NovoSorb®
BTM

26 February 2020

PolyNovo

PolyNovo Limited
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ASX Announcement

BTM sales up 129% H1 FY20, AND run rate accelerating

PolyNovo is pleased to release the attached slides summarising the Company's H1 results.

PolyNovo said today that NovoSorb BTM sales for the half year were 129% higher than the same period last year. However, the Company said the rate of increase in sales is growing in existing markets and should grow further as new markets come on stream. BTM sales in January 2020 were more than three times the sales in January 2019. While this is encouraging, especially in the US which had the largest month on month growth of any region, as previously advised we expect sales to be lumpy as each market develops. Based on year to date performance the company now expects that NovoSorb BTM sales for FY20 should comfortably double FY19.

PolyNovo's CEO, Mr Paul Brennan said, *"The past half year has been exciting for all of us because many areas of our business are experiencing rapid and dynamic growth. My personal highlights for the first half, apart from the sales growth referred to above include:*

- *CE Mark approval with a quick entry into the UK/Ireland and DACH region quickly followed by first patients*
- *Awarded breakthrough technology status by US FDA which will assist our BARDA PMA burn study*
- *Continued expansion of the sales teams in Australia, US and UK*
- *Our response to the White Island tragedy in New Zealand and bush fires in Australia*
- *Commenced the build of the hernia/breast cleanroom facility and delivery of manufacturing machinery*
- *Appointment of Dr. Robyn Elliott as Non-Executive Director bringing extensive global experience*
- *Completed the expansion and refurbishment of the head office to accommodate a growing team*
- *Expansion of the US office to accommodate more support staff for our sales team."*

PolyNovo's Chairman, Mr David Williams said, *"It is obvious that our customers and our staff are growing quickly. We don't want to lose momentum, but we want to step up our sales force, our new product development and the infrastructure needed to support them in a controlled way."*

This announcement has been authorised by Company Secretary Jan-Marcel Gielen.

Further information:

Paul Brennan Chief Executive Officer Mobile +61 427 662 317	David Williams Chairman Mobile +61 414 383 593

PolyNovo

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 a dermal scaffold for the regeneration of the dermis when lost through extensive surgery or burn.

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.polynovo.com.au

Half-Year Reports

Announcement of Half-Year Results

Appendix 4D
Half-Year Financial Report to 31 December 2019

PolyNovo Limited
ABN 96 083 866 862
26 February 2020

Announcement of Half-Year Results

26 February 2020

PolyNovo Half-Year Results

PolyNovo Limited ('Company' or 'PolyNovo') today announced the half year results for the period ending 31 December 2019.

The Company reported a net loss after income tax of $2.42m (2018 $1.92m). The increased loss includes $0.88m in share-based payments expense. Excluding this expense, the underlying loss has decreased on the prior year and reflects the significant growth in commercial sales of NovoSorb BTM locally and overseas.

Total revenue of $10.18m (2018 $5.67m) includes commercial sales of NovoSorb BTM of $8.57m and revenue from the BARDA clinical trial program of $1.61m. In addition, the Group recognised other income being interest of $0.03m (2018 $0.22m). A R&D tax credit was not recongised as revenue this half year as it is possible revenue will exceed $20 million for the full year, being the maximum revenue allowable for the claiming of a R&D cash refund. At 31 December 2019, the Company held $8.14m in cash and short-term investments.

PolyNovo continues to expand the US sales team in response to revenue growth. Today we have 24 sales people globally compared to February 2019 sales people of 11. We will continue to recruit sales people each month in response to customer demand and revenue opportunities.

PolyNovo's direct sales approach in Australia and New Zealand has proved successful. We now have 3 sales people covering Australia and New Zealand. This team will expand in the near term to further penetrate the market. Our strategy of appointing a sales manager in advance of the CE Mark has ensured we have immediate customer demand. We now have 3 sales people in the UK and see this market as an opportunity for rapid expansion. We have also appointed our first sales person in Singapore to cover the Singapore and Malaysia markets with direct representation.

Our distributor network now includes Polymedics (PMI) for Germany, Austria and Switzerland. PMI has already achieved sales post a 2020 launch and placed a second order for stock replenishment.

Other distributors are outlined in the body of the directors report.

PolyNovo achieved CE Mark approval on 13 December 2019. Since then we have had our first surgeries and sales in the UK and DACH regions in H2 FY20. Our US and ANZ businesses are growing and performing strongly.

