

# Half-Year Reports

**Announcement of Half-Year Results**

**Appendix 4D**

**Half-Year Financial Report**

PolyNovo Limited  
ABN 96 083 866 862  
15 February 2018

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# Announcement of Half-Year Results

15 February 2018



## Half Year Results

PolyNovo Limited ("Company" or "PolyNovo") today announced its half year results for the period ending 31 December 2017.

The Company reported a net loss after income tax of \$3.23 million (2016: \$1.97 million). The net loss for the six months January to June 2017 was \$3.04 million. The increased loss reflects the investments made in commercialisation of NovoSorb BTM, new product development and an allowance for inventory expiry.

Total revenue of \$2.75 million (2016: \$2.09 million) includes commercial sales of NovoSorb BTM of \$0.87 million. The total revenue for the six months January to June 2017 was \$1.67 million. Revenue from the BARDA contract for the period was \$1.85 million.

At 31 December 2017, the Company held \$25.7 million in cash and short term investments.

PolyNovo has expanded its US sales team from 3 to 5 and is currently recruiting an additional 2 people and a marketing director to accelerate sales. Following the early success of the US sales model, PolyNovo is also taking a direct sales approach in Australia and New Zealand for faster direct penetration and higher margins.

South African sales are strong through our partner who has made a significant investment in sales and marketing. PolyNovo has signed AMI Technologies as our distribution partner in Israel with first sales expected in the 2H FY18.

During the period, the Company's key initiatives and achievements include:

- First commercial sales in the USA in September 2017
- Commissioning of an enlarged cleanroom production facility
- Receipt of a new US FDA 510(k) certification for fenestrations of the NovoSorb BTM
- Increased the CE mark trial sites from one to four with the Royal North Shore, Royal Brisbane and Royal Women's hospitals all completing surgeries

- Completion of the first phase of the BARDA swine trial
- Increased US trial sites from three to five with the addition of Wake Forest and Phoenix hospitals
- Capital of \$23m raised via a placement and share purchase plan to support growth
- Further expansion of our team:
  - US sales team increased from three to five employees plus two contract sales representatives
  - R&D team enhanced with the addition of one scientist and another started in January 2018
  - increased numbers and depth of skill within the Q&A team
- Filing the regulatory dossier with TGA under the 'Priority Review Designation' to accelerate the CE Mark pathway
- Attended Medica to access EU market entry options
- Signing of a MOU for the co-development of breast products
- Signing of a distributor agreement for Israel
- Registering of trademarks for PolyNovo, NovoSkin and NovoSorb in various jurisdictions.

As outlined at the Annual General Meeting, our focus is on the commercialisation of NovoSorb BTM. We are actively pursuing opportunities in 3 continents and we believe we are on the cusp of a significant revenue uplift from world markets but especially in the US. The sales team have been working through the hospital procurement processes to ensure we have all the customer systems, staff education and access to enable success.

The recent publication of the use of NovoSorb BTM in necrotizing fasciitis demonstrates the use of our technology. Recent US medical conferences have provided a platform to share further clinical success with a wide range of surgeons. We are also pursuing familiarisation of the products in Plastics, Trauma, General Surgery and Burns Journals to expand our reach.

In the year ahead PolyNovo will also be focused on advancing our new product pipeline in the areas of:

- Breast product developments with our global partner, Establishment Labs
- Further development of our Hernia products
- Supporting BetaCell Technologies with possible human trials of NovoSorb BTM as a dermal depot for islet cell implants to treat Type I Diabetes
- Advancing our development of a drug eluting pellet for subcutaneous use.

A full commentary and analysis of the operations and the 31 December 2017 half year financial report can be found in the Appendix 4D.

## Further information:

David Williams  
Chairman  
Mobile: +61 414 383 593

Paul Brennan  
Chief Executive Officer  
Mobile: +61 427 662 317

## 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.

## 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)

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**Half-Year Report  
PolyNovo Limited  
ABN 96 083 866 862**

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

Reporting Period: Half-Year ended 31 December 2017

Previous Corresponding Period: Half-Year ended 31 December 2016

**2. Results for announcement to the market**

	Change from 2016			2017
2.1 Total revenue	up	31%	to	\$2,746,420
2.2 Loss after tax	up	64%	to	(\$3,227,300)
2.3 Loss after tax attributable to members	up	64%	to	(\$3,227,300)
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 2.4:	Refer to (i) the enclosed announcement by the Chairman and Chief Executive Officer and (ii) the Directors' Report contained in the enclosed Half-Year Financial Report.			

