936,560	1,934,652
Additions	65,519	1,908
<b>Closing balance</b>	<b>2,002,079</b>	1,936,560
<b>(ii) Accumulated depreciation</b>		
Opening balance	(1,263,284)	(979,615)
Depreciation for the year	(298,326)	(283,669)
<b>Closing balance</b>	<b>(1,561,610)</b>	(1,263,284)
<b>Net book value – leasehold improvements</b>	<b>440,469</b>	673,276
<b>Net book value – property, plant and equipment</b>	<b>6,008,219</b>	1,139,665

### 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.

Following the consistent commercial sales of NovoSorb BTM, amortisation of intangible assets commenced in FY2018 over the remaining finite life through to March 2028 being the remaining patent life period over which economic benefits will be consumed. No indicators of impairment related to the NovoSorb technology have been identified as at 30 June 2019.

	30 June 2019 \$	30 June 2018 \$
<b>Intangibles</b>		
<b>(i) Cost</b>		
Opening balance	2,519,788	2,519,788
Additions	-	-
<b>Closing balance</b>	<b>2,519,788</b>	2,519,788
<b>(ii) Accumulated amortisation</b>		
Opening balance	(123,924)	-
Amortisation for the year	(247,848)	(123,924)
<b>Closing balance</b>	<b>(371,772)</b>	(123,924)
<b>Net book value</b>	<b>2,148,016</b>	2,395,864

### 14. Trade and Other Payables

	30 June 2019 \$	30 June 2018 \$
Trade creditors and payables	581,698	223,355
Other payables	1,170,131	719,364
<b>Total trade and other payables</b>	<b>1,751,829</b>	942,719

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

### 15. Provisions

#### (a) Current provisions

	30 June 2019 \$	30 June 2018 \$
Annual leave	245,739	216,165
Long service leave	66,433	59,533
<b>Total current provisions</b>	<b>312,172</b>	275,698

#### (b) Non-current provisions

Long service leave	47,738	29,287
<b>Total non-current provisions</b>	<b>47,738</b>	29,287

# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 16. Contributed Equity and Reserves

### (a) Movement in contributed equity

	30 June 2019 \$	30 June 2018 \$
Contributed equity at beginning of year	138,120,502	114,476,370
Shares issued: capital raising	-	23,045,749
Costs of share issue	-	(818,276)
Exercise of options	950,000	1,416,659
<b>Contributed equity at end of year</b>	<b>139,070,502</b>	<b>138,120,502</b>

	Number of Shares	
On issue at start of year	658,088,044	563,049,010
Shares issued: capital raising	-	85,353,939
Exercise of options	3,000,000	9,685,095
<b>On issue at end of year</b>	<b>661,088,044</b>	<b>658,088,044</b>

### (b) Reserves

	30 June 2019 \$	30 June 2018 \$
Share-based payments reserve (i)	3,157,986	3,060,945
Foreign currency translation reserve (ii)	(375,939)	(159,300)
Acquisition of non-controlling interest reserve (iii)	(9,293,956)	(9,293,956)
<b>Balance at end of period</b>	<b>(6,511,909)</b>	<b>(6,392,311)</b>

#### (i) Share-based payments reserve

	30 June 2019	30 June 2018
Balance at beginning of period	3,060,945	2,925,541
Share-based payments movement	97,041	135,404
<b>Balance at end of period</b>	<b>3,157,986</b>	<b>3,060,945</b>

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

#### (ii) Foreign currency translation reserve

	30 June 2019	30 June 2018
Opening balance	(159,300)	-
Translation of foreign operations	(216,639)	(159,300)
<b>Balance at end of period</b>	<b>(375,939)</b>	<b>(159,300)</b>

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.

#### (iii) Acquisition of non-controlling interest reserve

	30 June 2019	30 June 2018
Opening balance	(9,293,956)	(9,293,956)
<b>Balance at end of year</b>	<b>(9,293,956)</b>	<b>(9,293,956)</b>

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

### (c) Accumulated losses

	30 June 2019 \$	30 June 2018 \$
Accumulated losses at beginning of year	(103,269,221)	(97,295,089)
Net loss attributable to members of the parent	(3,189,893)	(5,974,132)
<b>Accumulated losses at end of financial year</b>	<b>(106,459,114)</b>	<b>(103,269,221)</b>

## 17. Commitments and Contingencies

### Operating lease commitments

The Group has entered into new commercial office and laboratory leases. The lease for the premises in Port Melbourne is for a term of 10 years, from 2019 to 2029. The lease for the premises in San Diego is for a term of 3 years, from 2018 to 2021. Future minimum rentals payable under the non-cancellable operating leases are as follows:

	30 June 2019 \$	30 June 2018 \$
Not later than one year	311,385	298,022
Later than one year, but not later than five years	1,166,854	256,576
Later than 5 years	1,527,138	-
	<b>3,005,377</b>	<b>554,598</b>

The operating lease commitments do not include any lease option extensions which may be available to the Group in the office lease contracts.