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

- Significant sales growth in all direct markets
- Built the talent depth of the business in all functional areas
- Embedded CRM and digital marketing platforms in our business strategy
- Upgraded our ERP system to be a fully integrated manufacturing, forecasting, sales and business management system
- Refitted the offices in Port Melbourne allowing for team growth that will drive the business
- Signed the lease for an enlarged office facility in San Diego on 22 January 2020 to accommodate our growing US team and business
- Commenced the Hernia factory build which is due for completion by June 2020
- Purchased and received customised hernia manufacturing machinery. These machines are installed in an off-site facility, in advance of our factory completion, to allow the R&D and manufacturing teams to refine the commercial production processes.
- Established a Singapore and Malaysia business entity allowing for direct market access to Singapore and Malaysia
- Achieved breakthrough technology status with US FDA which will accelerate our BARDA funded pre-market approval (PMA) clinical trial program

Publication of the NovoSorb BTM full thickness burn CE Mark burn trial and the US feasibility trial results are on track for March 2020 release.

We continue to see NovoSorb BTM clinical presentations by key opinion leaders at all major Burns and Plastic Surgery Conferences. These conferences have been throughout the US, Australia, New Zealand, Europe and UK. Clinical publications of NovoSorb BTM performance continues in peer to peer journals and poster presentations. Full details are available on our website www.polynovo.com

The pace of business at PolyNovo is unrelenting with the year ahead showing significant promise:

- Acceleration of commercial execution in NovoSorb BTM sales in all our markets
- Expansion into further western Europe markets
- Rapid but considered expansion of our sales teams
- Ramping our product production with increased automation, improved cost of goods and capacity improvements from the existing facility
- Completing construction of the hernia cleanroom production facility
- Completion of the hernia product regulatory dossier submission for US FDA
- Implementation of an electronic quality management system
- Finalisation of the Pivotal clinical trial with US FDA and refine the BARDA budget to reflect the trial design and timeline. BARDA remains a committed partner in this program and we thank them for their ongoing and generous support

A full commentary and analysis of the operations and the 31 December 2019 half year financial report can be found in the Appendix 4D.

Further information

Paul Brennan
Chief Executive Officer
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David Williams
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, Europe, UK/Ireland, South Africa, Malaysia, Singapore, 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 Orthopedic applications. For further information and market presentations see www.polynovo.com

Appendix 4D - Rule 4.2A.3

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 2019**
Previous Corresponding Period:	Half-Year ended 31 December 2018

2. Results for announcement to the market

	Change from 2018			2019
2.1. Total revenue	up	80%	to	10,179,120
2.2. Loss after tax	up	26%	to	(2,418,557)
2.3. Loss after tax attributable to members	up	26%	to	(2,418,557)
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 Half-Year Financial Report.			

3. Net tangible assets

	31 December 2019	30 June 2019
Net tangible asset backing per ordinary security	$0.037	$0.039

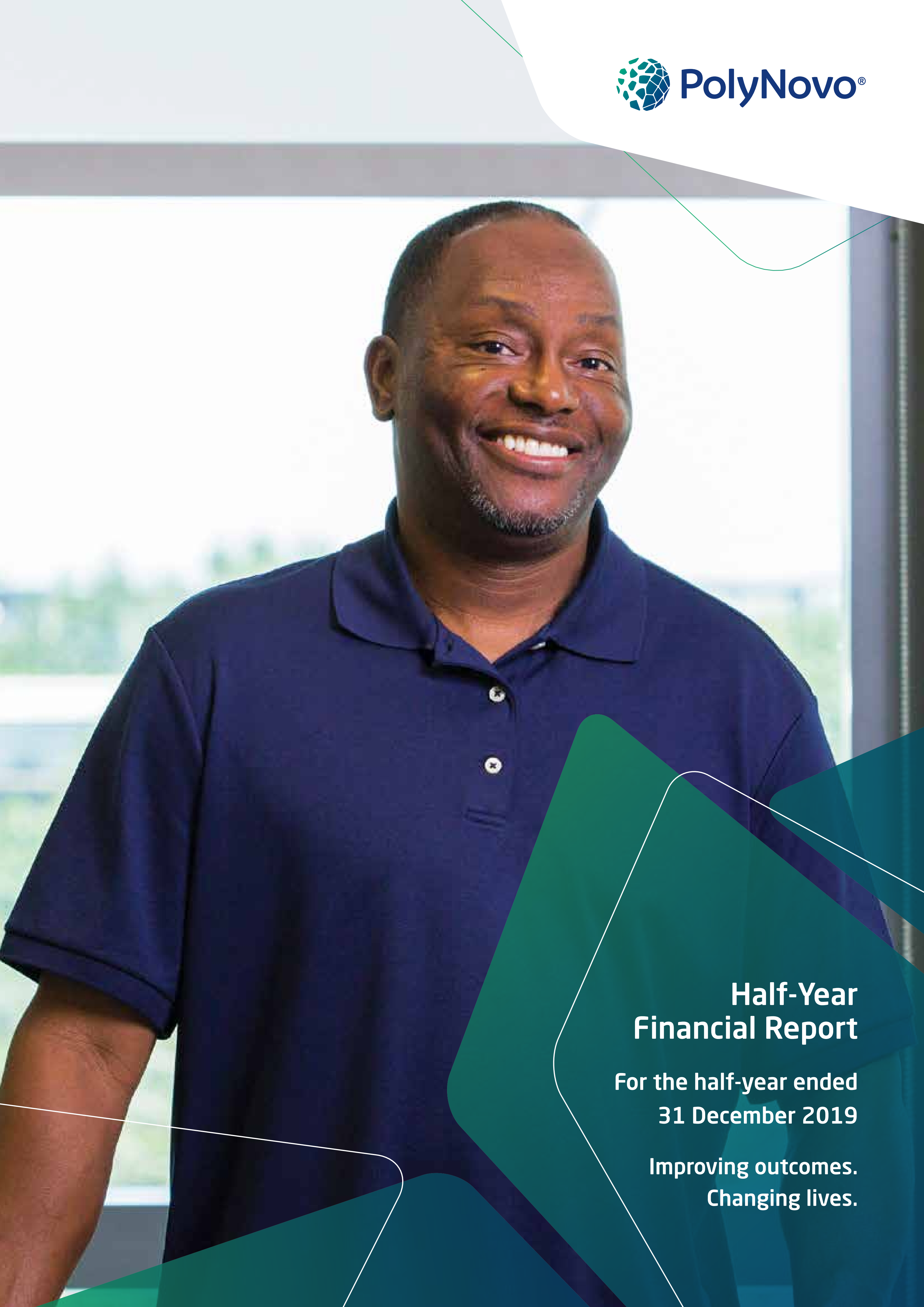
4. Details of control gained or lost over entities during the period	Not applicable
5. Details of individual dividends and payment dates	Not applicable
6. Details of dividend reinvestment plans	Not applicable
7. Details of associates and joint venture entities	Not applicable
8. For foreign entities, which set of accounting standards is used in compiling the report	