**3. Net tangible assets**

	31 December 2017	30 June 2017
Net tangible asset backing per ordinary security	\$0.043	\$0.015

**4. Consolidated Statements of Comprehensive Income, Financial Position, Changes in Equity and Cash Flow are contained in the enclosed Half-Year Financial Report.**

**5. Details of control gained or lost over entities during the period** Not applicable

**6. Details of individual dividends and payment dates** Not applicable

**7. Details of dividend reinvestment plans** Not applicable

**8. Details of associates and joint venture entities** Not applicable

**9. For foreign entities, which set of accounting standards is used in compiling the report** International Financial Reporting Standards

**9. The Half-Year Financial Report has been reviewed by Ernst & Young. The review report does not contain a modified opinion, emphasis of matter or other matter paragraph. The review report is included in the enclosed Half-Year Financial Report.**

The Half-Year Financial Report should be read in conjunction with the most recent annual financial report.

Date: 15 February 2018

**Gavin Smith**  
Company Secretary

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# Half-Year Financial Report

For the half-year ended  
31 December 2017

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This half-year financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2017 and any public announcements made by PolyNovo Limited during the interim reporting period in accordance with the continuous disclosure requirements of the ASX Listing Rules.

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The new and expanded cleanroom facility provides the production capacity anticipated through to 2020 on a single shift. The new US FDA 510(k) approval for the fenestrated version of the BTM will see stock transition to the new product format. Sales continue to ramp up with further acceleration anticipated with new accounts coming on stream and greater utilisation in existing accounts.



**South Africa** - sales in a wide range of applications including trauma, reconstruction and burns.

**Israel** - regulatory approval pending. Partnership with AMI Technologies for sales and distribution.

**Australia & New Zealand** - resume direct sales and marketing control from Device Technologies.

**US** - Team and sales expansion.

Further market entries in the coming months.



Further investment in the research & development programs in train. We are accelerating our product development pathway of hernia and breast products through team expansion and product manufacturing processes. Targeted waste reduction program in progress to further improve efficiency and reduce cost of goods.



Investment in people is providing PolyNovo with increased capacity to accelerate our R&D, improve our quality system and generate sales. Additional staff employed in research & development, quality management and sales (US and Australia) taking PolyNovo from 22 to 31 employees.



Additional R&D scientist employed during the period and a R&D director commenced in January 2018. This resource build enables PolyNovo to advance our product development schedule and commercial scale up requirements to bring hernia and breast products to market.

### HOA

MOU was signed with Establishment Labs for the co-development of a range of breast products. This has since progressed to a HOA. Further announcements will be made as this program advances.



PolyNovo has resumed direct sales responsibility for NovoSorb BTM in Australia and New Zealand. We thank Device Technologies for their support over the period. Assuming direct marketing and sales in our home markets will give PolyNovo direct customer access, improve our margins and ensure we continue to incorporate learnings from our customers into further product design and refinements.



September 2017 share placement and October 2017 share purchase plan raised \$23m. PolyNovo now well funded to pursue global and product expansion opportunities.

# Directors' Report

For the half-year ended 31 December 2017

The Board of Directors of PolyNovo Limited present their report in respect of the financial half-year ended 31 December 2017 ("the Period").

## Directors and Management

The Company's Directors in office during or since the end of the Period are as detailed below. Directors were in office for the entire reporting period unless otherwise stated.

Mr. David Williams, Non-Executive Chairman  
Mr. Leon Hoare, Non-Executive Director  
Mr. Max Johnston, Non-Executive Director  
Dr. David McQuillan, Non-Executive Director  
Mr. Philip Powell, Non-Executive Director  
Mr. Bruce Rathie, Non-Executive Director

During the Period, the key initiatives and achievements made by PolyNovo include:

- First commercial sales in the USA;
- Commissioning of the enlarged cleanroom production facility;
- Receipt of a new US FDA 510(k) certification for fenestrations of the NovoSorb BTM;
- Increased the CE mark trial sites from one to four with the Royal North Shore, Royal Brisbane and Royal Women's hospitals all completing surgeries;
- Completion of the first phase of the BARDA swine trial;
- Increased US trial sites from three to five, for the BARDA clinical trial;
- Capital of \$23 million raised via a share placement and share purchase plan to support growth initiatives;

"Our Research and Development programs are focused on NovoSorb Hernia and Breast products. Further applications of NovoSorb as a drug elution pellet, dermal depot for Beta cell implants, implant coatings and several other applications are also at various stages of development."

- Further expansion of our team:
  - US sales team increased from three to five employees plus two contract sales representatives.
  - R&D team enhanced with addition of one scientist and another to start in 2018.
  - Increased numbers and depth of skill within the Q&A team.
- Filing the regulatory dossier with the Australian Therapeutic Goods Administration (TGA) under the 'Priority Review Designation' to accelerate the CE Mark pathway;
- Attended Medica to access EU market entry options;
- Signing of a Memorandum of Understanding (MOU) for the co-development of breast products, since updated to a Heads Of Agreement (HOA);
- Signing of a distributor agreement for Israel;
- Registering of trademarks for PolyNovo, NovoSkin and NovoSorb in various jurisdictions.