### Manufacturing equipment commitments

The Group has entered into new contractual agreements with suppliers for the supply of manufacturing equipment. The equipment will be received in FY2020 and the remaining balance of \$3,084,476 will be paid accordingly.

### Contingencies

The Directors are not aware of any other contingent liabilities or contingent assets at 30 June 2019. 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 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 2019 \$	30 June 2018 \$
An audit or review of the Financial Reports of the entity:		
- Half-year and full-year audits	145,577	110,722
Other services in relation to the entity:		
- Tax compliance services	111,422	89,546
- Other compliance services supporting GST and importer registrations into NZ	950	5,449
- Advice on mileage and petrol reimbursements in the USA	6,958	-
<b>Total auditor's remuneration</b>	<b>264,907</b>	<b>205,717</b>

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 2019 \$	30 June 2018 \$
Current assets	47,644,550	45,863,400
Total assets	53,676,752	51,900,336
Current liabilities	1,433,889	213,298
Total liabilities	1,433,889	213,298
Issued capital	139,070,502	138,120,502
Retained earnings	(84,021,405)	(83,530,190)
Total reserves	(2,806,234)	(2,903,274)
Total shareholders' equity	52,242,863	51,687,038
Loss of the parent entity	(491,215)	(420,975)
Total comprehensive loss of the parent entity	(491,215)	(420,975)

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



# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 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 and other financial assets.

	30 June 2019 \$	30 June 2018 \$
Cash and cash equivalents	13,920,695	3,147,081
Trade and other receivables	4,405,047	2,679,675
Other financial assets (at amortised cost) <sup>1,2</sup>	50,000	19,050,000
Trade and other payables	1,751,829	942,719

1. At 30 June 2018, the carrying value of \$19,000,000 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.

### (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.

### (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 2019, 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 \$
<b>2019</b>								
<b>Financial assets:</b>								
Cash and cash equivalents	1.39%	13,920,695	-	-	-	-	-	13,920,695
Other financial assets	2.64%	-	-	50,000	-	-	-	50,000
Receivables	-	-	-	-	-	-	3,680,081	3,680,081
<b>Total financial assets</b>		<b>13,920,695</b>	<b>-</b>	<b>50,000</b>	<b>-</b>	<b>-</b>	<b>3,680,081</b>	<b>17,50,776</b>
<b>Financial liabilities:</b>								
Trade and other payables	-	-	-	-	-	-	1,751,829	1,751,829
<b>Total financial liabilities:</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,751,829</b>	<b>1,751,829</b>
<b>2018</b>								
<b>Financial assets:</b>								
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
<b>Total financial assets</b>		<b>3,147,081</b>	<b>19,000,000</b>	<b>50,000</b>	<b>-</b>	<b>-</b>	<b>2,679,675</b>	<b>24,876,756</b>
<b>Financial liabilities:</b>								
Trade and other payables	-	-	-	-	-	-	942,719	942,719
<b>Total financial liabilities:</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>942,719</b>	<b>942,719</b>

There has been no change to the Group's exposure to interest rate risk, other than the fact that cash holdings are lower 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.

The Group had a large component of cash invested in fixed term deposits in the 2018 financial year as the Company received \$22.2 million (net of costs) from a capital raising and \$1.4 million from the exercise of employee share options. As the various fixed terms expired, the funds have been reinvested short-term in the expectation that cash is required to fund current operations but to a lesser extent due to the build in trade receivables commensurate with the increase in commercial product sales to hospitals and distributors.

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) 2019 \$	Loss (higher)/lower Equity higher/(lower) 2018 \$
+ 1% (100 basis points)	139,707	190,659
- 1% (100 basis points)	(139,707)	(190,659)

The range of +1%/-1% as an assumption is based on current macro-market economic conditions in which the group holds its cash and cash equivalent balances.

# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 22. Financial Risk Management Objectives and Policies continued

### (e) Financial risk management continued

#### 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 2019, the contract asset at 30 June 2019 includes \$373,005 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 2019, the trade receivables balance at 30 June 2019 includes \$1,935,512 owing by customers. Trade receivables has grown significantly and this is expected to continue 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 \$
<b>2019</b>					
Trade and other receivables	2,452,198	323,983	66,079	143,219	2,985,479
<b>2018</b>					
Trade and other receivables	1,606,847	95,793	42,706	140,074	1,885,420

The above total trade and other receivable amounts as at 30 June 2019 and 30 June 2018 do not include the R&D tax credit receivable amounts of \$694,602 and \$794,255 respectively.

The Group considers the maximum credit risk from potential default of the counter party to be equal to the carrying amount of the asset. Receivable balances are monitored on an ongoing basis with the result that the Group's exposure to credit loss is not significant.

#### 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 is set out below:

	0-30 days \$	30-60 days \$	60-90 days \$	90+ day \$	Total \$
<b>2019</b>					
Trade and other payables	1,342,643	182,905	152,939	73,342	1,751,829
<b>2018</b>					
Trade and other payables	942,226	74	34	385	942,719

#### 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 and NZD. To reduce foreign currency risk exposure, the Group maintains an amount of cash and cash equivalents in USD and NZD. The Group receives payment from its overseas customers in USD and NZD, and pays USD and NZD trade payables from its USD and NZD funds. EURO denominated payable balances carry some foreign currency risk, however these payable balances are typically infrequent and low in value and are therefore considered to expose the Group to minimal risk. At 30 June 2019 the Group had a EURO denominated prepaid balance of \$672,209 representing a non-refundable deposit on R&D manufacturing equipment the Group will receive in FY20. The Company has subsequently opened a EURO bank account to mitigate foreign currency exposure.

The holdings of cash and cash equivalents, trade receivables and trade payables analysed by nominated currency at 30 June 2019, along with prior year comparatives, were as follows.

	Denominated in AUD \$	Denominated in USD \$	Denominated in NZD \$	Denominated EURO \$	Denominated In GBP \$	Total \$
<b>2019</b>						
<b>Financial assets</b>						
Cash and cash equivalents	10,464,990	3,233,959	221,746	-		13,920,695
Receivables	964,175	2,759,895	8,768	672,209	-	4,405,047
<b>Total financial assets</b>	<b>11,429,165</b>	<b>5,993,854</b>	<b>230,514</b>	<b>672,209</b>	<b>-</b>	<b>18,325,742</b>
<b>Financial liabilities</b>						
Trade and other payables	668,452	1,040,821	27,436	-	15,120	1,751,829
<b>Total financial liabilities</b>	<b>668,452</b>	<b>1,040,821</b>	<b>27,436</b>	<b>-</b>	<b>15,120</b>	<b>1,751,829</b>

A hypothetical 10% strengthening in the exchange rate of the Australian dollar against the US dollar (as at 30 June 2019) with all other variables held constant would have a \$65,950 unfavourable effect on the loss and equity for the 2019 financial year. A 10% strengthening in the exchange rate has been applied based on current market economic conditions.

	Denominated in AUD \$	Denominated in USD \$	Denominated in NZD \$	Total \$
<b>2018</b>				
<b>Financial assets</b>				
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
<b>Total financial assets</b>	<b>2,616,166</b>	<b>3,183,231</b>	<b>27,359</b>	<b>5,826,756</b>
<b>Financial liabilities</b>				
Trade and other payables	495,462	446,468	789	942,719
<b>Total financial liabilities</b>	<b>495,462</b>	<b>446,468</b>	<b>789</b>	<b>942,719</b>

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. A 10% strengthening in the exchange rate has been applied based on current market economic conditions.

## 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 2019 and 2018 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.

# Notes to the Financial Statements continued

For the year ended 30 June 2019

## 23. Key Management Personnel Disclosures continued

### (b) Compensation by category: key management personnel

	30 June 2019 \$	30 June 2018 \$
Short term	888,135	820,694
Post-employment – superannuation	72,106	60,612
Leave allowances	42,752	27,512
Share-based payments	54,086	58,630
Termination benefits	-	68,458
	<b>1,057,079</b>	1,035,906

### (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	2019 number outstanding	2018 number outstanding
2016	01/02/19	\$0.25	-	500,000
2016	01/02/19	\$0.33	-	500,000
2017	30/06/19	\$0.35	-	1,000,000
2019	30/06/21	\$0.60	300,000	-
2019	30/06/22	\$0.60	300,000	-
2019	30/06/23	\$0.60	400,000	-
	1,000,000	2,000,000	<b>1,000,000</b>	2,000,000