9. The Half-Year Financial Report is not subject to a review report that includes a modified opinion, emphasis of matter or other matter paragraph (a copy of the review report is included in the Half-Year Financial report enclosed).

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

Date: 26 February 2020

Jan Gielen
Company Secretary



PolyNovo®

Half-Year Financial Report

For the half-year ended 31 December 2019

Improving outcomes. Changing lives.

Contents

Our Performance	1
Directors' Report	2
Auditor's Independence Declaration	5
Consolidated Statement of Comprehensive Income for the half-year ended 31 December 2019	6
Consolidated Statement of Financial Position as at 31 December 2019	7
Consolidated Statement of Changes in Equity for the half-year ended 31 December 2019	8
Consolidated Cash Flow Statement for the half-year ended 31 December 2019	9
Notes to the Consolidated Financial Statements for the half-year ended 31 December 2019	10
Directors' Declaration	19
Independent Review Report to the Members of PolyNovo Limited	20
Corporate Directory	22

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 2019 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.

Cover: Patient – Malcolm Leflore

Our Performance

For the half-year ended 31 December 2019

Total Sales of NovoSorb BTM

$8.57 million 2019

$3.75 million 2018

Increase | +129%

Total BARDA Revenue

$1.61 million 2019

$1.92 million 2018

Decrease | –16%

Cash on Hand

$8.14 million 2019

$20.81 million 2018

Decrease | –61%

Inventory Value

$1.05 million 2019

$0.70 million 2018

Increase | +50%

Total Employees

65 People 2019

41 People 2018

Increase | +59%

Employee Expenditure

$6.79 million 2019

$3.66 million 2018

Increase | +86%

R&D and New Capital Expenditure

$3.22 million 2019

$1.68 million 2018

Increase | 92%

Net Loss

$2.42 million 2019

$1.92 million 2018

Increase | +26%

Achievements

- CE Mark Approval
- FDA Breakthrough Device Granted
- Singapore Regulatory Approval
- First $2 million Month for Product Sales
- ASX200 Achieved
- UK First BTM Surgeries January 2020
- Germany First BTM Surgeries January 2020
- Market Capitalisation of $2 billion

Director's Report

For the half-year ended 31 December 2019

The Board of Directors of PolyNovo Limited present their report in respect of the financial half-year ended 31 December 2019 ('the Period').

Directors

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

Dr Robyn Elliott
Non-Executive Director
(appointed 22 October 2019)

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

Review of Principal Activities and Operations

During the Period, the key initiatives and achievements by PolyNovo included:

- Regulatory approval and market entry of NovoSorb BTM in Europe, UK and Ireland, Malaysia and Singapore;
- Accelerated revenue from NovoSorb BTM sales in all direct markets;
- Continued sales team growth in the US and Australia;
- Responded to the White Island (NZ) disaster;
- Breakthrough Technology recognition with the US FDA for the BARDA funded pre-market approval (PMA) Burn trial process;
- Commenced building the new hernia/ breast cleanroom production facility;
- Refurbished the expanded office at Port Melbourne allowing for team growth;
- Signed contract on 22 January 2020 for expanded office lease in San Diego for US team growth;
- Appointment of Dr Robyn Elliott as Non-Executive Director. Robyn brings a wealth of commercial, strategic, quality system, regulatory and manufacturing experience to PolyNovo; and
- Achieved our first $2m sales revenue month, in December 2019.