## Review of Principal Activities and Operations

PolyNovo has a platform technology in NovoSorb biodegradable polymer. NovoSorb Biodegradable Temporising Matrix (BTM) is a dermal matrix used to regenerate missing or damaged dermis. The NovoSorb BTM with US FDA 510(k) approval is the first commercial product sold by PolyNovo. Our Research and Development programs are focused on NovoSorb Hernia and Breast products. Further applications of NovoSorb as a drug elution pellet, dermal depot for Beta cell implants, implant coatings and several other applications are also at various stages of development.

## Biodegradable Temporising Matrix (BTM)

A new US FDA 510(k) approval for NovoSorb BTM with fenestrations has been approved for use in surgical wound repair. We expanded our US sales team in response to increased hospital activity, trial of the NovoSorb BTM and revenue generation. This success in the US has prompted PolyNovo to assume direct sales control in the New Zealand and the Australian markets. South Africa has achieved sales and re-orders for the NovoSorb BTM after several successful surgeries in various hospitals.

# Directors' Report continued

## For the half-year ended 31 December 2017

Our Biomedical Advanced Research and Development Authority (BARDA) contract commenced on 28 September 2015.

This is a non-dilutive capital contract that supports a projected five year clinical pathway that could lead to a Premarket Approval (PMA) application with the US FDA, and the use of our polymer in full thickness acute burns. The contract is a cost-plus-fixed-fee contract and it will progress in specific stages; a feasibility study, a swine study for total degradation and a pivotal trial phase. We are well progressed with the feasibility study and anticipate recruitment to conclude in calendar year 2018.

The CE Mark trials have continued with the addition of three more Australian sites, as outlined above. All sites have conducted successful surgeries and we have currently recruited 26 out of the 30 required participants. It is difficult to predict finalising the recruitment phase however we are optimistic of this concluding in calendar year 2018.

The clean room expansion has allowed greater production efficiencies and improved quality. We are now well established to service market demands through to 2020.

### Breast Products

PolyNovo entered a co-development MOU for a range of breast products with Establishment Labs a global breast prosthesis manufacturer. This progressed to a heads of agreement in January 2018 with further announcements to follow in regards to the terms for payments and royalties. Our current prototypes will undergo further design revision with our partner's input. Detailed project plans will act as the performance measures of both parties ensuring we can bring this innovative technology to market in the shortest possible time.

### Hernia Products

We have conducted surgeon focus groups across the US to gain insights into our product design, fields of use and market positioning. This process has been valuable, and we are now in the process of refining the design, filing further patent protection and developing the commercial manufacturing processes. We anticipate continued development of these products in-house and will consider partnerships once we have a mature product offering.

### BetaCell, Diabetes Developments

BetaCell has successfully concluded a series of three pig trials demonstrating the effectiveness of the NovoSorb BTM to act as a dermal "depot" for implanting Pancreatic Islet cells. BetaCell has funding from the US JDRF (Juvenile diabetes research foundation). They are aiming to conduct human trials in 2018. PolyNovo is supporting the program through the provision of NovoSorb BTM for the trial. This treatment holds significant promise for the future through reducing the number of donor pancreases required to treat patients and a simpler and safer procedure for implanting the Islet cells.

### Drug Eluting Depot

PolyNovo has been in discussion with a major US company for the development of our polymer to act as a dermal depot (pellet) which would elute a measured drug dose per day when implanted subcutaneously. The NovoSorb polymer performed very well however the commercial terms are not yet acceptable. PolyNovo will further develop this technology ourselves before seeking a partner.

### Commercialisation NovoSorb BTM: New Markets

During the Period, PolyNovo refined its market entry strategy and signed major contracts as follows:

- **Israel:** AMI Technologies has signed as our distribution partner for the Israel market. This enabled PolyNovo to file the required product registration dossier and we anticipate the commencement of commercial sales from May 2018.
- **Saudi Arabia:** We are in contract negotiations with a distributor for the Kingdom of Saudi Arabia (KSA) and other middle-east markets. We aim to conclude this process in early 2018.

- **India:** We have filed trademark protections and submitted regulatory documents for the Indian market. We have an active screening process to identify a distributor.
- **Other markets:** We have considerable interest in the NovoSorb BTM from many markets after attending the Medica conference in Germany in November 2017. We are working through the regulatory requirements for the various markets and prioritising market entries.

### Financial Result

The net loss of the consolidated entity attributable to members of the parent entity for the Period, after income tax was \$3,227,300 (2016: \$1,965,277). Net loss before income tax totalled \$3,227,300 (2016: \$1,965,277).

The consolidated entity commenced significant commercial sales of product to overseas jurisdictions with revenue of \$868,924 for the Period (2016: \$16,750). Product evaluations continue at many overseas hospitals with the expectation of conversion to sales throughout calendar year 2018.