### (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

There were transactions with Directors during the year ended 30 June 2019 as follows:

- David McQuillan and Associates LLC, an entity associated with Dr David McQuillan, received payments in the amount of \$69,912 (2018: \$50,517). These payments were in respect to consulting services provided to PolyNovo North America LLC in relation to advisory and consulting services for the hernia project. 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:

	Country of incorporation	Percentage owned	
		30 June 2019 %	30 June 2018 %
<b>Company:</b>			
PolyNovo Limited	Australia	100%	100%
<b>Subsidiaries of PolyNovo Limited:</b>			
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 NZ Limited	New Zealand	100%	-
PolyNovo UK Limited	United Kingdom	100%	-



# Directors' Declaration

## For the year ended 30 June 2019

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 2019 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 2019.

On behalf of the Board,



**Mr David Williams**  
Chairman

22 August 2019

# Independent Auditor's Report

For the year ended 30 June 2019



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Ernst & Young  
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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 2019, 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 2019 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.

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.



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## Recognition of revenue

Why significant	How our audit addressed the key audit matter
<p>The Group has recognised revenue from the sale of commercial products and revenue from services performed in respect of research and development.</p> <p>For sales of commercial products, revenue is recognised upon delivery of the product to the customer. The Group sells to customers in various territories. Commercial product sales have significantly increased this financial year.</p> <p>The Group was required to consider the requirements of AASB 15 <i>Revenue from Contracts with Customers</i> with respect to its revenue streams as this standard became applicable for the first time this financial year.</p> <p>Notes 2, 3 and 4 of the financial statements outline the Company's accounting policies with respect to revenue recognition and revenue disclosures.</p> <p>Revenue recognition was considered a key audit matter due to the increasing sales profile of the Group and the first time application of AASB 15.</p>	<p>Our audit procedures with respect to the Group's revenue recognition included:</p> <ul style="list-style-type: none"> <li>▶ reviewing contracts with customers for terms and conditions that could impact the timing of recognition and measurement of revenue;</li> <li>▶ assessing the operating effectiveness of the Group's controls by testing a sample of controls with respect to the initiation and recording of commercial sales transactions;</li> <li>▶ assessing on a sample basis, whether revenue was correctly recognised based on the products delivered as at 30 June 2019 with reference to supporting documentation including contracts, purchase orders and proof of delivery;</li> <li>▶ assessing the Group's performance obligations under the services contract to check that revenue is recognised only for services provided during the year and at the contracted rate;</li> <li>▶ assessing whether the Company's revenue disclosures as outlined in Notes 2, 3 and 4 are complete and meet the requirements of Australian Accounting Standards.</li> </ul>

## Existence and valuation of inventory

Why significant	How our audit addressed the key audit matter
<p>At 30 June 2019, the Group held inventory of \$1.2 million which comprised raw materials, work in progress and finished goods.</p> <p>Material inventories were held at a central warehouse in Australia and by a third-party logistics provider in the United States of America ('US').</p> <p>The cost of inventory is determined based on the standard cost of production and capitalisable manufacturing variances. The net realisable value of the inventory is assessed at year end considering inventory sales, forecast usage and expiry dates of products.</p> <p>The existence and valuation of inventory was considered a key audit matter given the significance of the inventory balance at 30 June 2019 and the judgements required in determining the valuation of inventory at year end.</p>	<p>Our procedures with respect to existence and valuation of inventory included:</p> <ul style="list-style-type: none"> <li>▶ attending the inventory counts that occurred, reperforming the inventory counts and agreeing count results into the year end inventory listing;</li> <li>▶ assessing that the nature of costs included in inventory including allocations of labour and manufacturing overheads, were consistent with the requirements of Australian Accounting Standards;</li> <li>▶ agreed, on a sample basis, the amount of costs capitalised in inventory to supporting documentation;</li> <li>▶ assessing and recalculating the Group's judgement related to the stock turn used in capitalising manufacturing variances; and</li> <li>▶ assessed the inventory net realisable values with reference to the ageing of inventory, expiry dates, gross margins achieved and sales forecasts.</li> </ul>

# Independent Auditor's Report continued

For the year ended 30 June 2019



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## Accounting for share based payment arrangements

### Why significant

During the year, the Group issued options to certain employees, including the new Chief Financial Officer, under share based payment arrangements. The share based payment arrangements included both market based and non-market based vesting conditions. In determining the value of the new arrangement, the Group used the services of a third-party valuation specialist.