PolyNovo has a platform technology in NovoSorb biodegradable polymer. NovoSorb Biodegradable Temporising Matrix (BTM) is a dermal matrix used to regenerate the missing or damaged dermis. The NovoSorb BTM with US FDA 510(k), CE Mark, TGA ATRG listing and various other country approvals is the first commercial product to be sold by PolyNovo. Our research and development (R&D) programs are focused on NovoSorb based hernia and breast medical devices. Further applications of NovoSorb as a drug elution pellet, dermal depot for Beta/Islet cell implantation, device implant coatings and several other applications are also at various stages of development.

Biodegradable Temporising Matrix (BTM)

NovoSorb BTM is sold by PolyNovo using a direct salesforce in Australia, New Zealand, US, UK and Ireland, Singapore and Malaysia. PolyNovo utilises distributors for sales of NovoSorb BTM in DACH (Germany, Austria and Switzerland), South Africa, Saudi Arabia, India and Israel. We continue to work on regulatory approvals in several markets to enable market entries in the year ahead.

Our Biomedical Advanced Research and Development Authority (BARDA) contract commenced on 28 September 2015. This is a non-dilutive capital contract that supports a clinical trial on full thickness burns that could lead to a Premarket Approval (PMA) application with the US FDA. The recent granting of Breakthrough Technology status with the US FDA will increase the dialogue and guidance of the pivotal trial through the PMA process. The BARDA contract is a cost-plus-fixed-fee contract and it will progress in three stages; a feasibility study, a swine study for total degradation and a pivotal trial phase.

The feasibility trial results will be published in March 2020. Further announcements on the pivotal trial will be made post FDA submission of the protocol in April/May 2020.

The CE Mark full thickness burn trials results will also be published in March 2020. This trial will provide solid clinical evidence of the effectiveness of NovoSorb BTM and support the existing regulatory dossiers and marketing claims.

Hernia Products

PolyNovo has commissioned and received the production equipment required for commercial production of our two hernia products. This equipment has been installed at an off-site location for the R&D and production teams to refine the manufacturing processes, protocols and write the standard operating procedures (SOPs). This is in advance of completing construction of our own facility between May to June 2020 and ensures we maintain an aggressive timeline for market entry. Trademarks for hernia products have also been filed for the brands.

Breast Products

Our partnership with Establishment Labs is progressing. The two development teams have a defined project plan and strategy in place. The finalised product will be manufactured on the same machinery as the hernia devices however it will have unique attributes for it's intended use. Further announcements on these products will follow in the near term.

BetaCell, Diabetes Developments

PolyNovo is supplying NovoSorb BTM in modified sizes to BetaCell Technologies. BetaCell and PolyNovo are also working with a global supplier of stem cell derived Islet cells for use in this program. BetaCell have indicated they will commence human trials during calendar 2020 with funding from the US JDRF (Juvenile Diabetes Research Foundation). This treatment holds significant promise for treating Type I diabetes with reduced reliance on donor pancreas and potentially addressing graft versus host reactions.

Corporate, administration and overhead expenses recognised for the Period have increased to $3,110,261 (2018: $1,614,754) to support business growth.

Interest income for the Period was $33,526 (2018: $222,103) due to low market interest rates and reduced cash reserves through investment in market and sales expansion.

Inventory on hand was $1,047,909 (2018: $1,215,450).

Cash and short-term investments

As at 31 December 2019, PolyNovo held total cash, including short-term investments, of $8,144,298 (June 2019: $13,920,695).

Term deposits exceeding three months term amounting to $50,000 at 31 December 2019 (June 2019: $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 medical devices and getting them to a marketable stage. The clinical trial process is designed to assess the safety and efficacy of a medical device prior to commercialisation and a significant proportion of 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 uncertainties caused by the rapid advancements in technology.

Drug Eluting Depot

PolyNovo has completed preliminary work on the binding and release of drugs with the NovoSorb polymer. Further work on this project will occur once our Hernia development program transitions from R&D to production. The drug elution depot holds promise for the treatment of chronic conditions where drug compliance is variable or a consistent titration of drug would yield improved outcomes.

Financial Result

The net loss of the consolidated entity attributable to members of the parent entity for the Period, after income tax was $2,418,557 (2018: $1,917,758). Net loss before income tax was $2,418,557 (2018: $1,917,758).