Revenue from the BARDA contract has decreased to \$1,846,768 compared to \$1,970,879 in 2016 due to a lower level of activity in the six month period ended on 31 December 2017 half year. The consolidated entity accrued other income of \$359,775 (2016: \$318,003) with respect to the Research & Development tax benefit for the half year.

"Our BARDA contract commenced on 28 September 2015. This is a non-dilutive capital contract that supports a projected five year clinical pathway that could lead to a PMA application with the US FDA, and the use of our polymer in full thickness acute burns."

# Directors' Report continued

## For the half-year ended 31 December 2017

Employee expenses of \$2,642,877 were recognised for the six month period ended on 31 December 2017 (2016: \$2,051,683). The increase in employee expenses is due to increasing headcount from 22 to 31 primarily within sales, regulatory and other support areas to drive business growth.

Research and development costs of \$1,906,733 were recognised for the Period in respect of the BARDA project and other additional projects to support new product initiatives (2016: \$1,436,788).

Corporate, administration and overhead expenses recognised for the Period have increased to \$1,159,634 (2016: \$819,416) to support business growth.

A reduction in the value of inventories during the Period was the major reason for the \$223,073 increase in the net loss from the changes in inventories of finished goods and work in progress (2016: \$258,466 reduction in the net loss). During the Period, some inventory has been written down primarily due to expiry dates.

### Cash and Short-term Investments

As at 31 December 2017, PolyNovo held total cash, including short term investments, of \$25,759,407 (June 2017: \$5,496,609).

During the Period, the Company issued new shares as a result of a capital raising. The Company successfully completed a placement to professional and sophisticated investors and to existing shareholders via a share purchase plan which raised a net amount of \$22.2 million.

During the Period, the Company issued new shares as a result of options being exercised raising \$1.0 million.

Since 31 December 2017, \$19 million of the surplus funds have been invested in term deposits.

Term deposits exceeding 3 months term amounting to \$50,000 at 31 December 2017 (June 2017: \$50,000) have been classified as other financial assets in the statement of financial position.

There are no external borrowings at the date of this report.

### Inherent Risks of Investment in Biotechnology Companies

There are many inherent risks associated with the development of pharmaceutical and medical device 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 in part dependent on the success of their research projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Thus investment in companies specialising in these, such as PolyNovo, must be regarded as highly speculative. PolyNovo strongly recommends that professional investment advice be sought prior to such investments.

### Forward-looking statements

This report may contain forward-looking statements regarding the potential of the Company's projects and interests and the development and therapeutic potential of the Company's research and development. Any statement describing a goal, expectation, intention or belief of the Company is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercialising drugs that are safe and effective for use as human therapeutics and the financing of such activities. There is no guarantee that the Company's research and development projects and interests (where applicable) will receive regulatory approvals or prove to be commercially successful in the future. Actual results of further research could differ from those projected or detailed in this report. As a result, you are cautioned not to rely on forward-looking statements. Consideration should be given to these and other risks concerning the Company's research and development program referred to in this report.

### Auditor's Independence Declaration

The auditor's independence declaration as required by section 307C of the Corporations Act 2001 is set out on the following page.

Signed in accordance with a resolution of the Directors.



**Mr David Williams**  
Chairman  
15 February 2018

# Auditor's Independence Declaration

## To the Directors of PolyNovo Limited



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### Auditor's Independence Declaration to the Directors of PolyNovo Limited

As lead auditor for the review of PolyNovo Limited for the half-year ended 31 December 2017, 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 review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

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

*Ernst + Young*

Ernst & Young

*Joanne Lonergan*

Joanne Lonergan  
Partner  
15 February 2018

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# Consolidated Statement of Comprehensive Income

For the half-year ended 31 December 2017

	Notes	31 December 2017 \$	31 December 2016 \$
<b>Revenue</b>			
Sales of finished goods	4	868,924	16,750
Sale of materials		1,227	-
Royalty revenue		52	1,311
BARDA revenue		1,846,768	1,970,879
Finance revenue		29,449	102,222
<b>Total revenue</b>		<b>2,746,420</b>	<b>2,091,162</b>
<b>Other income</b>			
Research and development tax benefit		359,775	318,003
Changes in inventories of finished goods and work in progress		(223,073)	258,466
Raw materials and consumables used		(19,063)	(31,209)
Operating leases		(181,720)	(172,439)
Employee related expenses	5	(2,642,877)	(2,051,683)
Research & development expenses		(1,906,733)	(1,436,788)
Depreciation and amortisation expense		(200,395)	(121,373)
Corporate, administrative and overhead expenses		(1,159,634)	(819,416)
Net loss before income tax		(3,227,300)	(1,965,277)
Income tax benefit		-	-
<b>Net loss for the period</b>		<b>(3,227,300)</b>	<b>(1,965,277)</b>
<b>Other comprehensive income</b>			
Net fair value gains on available for sale financial asset		-	-
<b>Total comprehensive loss for the period</b>		<b>(3,227,300)</b>	<b>(1,965,277)</b>
<b>Loss for the period attributable to:</b>			
Owners of the parent		(3,227,300)	(1,965,277)
<b>Loss attributable to members of the parent entity</b>		<b>(3,227,300)</b>	<b>(1,965,277)</b>
<b>Loss per share</b>			
Basic loss per share (cents per share)	6	(0.54)¢	(0.35)¢
Diluted loss per share (cents per share)	6	(0.54)¢	(0.35)¢

The accompanying notes form part of these financial statements.