The Group also has existing share based payment arrangements with the former Chief Financial & Operating Officer and other employees.

Details of these share based payment arrangements are disclosed in Note 6 of the financial report and the Remuneration Report with respect to the arrangements with the Chief Financial Officers.

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.

### How our audit addressed the key audit matter

Our procedures with respect to share based payment arrangements included:

- ▶ agreeing the terms of the share based payment arrangements issued during the period to contracts;
- ▶ assessing, in conjunction with our Valuation specialists, the appropriateness of the valuation methodology used by management's specialist and the key input assumptions such as volatility rates, expected life and probability of achieving the market-based performance condition;
- ▶ assessing the Group's judgements in relation to the probability of achieving non-market based vesting conditions;
- ▶ recalculating the share based payments expense recorded in the Statement of Comprehensive Income over the relevant vesting periods; and
- ▶ assessing the disclosures in Note 6 and the Remuneration Report 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 2019 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.

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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 judgment 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.



# Independent Auditor's Report continued

For the year ended 30 June 2019



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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.

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

## Report on the 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 2019.

In our opinion, the Remuneration Report of PolyNovo Limited for the year ended 30 June 2019, 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.

A handwritten signature in black ink that reads 'Ernst + Young'.

Ernst & Young

A handwritten signature in black ink that reads 'Joanne Lonergan'.

Joanne Lonergan  
Partner Melbourne  
22 August 2019

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# Additional Information Required by ASX

For the year ended 30 June 2019

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

## Ordinary Shares

As at 12 August 2019 there were 661,088,044 ordinary shares on issue held by 10,313 shareholders. Each ordinary share carries one vote per share.

## Top 20 Shareholders as at 12 August 2019

Shareholder	No. of shares	%
HSBC Custody Nominees (Australia) Limited	58,830,306	8.90
J P Morgan Nominees Australia Pty Limited	33,667,129	5.09
Moggs Creek Pty Ltd <Moggs Creek Super A/C>	16,000,000	2.42
Merrill Lynch (Australia) Nominees Pty Limited	14,962,331	2.26
Citicorp Nominees Pty Limited	14,626,121	2.21
National Nominees Limited	11,368,395	1.72
Lateral Innovations Pty Ltd <Trust A/C>	10,924,103	1.65
Monash Investment Holdings Pty Ltd	9,607,520	1.45
The Trust Company (Australia) Limited <MOF A/C>	9,500,000	1.44
Dr John Edward Greenwood <The Greenwood Family A/C>	9,457,864	1.43
Sandhurst Trustees Ltd <Jmfg Consol A/C>	7,890,796	1.19
Mr Anthony Shane Kittel + Mrs Michele Therese Kittel <Kittel Family Super A/C>	7,620,000	1.15
BNP Paribas Nominees Pty Ltd <IB AU Noms Retailclient DRP>	5,788,011	0.88
J A B Investments (SA) Pty Ltd <J A B A/C>	5,055,555	0.76
Ms Simone Maree Beks	4,185,095	0.63
Mr Paul Gerard Brennan	4,185,095	0.63
Mr Laurent Fossaert	4,110,694	0.62
Commonwealth Scientific and Industrial Research Organisation	4,081,250	0.62
Mr David Kenley	3,860,000	0.58
BNP Paribas Nominees Pty Ltd <Agency Lending DRP A/C>	3,850,330	0.58
Total	239,570,595	36.24

# Additional Information Required by ASX<sup>continued</sup>

For the year ended 30 June 2019

## Unquoted Securities

### Options over unissued shares

As at 30 June 2019, a total of 1,000,000 options over ordinary shares are on issue held by one individual holder. There are no 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 2019. 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 12 August 2019 is as follows:

Range of units	No. of holders	No. of shares
1 – 1000	1,517	929,040
1,001 – 5,000	3,162	9,175,896
5,001 – 10,000	1,688	13,485,032
10,001 – 100,000	3,162	107,312,704
100,001 and over	784	530,185,372
Number of holders with less than a marketable parcel	332	32,305

## 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	58,830,306
J P Morgan Nominees Australia Pty Limited	33,667,129

## 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 Jan Gielen

## 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 3000

## Website

[www.polynovo.com.au](http://www.polynovo.com.au)

## Australian Securities Exchange

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



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