The consolidated entity significantly increased commercial sales of product locally and overseas with revenue of $8,571,640 for the Period (2018: $3,750,728). Product sales continue to build strongly as we gain market penetration through an expanded sales force and increased marketing activities.

Revenue from the BARDA contract was $1,607,480 (2018: $1,915,136). This decrease is reflective of the lower hospital activity in the transition from feasibility to pivotal trial. We expect to see this increase once we have final US FDA protocol approval and commence patient recruitment in June/July 2020.

The consolidated entity did not accrue other income (2018: $316,146) through the research and development tax credit for the half-year as it is possible revenue will exceed $20 million for the full year, being the maximum revenue allowable for the claiming of a R&D cash refund. This will be revisited during the year.

Employee expenses of $6,786,640 were recognised for the six-month period ended 31 December 2019 (2018: $3,657,035).

The increase in employee expenses is due to share-based payments provided to key management personnel and to headcount increases to drive growth primarily within sales, marketing, production, quality and human resources.

Research and development costs of $1,359,616 were recognised for the Period in respect of the hernia, breast and BARDA projects along with other projects to support new product pipeline initiatives (2018: $1,613,699).

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 such as PolyNovo must be regarded as risky and highly speculative. PolyNovo strongly recommends that professional investment advice be sought prior to investing in the Company.

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 and devices that are safe and effective for use as human therapeutics and devices 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
26 February 2020

Auditor's Independence Declaration
to the Directors of PolyNovo Limited

Building a better working world

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Auditor's Independence Declaration to the Directors of PolyNovo Limited

As lead auditor for the review of the half-year financial report of PolyNovo Limited for the half-year ended 31 December 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 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
Partner
26 February 2020

Consolidated Statement of Comprehensive Income

For the half-year ended 31 December 2019

	Note	31 December 2019 $	31 December 2018[1] $
Revenue from contracts with customers	4	**10,179,120**	**5,665,864**
Other income			
Research and development tax benefit	9	–	316,146
Finance revenue		33,526	222,103
Changes in inventories of finished goods and work in progress		(927,324)	(964,580)
Operating leases		–	(116,616)
Employee related expenses	5	(6,786,640)	(3,657,035)
Research and development expenses		(1,359,616)	(1,613,699)
Depreciation and amortisation expense		(399,811)	(155,187)
Corporate, administrative and overhead expenses		(3,110,261)	(1,614,754)
Lease liability interest expense		(47,551)	–
Net loss before income tax		(2,418,557)	(1,917,758)
Income tax benefit		–	–
Net loss for the period		**(2,418,557)**	**(1,917,758)**
Other comprehensive income			
Loss on translation of foreign operation	14	(37,772)	(198,977)
Total comprehensive loss for the period		**(2,456,329)**	**(2,116,735)**
Loss for the period attributable to:			
Owners of the parent		(2,418,557)	(1,917,758)
Loss attributable to members of the parent entity		**(2,418,557)**	**(1,917,758)**
Total comprehensive loss for the period attributable to:			
Owners of the parent		(2,456,329)	(2,116,735)
Loss attributable to members of the parent entity		(2,456,329)	**(2,116,735)**
Loss per share			
Basic loss per share (cents per share)	6	$(0.37)	$(0.29)
Diluted loss per share (cents per share)	6	$(0.37)	$(0.29)

1. The Group has initially applied AASB 16 using the modified retrospective approach. Under this approach, comparative information is not restated. And the cumulative effect of initially applying AASB 16 is recognised in retained earnings (refer to Note 12).

The accompanying notes form part of these financial statements.

Consolidated Statement of Financial Position

As at 31 December 2019

	Note	31 December 2019 $	30 June 2019[1] $
Assets			
Current assets			
Cash and cash equivalents	7	8,144,298	13,920,695
Inventories	8	1,047,909	1,215,450
Receivables	9	4,389,237	4,405,047
Prepayments	10	3,683,050	310,321
Other financial assets		50,000	50,000
Total current assets		**17,314,494**	**19,901,513**
Non-current assets			
Property, plant and equipment	11	7,707,194	6,008,219
Intangible assets		2,024,092	2,148,016
Right of use asset	12	2,365,265	–
Other assets		177,260	170,767
Total non-current assets		**12,273,811**	**8,327,002**
Total assets		**29,588,305**	**28,228,515**
Liabilities			
Current liabilities			
Trade and other payables		2,139,011	1,751,829
Provisions		368,856	312,172
Lease liability	2(b)	249,988	–
Total current liabilities		**2,757,855**	**2,064,001**
Non-current liabilities			
Provisions		141,499	47,738
Lease liability	2(b)	2,170,564	17,297
Total non-current liabilities		**2,312,063**	**65,035**
Total liabilities		**5,069,918**	**2,129,036**
Net assets		**24,518,387**	**26,099,479**
Equity			
Contributed equity	13	139,070,502	139,070,502
Reserves	14	(5,671,087)	(6,511,909)
Retained earnings/(accumulated losses)		(108,881,028)	(106,459,114)
Parent interests		**24,518,387**	**26,099,479**
Total equity		**24,518,387**	**26,099,479**

1. The Group has initially applied AASB 16 using the modified retrospective approach. Under this approach, comparative information is not restated. And the cumulative effect of initially applying AASB 16 is recognised in retained earnings (refer to Note 12).