# Consolidated Statement of Financial Position

As at 31 December 2017

	Notes	31 December 2017 \$	30 June 2017 \$
<b>Current assets</b>			
Cash and cash equivalents	7	25,709,407	5,496,609
Inventories	8	752,166	981,112
Receivables	9	1,535,242	1,369,535
Prepayments		382,708	62,006
Other financial assets		50,000	50,000
<b>Total current assets</b>		<b>28,429,523</b>	<b>7,959,262</b>
<b>Non-current assets</b>			
Property, plant and equipment	10	1,280,719	1,452,354
Intangible assets		2,519,788	2,519,788
Other assets		125,975	124,460
<b>Total non-current assets</b>		<b>3,926,482</b>	<b>4,096,602</b>
<b>Total assets</b>		<b>32,356,005</b>	<b>12,055,864</b>
<b>Current liabilities</b>			
Trade and other payables		1,081,207	892,737
Provisions		199,376	176,874
<b>Total current liabilities</b>		<b>1,280,583</b>	<b>1,069,611</b>
<b>Non-current liabilities</b>			
Provisions		18,175	14,623
Deferred rent liability		137,482	158,764
<b>Total non-current liabilities</b>		<b>155,657</b>	<b>173,387</b>
<b>Total liabilities</b>		<b>1,436,240</b>	<b>1,242,998</b>
<b>Net assets</b>		<b>30,919,765</b>	<b>10,812,866</b>
<b>Equity</b>			
Contributed Equity	11	137,744,686	114,476,370
Reserves	12	(6,302,532)	(6,368,415)
Retained Earnings/(Accumulated losses)		(100,522,389)	(97,295,089)
<b>Parent interests</b>		<b>30,919,765</b>	<b>10,812,866</b>
<b>Total equity</b>		<b>30,919,765</b>	<b>10,812,866</b>

The accompanying notes form part of these financial statements.

# Consolidated Statement of Changes in Equity

For the half-year ended 31 December 2017

	Contributed equity \$	Other reserves \$	Acquisition of non- controlling interest reserve \$	Retained earnings/ (Accumulated losses) \$	Owners of the parent \$	Total \$
<b>As at 1 July 2016</b>	<b>114,099,712</b>	<b>2,595,045</b>	<b>(9,293,956)</b>	<b>(92,289,075)</b>	<b>15,111,726</b>	<b>15,111,726</b>
- Loss for the period	-	-	-	(1,965,277)	(1,965,277)	(1,965,277)
- Other comprehensive income	-	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	(1,965,277)	(1,965,277)	(1,965,277)
<b>Transactions with owners in their capacity as owners</b>						
- Issue of shares	-	-	-	-	-	-
- Issue of shares on exercise of options	376,658	-	-	-	376,658	<b>376,658</b>
- Issue of shares on acquisition of non-controlling interest	-	-	-	-	-	-
- Acquisition of non-controlling interest	-	-	-	-	-	-
- Share based payments	-	265,262	-	-	265,262	<b>265,262</b>
<b>As at 31 December 2016</b>	<b>114,476,370</b>	<b>2,860,307</b>	<b>(9,293,956)</b>	<b>(94,254,352)</b>	<b>13,788,369</b>	<b>13,788,369</b>
<b>As at 1 July 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	-	-	-	(3,227,300)	(3,227,300)	(3,227,300)
- Other comprehensive income	-	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	(3,227,300)	(3,227,300)	(3,227,300)
<b>Transactions with owners in their capacity as owners</b>						
- Issue of shares on exercise of options	1,040,000	-	-	-	1,040,000	<b>1,040,000</b>
- Issue of shares on capital raise	22,228,316	-	-	-	22,228,316	<b>22,228,316</b>
- Share based payments	-	65,883	-	-	65,883	<b>65,883</b>
<b>As at 31 December 2017</b>	<b>137,744,686</b>	<b>2,991,424</b>	<b>(9,293,956)</b>	<b>(100,522,389)</b>	<b>30,919,765</b>	<b>30,919,765</b>

The accompanying notes form part of these financial statements.