The accompanying notes form part of these financial statements.

Consolidated Statement of Changes in Equity

For the half-year ended 31 December 2019

	Contributed equity $	Other reserves $	Acquisition of on-interest controlling reserve $	Retained earnings/ accumulated losses) $	Owners of the parent $	Total $
As at 1 July 2018	**138,120,502**	**2,901,645**	**(9,293,956)**	**(103,269,221)**	**28,458,970**	**28,458,970**
– Loss for the period	–	–	–	(1,917,758)	(1,917,758)	**(1,917,758)**
– Other comprehensive income (Translation)	–	(198,977)	–	–	(198,977)	(198,977)
Total comprehensive income for the period	–	(198,977)	–	(1,917,758)	(2,116,735)	**(2,116,735)**
Transactions with owners in their capacity as owners						
– Issue of shares	–	–	–	–	–	**–**
– Issue of shares on exercise of options	660,000	–	–	–	660,000	**660,000**
– Issue of shares on capital raise	–	–	–	–	–	**–**
– Translation of foreign operations	–	–	–	–	–	**–**
– Share-based payments	–	40,128	–	–	40,128	**40,128**
As at 31 December 2018	138,780,502	2,742,796	(9,293,956)	(105,186,979)	27,042,363	**27,042,363**
As at 1 July 2019	139,070,502	2,782,047	(9,293,956)	(106,459,114)	26,099,479	**26,099,479**
Adjustment related to new Accounting standards	–	–	–	(3,357)	(3,357)	**(3,357)**
Adjusted balance at 1 July 2019	139,070,502	2,782,047	(9,293,956)	(106,462,471)	26,096,122	**26,096,122**
– Loss for the period	–	–	–	(2,418,557)	(2,418,557)	**(2,418,557)**
– Other comprehensive income (translation)	–	(37,772)	–	–	(37,772)	**(37,772)**
Total comprehensive income for the period	**–**	**(37,772)**	**–**	**(2,418,557)**	**(2,456,329)**	**(2,456,329)**
Transactions with owners in their capacity as owners						
– Issue of shares on new operations	–	–	–	–	–	–
– Share-based payments	–	878,594	–	–	878,594	878,594
As at 31 December 2019	**139,070,502**	**3,622,869**	**(9,293,956)**	**(108,881,028)**	**24,518,387**	**24,518,387**

The accompanying notes form part of these financial statements.

Consolidated Cash Flow Statement

For the half-year ended 31 December 2019

	Note	31 December 2019 $	31 December 2018[1] $
Cash flows from operating activities			
Receipts from customers		8,061,816	2,597,570
Receipts from BARDA reimbursements and advances		1,684,778	2,518,699
Receipts of research and development income tax credit	9	–	794,256
Receipts from royalty revenue		123	128
Payments to suppliers and employees		(11,915,269)	(8,127,490)
Net cash outflows used in operating activities		(2,168,552)	**(2,216,837)**
Cash flows from investing activities			
Interest received		24,103	424,853
Payments for purchase of property, plant and equipment		(3,457,595)	(89,374)
Payments for deposit on property		–	(460,000)
Short-term cash deposits		–	19,000,000
Net cash (outflows)/inflows used in investing activities		(3,433,492)	**18,875,479**
Cash flows from financing activities			
Payment of lease liabilities		(178,318)	–
Proceeds from the exercise of options	14	–	660,000
Net cash flows from financing activities		(178,318)	**660,000**
Net (decrease)/increase in cash and cash equivalents		(5,780,362)	17,318,642
Cash and cash equivalents at beginning of period		13,920,695	3,147,082
Effects of foreign exchange rate changes		3,965	348,636
Cash and cash equivalents at the end of period	7	8,144,298	**20,814,360**

1. The Group has initially applied AASB 16 using the modified retrospective approach. Under this approach, comparative information is not restated. And the cumulative effect of initially applying AASB 16 is recognised in retained earnings (refer to Note 12).

The accompanying notes form part of these financial statements.

Notes to the Consolidated Financial Statements

For the half-year ended 31 December 2019

1. Corporate Information

The financial report of PolyNovo Limited and its controlled entities for the half-year ended 31 December 2019 was authorised for issue in accordance with a resolution of the Directors on 26 February 2020.

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 2019, which was prepared in accordance with the requirements of the *Corporations Act 2001*. This financial report also complies with IAS 34 Interim Financial Reporting, as issued by the International Accounting Standards Board.

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 2019 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 2019 is a condensed interim financial statements, 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

1. Significant Accounting Estimates, Judgements and Assumptions

The preparation of the Group's interim condensed consolidated financial statements requires management to make estimates, judgements and assumptions.

In preparing the interim condensed consolidated financial statements, the significant estimates, judgements and assumptions made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the most recent consolidated financial statements as at and for the year ended 30 June 2019.

As at 31 December 2019, there has been no new judgements with respect AASB Interpretation 23 Uncertainty over Income Tax Treatments. Other new estimates in relation to AASB 16 Leases included the application of an incremental borrowing rate with respect to discounting of future lease liabilities if the interest rate implicit in the lease is not readily determinable. The Group applies judgement in evaluating whether it is reasonably certain to exercise the option to renew. That is, it considers all relevant factors that create an economic incentive for it to exercise the renewal. As at 31 December 2019, there is no reasonable certainty to renewal of leases.

1.1 New standards, interpretations and amendments adopted by the Group

The accounting policies applied by the Group in this half-year financial report are consistent with those applied by the Group in its annual consolidated financial report as at and for the year ended 30 June 2019, except for the adoption of new standards effective as of 1 July 2019.

AASB Interpretation 23 *Uncertainty over Income Tax Treatment*

The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of the recognition and measurement criteria in AASB 112 Income Taxes. The Interpretation specifically addresses the following:

- Whether an entity considers uncertain tax treatments separately
- The assumptions an entity makes about the examination of tax treatments by taxation authorities
- How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- How an entity considers changes in facts and circumstances

The Group has assessed whether the Interpretation had an impact on its interim condensed consolidated financial statements. Upon adoption of the Interpretation, the Group considered whether it had any uncertain tax positions with no impact on the interim condensed consolidated financial statements of the Group.

AASB 16 *Leases*

The Group adopted AASB 16 Leases using the modified retrospective approach from 1 July 2019, and the impact that this initial application of AASB 16 has on the consolidated financial statements, is described below.

AASB 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognises a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. AASB 16 replaces existing leases guidance, including AASB 117 Leases, Interpretation 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.

Leases in which the Group is a lessee

The Group will recognise new assets and liabilities for its operating leases of its office premises and office equipment. The nature of expenses related to those leases will now change because the Group will recognise a depreciation charge for right-of-use assets and interest expense on lease liabilities.

The Group also applied the available practical expedients wherein it:

- Relied on its assessment of whether leases are onerous immediately before the date of initial application
- For lease payments the Group applies the practical expedient wherein it does not separate non-lease components from lease components, and instead accounts for each lease component and any associated non-lease components as a single lease component
- Used a single discount rate to a portfolio of leases with reasonably similar characteristics
- Applied the short-term leases exemptions to leases with lease term that ends within 12 months at the date of initial application
- Applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

Summary of new accounting policies

Right-of-use assets

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognised right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

Lease liabilities
At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

The adoption of AASB 16 required the Group to make a number of judgements, estimate and assumptions, these included:

- The estimated lease term – The term of each lease was based on the non-cancellable lease unless management was 'reasonably certain' to exercise options to extend the lease.
- The discount rate used to determine the lease liability –The Group uses an incremental borrowing rate of 3.9% for Australian based lease arrangements and 3.9% for US based lease arrangements at the lease commencement date if the interest rate implicit in the lease is not readily determinable and may vary based on the lease term. As the Group has no observable debt and no specific interest rates in existing lease contracts in place as at 1 July 2019, market information has been used. This is the most practical and readily observable starting point.
- Interest payments on lease liabilities have been recorded in cash flows from operating activities within the Statement of Cash Flows.

Transition
The application date of AASB 16 for the Group was 1 July 2019. Using the modified retrospective approach the right-of-use assets for operating leases were recognised based on the carrying amount as if the standard had always been applied, apart from the use of incremental borrowing rate at the date of initial application. Therefore, the cumulative effect of adopting AASB 16 is recognised as an adjustment to the opening balance of retained earnings at 1 July 2019, with no restatement of comparative information.

The Group applies the following transition practical expedients:

- A single discount rate to a portfolio of leases with reasonable similar characteristics;
- Applied a short-term leases exemptions to leases with lease term that ends within 12 months at the date of initial a initial application;
- Excluded the initial direct costs from the measurement of the right-of-use asset at the date of the initial application.

The transitional impact upon initial adoption of AASB 16 as at 1 July 2019 is:

- Inclusion of right of use asset of $2.5m;
- Inclusion of a lease liability of $2.5m;
- Decrease in retained earnings by $0.004m.