# Consolidated Cash Flow Statement

For the half-year ended 31 December 2017

	Notes	31 December 2017 \$	31 December 2016 \$
<b>Cash flows from operating activities</b>			
Receipts from customers		600,662	6,350
Receipts from BARDA reimbursements and advances		1,495,802	2,613,419
Receipts of Research and Development income tax credit		833,125	783,356
Receipts from Royalty revenue		448	1,512
Payments to suppliers and employees		(5,794,588)	(4,690,353)
<b>Net cash outflows used in operating activities</b>		<b>(2,864,551)</b>	<b>(1,285,716)</b>
<b>Cash flows from investing activities</b>			
Interest received		27,765	62,562
Payments for purchase of property, plant and equipment		(164,285)	(201,063)
<b>Net cash inflows/(outflows) used in investing activities</b>		<b>(136,520)</b>	<b>(138,501)</b>
<b>Cash flows from financing activities</b>			
<b>Net cashflows from financing activities</b>			
Proceeds from the issue of share capital (net of costs)		22,228,316	-
Proceeds from the exercise of options		1,040,000	376,659
<b>Cash flows from financing activities</b>		<b>23,268,316</b>	<b>376,659</b>
Net increase/(decrease) in cash and cash equivalents		20,267,245	(1,047,558)
Cash and cash equivalents at beginning of period		5,496,609	10,746,691
Effects of foreign exchange rate changes		(54,447)	84,185
<b>Cash and cash equivalents at the end of period</b>	7	<b>25,709,407</b>	<b>9,783,318</b>

The accompanying notes form part of these financial statements.

# Notes to the Financial Statements

## For the half-year ended 31 December 2017

### 1. Corporate Information

The financial report of PolyNovo Limited and its controlled entities for the half-year ended 31 December 2017 was authorised for issue in accordance with a resolution of the Directors on 15 February 2018.

PolyNovo Limited is a company limited by shares incorporated in Australia whose shares are publicly traded on the Australian Securities Exchange (ASX code: PNV).

### 2. Basis of Preparation of the Half-Year Financial Report

This half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full annual financial report.

This half-year financial report should be read in conjunction with the annual financial report of PolyNovo Limited for the year ended 30 June 2017, which was prepared in accordance with the requirements of the *Corporations Act 2001*, the ASX Listing Rules, applicable Australian Accounting Standards (which are equivalent to International Financial Reporting Standards) and other mandatory professional reporting requirements.

It is also recommended that the half-year financial report be considered together with any public announcements made by PolyNovo Limited during the half-year ended 31 December 2017 in accordance with the continuous disclosure requirements of the *Corporations Act 2001* and the ASX Listing Rules.

#### (a) Basis of accounting

This half-year financial report for the period ended 31 December 2017 is a general-purpose financial report, which has been prepared in accordance with the requirements of the *Corporations Act 2001*, AASB 134 Interim Financial Reporting and other mandatory professional reporting requirements.

The half-year financial report has been prepared on an historical cost basis.

The half-year financial report is presented in Australian dollars.

For the purpose of preparing the half-year financial report, the half-year has been treated as a discrete reporting period.

#### (b) Significant accounting policies

The accounting policies adopted in this half-year financial report are consistent with those used in the annual financial report for the year ended 30 June 2017.

No new standards (including early adoption), amendments to standards and interpretations affected the group for the year beginning 1 July 2017.

### 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. Revenue from the sale of finished goods is predominantly to overseas jurisdictions.

The chief operating decision maker from 13 February 2015 is the Chief Executive Officer of PolyNovo Limited.

The chief operating decision maker reviews the results of the business on a single entity basis.

For financial results refer to the Statement of Comprehensive Income and Statement of Financial Position.

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

Sales revenue to external customers in the USA is 25% of the total sales revenue. There were no non-current assets in the USA.

# Notes to the Financial Statements continued

## For the half-year ended 31 December 2017

### 4. Sales of Goods

During the half-year ended 31 December 2017, the consolidated entity realised \$868,924 (2016: \$16,750) sales revenue from commercial sales of the BTM wound dressing.

### 5. Expenses

	31 December 2017 \$	31 December 2016 \$
Employee related expense		
Wages and salaries	(1,879,244)	(1,236,947)
Superannuation	(134,147)	(104,754)
Share-based payments expense	(65,883)	(265,267)
Directors' fees (including superannuation)	(162,112)	(162,112)
Severance payments (including superannuation)	(68,565)	(16,425)
Long service leave provision	(5,998)	944
Annual leave provision	(20,055)	(729)
Payroll taxes	(98,256)	(90,016)
Administration	(62,852)	(28,719)
Employee welfare	(25,965)	(13,261)
Recruitment fees	(119,800)	(134,397)
	<b>(2,642,877)</b>	<b>(2,051,683)</b>

### 6. Loss Per Share

	31 December 2017	31 December 2016
Basic loss per share (cents per share)	(0.54)¢	(0.35)¢
Diluted loss per share (cents per share)	(0.54)¢	(0.35)¢
(a) Net loss used in the calculation of basic and diluted loss per share	(\$3,227,300)	(\$1,965,277)
(b) Weighted average number of ordinary shares on issue used in the calculation of basic loss per share	600,953,531	560,749,505

### 7. Cash and Cash Equivalents

Cash and cash equivalents are comprised of the following:

	31 December 2017 \$	30 June 2017 \$
Cash at bank and in hand	25,709,407	5,496,609
	<b>25,709,407</b>	<b>5,496,609</b>

As at 31 December 2017 the Company holds \$50,000 (June 2017: \$50,000) in term deposits with maturity date exceeding 90 days. These deposits are classified in the Statement of Financial Position as other financial assets.

PolyNovo has no borrowings at the date of this report.

# Notes to the Financial Statements continued

## For the half-year ended 31 December 2017

### 8. Inventories

Inventories are comprised of the following:

	31 December 2017 \$	30 June 2017 \$
Finished goods	630,364	381,027
Work in progress	83,791	556,201
Raw materials and other	714,155	937,228
	38,011	43,884
	<b>752,166</b>	<b>981,112</b>

During the period, the Company has written off \$474,008 of inventory as a result of a review of volume sales demand, product expiry dates and new packaging requirements.

### 9 Receivables

Receivables are comprised of the following:

	31 December 2017 \$	30 June 2017 \$
Trade receivables	1,139,566	485,589
Research and development income tax credit	359,775	833,126
Other	35,901	50,820
	<b>1,535,242</b>	<b>1,369,535</b>

The 31 December 2017 balance relates predominantly to PolyNovo's BARDA project \$832,048 (June 2017 \$485,589) and trade receivables from customers \$307,518 (June 2017: \$nil).

#### 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 receivables.

At 31 December 2017, the receivables balance includes \$832,048 (June 2017: \$485,589) owing from BARDA, a US government agency. BARDA is contractually obliged to reimburse the Group for services provided and is considered to be low credit risk.

As noted, the Company has commenced making commercial sales of product to hospitals and distributors. At 31 December 2017, the trade receivables balance is \$307,518 (June 2017: \$nil) none of which is past due. To reduce risk exposure, the Company has implemented stringent control procedures including a review of customer profile reports from debtor collection agencies prior to establishing the account.

### 10. Property, Plant and Equipment

#### Acquisitions and disposals

During the half-year ended 31 December 2017, the consolidated entity acquired assets with a cost of \$28,760 (2016: \$214,155).

#### Impairment

Impairment expenses of \$nil were recognised by the consolidated entity during the half-year ended 31 December 2017 (2016: \$nil).

# Notes to the Financial Statements continued

For the half-year ended 31 December 2017

## 11. Contributed Equity

	31 December 2017		30 June 2017	
	No. of Shares	\$	No. of Shares	\$
Fully paid ordinary shares	653,902,949	137,744,686	563,049,010	114,476,370

### Shares issued on capital raising

During the period under review the Company issued shares resulting from a capital raising.

On 25th September 2017, the Company completed a placement to professional and sophisticated investors raising \$7.0 million at \$0.27 per share. This placement resulted in the issue of 25,925,925 fully paid ordinary shares.

On 27th October 2017, the Company issued 59,428,014 fully paid ordinary shares at \$0.27 per share to existing shareholders via a share purchase plan. A total of \$16 million was raised.

Costs in relation to the capital raising totalled \$0.817 million.

### Exercise of options

During the period under review the Company issued new shares as a result of options being exercised.

On 3rd July 2017, Mr David Williams, the Chairman of the Company exercised his remaining 2,500,000 options granted on 19th May 2014. The options were converted into 2,500,000 fully paid ordinary shares at an exercise price of \$0.20.

On 30th August 2017, Mr Philip Powell, a Director of the Company exercised 500,000 options of his 1,000,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.14. On 12th October 2017, he exercised his remaining 500,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.20.

On 12th October 2017, Mr Max Johnston, a Director of the Company exercised 500,000 options of his 1,000,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.14. On 12th October 2017, he exercised his remaining 500,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.20.

On 17th October 2017, Dr David McQuillan, a Director of the Company exercised his remaining 500,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.20.

On 3rd November 2017, Mr Bruce Rathie, a Director of the Company exercised his remaining 500,000 options granted on 17th November 2014. The options were converted into 500,000 fully paid ordinary shares at an exercise price of \$0.20.

# Notes to the Financial Statements continued

## For the half-year ended 31 December 2017

### 12. Reserves

	31 December 2017 \$	30 June 2017 \$
Share based payments reserve (i)	2,991,424	2,925,541
Acquisition of non-controlling interest reserve	(9,293,956)	(9,293,956)
Balance at end of period	<b>(6,302,532)</b>	<b>(6,368,415)</b>

(i) This reserve is used to recognise the fair value of options issued.

	31 December 2017		30 June 2017	
	No. of Options	\$	No. of Options	\$
Share Based Payments Reserve	7,185,095	2,991,424	12,685,095	2,925,541

During the period under review 5,500,000 options were exercised as disclosed under Note 11.

Options on issue as at the beginning and at the end of the reporting period are detailed in the following table.

Date of Issue	19/05/14 <sup>1</sup>	17/11/14 <sup>1</sup>	17/11/14 <sup>1</sup>	6/08/15 <sup>2</sup>	18/11/16 <sup>1</sup>	9/12/16 <sup>2</sup>	Total
On issue at beginning of the year	2,500,000	2,000,000	1,000,000	4,185,095	1,000,000	2,000,000	12,685,095
Granted during the year	-	-	-	-	-	-	-
Exercised during the year	2,500,000	2,000,000	1,000,000	-	-	-	5,500,000
Expired unexercised during the year	-	-	-	-	-	-	-
Forfeited/forfeited during the period	-	-	-	-	-	-	-
On issue at balance date	-	-	-	4,185,095	1,000,000	2,000,000	7,185,095
Issued subsequent to balance date	-	-	-	-	-	-	-
Exercised subsequent to balance date	-	-	-	-	-	-	-
Forfeited/forfeited subsequent to balance date	-	-	-	-	-	-	-
On issue at date of Directors' Report	-	-	-	4,185,095	1,000,000	2,000,000	7,185,095
Current number of recipients	1	4	2	1	1	2	
Exercise price	\$0.20	\$0.20	\$0.14	\$0.09	\$0.25 \$0.33	\$0.33	
Exercise period: From	4/07/14	17/11/14	17/11/14	vesting hurdle being met	18/11/16	vesting hurdle being met	
To	4/07/17	17/11/17	17/11/17	3 months from vesting	1/02/19	3 months from vesting	
Expiration date	4/07/17	17/11/17	17/11/17	5/08/18		31/12/18	

1. All options issued vested immediately.

2. The options vest as soon as the vesting hurdles are achieved.

# Notes to the Financial Statements continued

For the half-year ended 31 December 2017

## 13. Contingent Liabilities and Contingent Assets

The Directors were not aware of any contingent liabilities or contingent assets as at 31 December 2017.

## 14. Corporate Information

PolyNovo Limited is a company limited by shares that is incorporated and domiciled in Australia.

## 15. Related Party Disclosures

Kidder Williams Ltd, an entity associated with a Director, Mr David Williams, received payments in the amount of \$691,372 (2016: \$nil). These payments were in respect to consulting services provided to PolyNovo Limited in relation to the capital raising.

## 16. Events After the Balance Sheet Date

The Directors are not aware of any other matters or circumstances since the end of the half year review period, not 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 years.

# Directors' Declaration

## For the period ended 31 December 2017

In accordance with a resolution of the directors of PolyNovo Limited, we state that:

In the opinion of the Directors:

1. (a) The financial statements and notes of the consolidated entity are in accordance with the *Corporations Act 2001*, including:
  - (i) give a true and fair view of the financial position as at 31 December 2017 and the performance for the half-year ended on that date;
  - (ii) comply with Accounting Standard AASB134 "Interim Financial Reporting" and the Corporations Regulations 2001; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

On behalf of the Board.



**Mr David Williams**  
**Chairman**

15 February, 2018

# Independent Review Report to the Members of PolyNovo Limited



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## Independent Auditor's Review Report to the Members of PolyNovo Limited

### Report on the Half-Year Financial Report

#### Conclusion

We have reviewed the accompanying half-year financial report of PolyNovo Limited (the Company) and its subsidiaries (collectively the Group), which comprises the condensed statement of financial position as at 31 December 2017, the condensed statement of comprehensive income, condensed statement of changes in equity and condensed statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the half-year financial report of the Group is not 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 31 December 2017 and of its consolidated financial performance for the half-year ended on that date; and
- b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

#### Directors' Responsibility for the Half-Year Financial Report

The directors of the Company are responsible for the preparation of the half-year 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 half-year financial report that is free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, anything has come to our attention that causes us to believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the Group's consolidated financial position as at [period date] and its consolidated financial performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of the Group, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

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# Independent Review Report to the Members of PolyNovo Limited

continued



## Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

*Ernst + Young*

Ernst & Young

*Joanne Lonergan*

Joanne Lonergan  
Partner  
Melbourne  
15 February 2018

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# Corporate Directory

ABN 96 083 866 862

## Non-executive Chairman

Mr David Williams

## Non-executive Directors

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

## Chief Executive Officer

Mr Paul Brennan

## Company Secretaries

Mr Greg Lewis  
Mr Gavin Smith

## Registered office

Unit 2/320 Lorimer Street  
Port Melbourne  
Victoria Australia 3207  
T (03) 8681 4050  
F (03) 8681 4099

## Share registry

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

## Auditors

Ernst & Young  
8 Exhibition Street  
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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