The weighted average borrowing rate used upon adoption of AASB 16 Leases was 3.6%.

The transitional impact upon initial adoption of AASB 16 Leases as at 1 July 2019 was as follows for the operating lease commitments:

Lease commitments reconciliation	**$**
Minimum lease payments contracted for as at 30 June 2019	3,005,377
Payments in optional extension periods not recognised as at 30 June 2019	–
Less: short term leases not recognised as a liability	(23,074)
Gross lease commitments as at 1 July 2019	2,982,303
Weighted average incremental borrowing rate at 1 July 2019	3.6%
Lease liabilities at 1 July 2019 as a result of initial application of AASB 16	**2,516,582**

Current lease liabilities of $249,988 and non-current lease liabilities of $2,170,564 are shown in The Statement of Financial Position. The total cash outflow for leases in the Half Year ended 31 December 2019 was $178,318.

Previously, the Group recognised an operating lease expenses on a straight-line basis over the term of the lease, and recognised assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognised.

Leases in which the Group is a lessor

The group did not enter into any arrangements as at transition date where it was considered as lessor.

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, one customer (BARDA) in the United States of America, represented more than 10% of total sales revenue from contracts with customers. The sales percentage was 16%.

	31 December 2019 $	31 December 2018 $
Revenue from contracts with customers		
Geographical areas		
United States of America	8,361,968	4,802,869
Australia and New Zealand	1,731,612	847,032
Rest of world	85,540	15,963
	10,179,120	**5,665,864**

	31 December 2019 $	31 December 2018 $
Non-current assets		
Geographical areas		
United States of America	283,211	67,386
Australia and New Zealand	11,990,600	3,389,502
	12,273,811	**3,456,888**

4. Revenue from Contracts with Customers

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

	31 December 2019 $	31 December 2018 $
Commercial product sales	8,571,640	3,750,728
BARDA revenue	1,607,480	1,915,136
	10,179,120	**5,665,864**

5. Expenses

	31 December 2019 $	31 December 2018 $
Employee related expense		
Wages and salaries	(4,724,014)	(2,902,767)
Superannuation	(251,702)	(163,555)
Share-based payments expense (note 14)	(878,594)	(40,128)
Other	(932,330)	(550,585)
	(6,786,640)	**(3,657,035)**

6. Loss Per Share

	31 December 2019	31 December 2018
Basic loss per share (cents)	$(0.37)	$(0.29)
Diluted loss per share (cents)	$(0.37)	$(0.29)
(a) Net loss used in the calculation of basic and diluted loss per share	($2,418,557)	($1,917,758)
(b) Weighted average number of ordinary shares on issue used in the calculation of basic loss per share	661,088,044	658,359,783

7. Cash and Cash Equivalents

Cash and cash equivalents are comprised of the following:

	31 December 2019 $	30 June 2019 $
Cash at bank and in hand	8,144,298	13,920,695
	8,144,298	**13,920,695**

As at 31 December 2019 the Company holds $50,000 (June 2019: $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.

8. Inventories

Inventories are comprised of the following:

	31 December 2019 $	30 June 2019 $
Finished goods	880,093	947,926
Provision for finished goods	(4,589)	–
	875,504	947,926
Work in progress	99,872	218,719
	975,376	1,166,645
Raw materials and other	72,533	48,805
	1,047,909	**1,215,450**

During the period, the Company did not write-off any inventory.

9. Receivables

Receivables are comprised of the following:

	31 December 2019 $	30 June 2019 $
Trade receivables	3,083,949	2,483,424
Contract assets	590,089	442,405
Research and development income tax credit	694,602	694,602
Interest receivable	7	–
GST recoverable	–	43,755
Sundry receivables	20,590	740,861
	4,389,237	4,405,047

The 31 December 2019 balance for research and development income tax credit of $694,602 relates to the 2019 financial year. This refund was received on 10 January 2020. At 31 December 2019, a research and development income tax credit has not been recognised as it is possible revenue will exceed $20 million for the full year, being the maximum revenue allowable for the claiming of a cash refund.

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 2019, the contract asset balance includes $424,053 (June 2019: $373,005) 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 2019, the trade receivables balance is $3,083,949 (June 2019: $2,483,424) offset by an expected credit loss amount of $27,076. To reduce risk exposure, the Company continues to apply stringent control procedures including a review of customer profile reports from debtor collection agencies prior to establishing the account.

10. Prepayments

Included in prepayments is an amount of $2,695,359 related to initial payments required for the purchase of manufacturing equipment. The manufacturing equipment will be installed in the new Port Melbourne manufacturing facility currently being constructed.

11. Property, Plant and Equipment

Acquisitions and disposals

During the six months ended 31 December 2019, the Group acquired assets with a cost of $1,943,832 (2018: $89,374). Of the cost recognised, $610,034 relates to construction costs for the new manufacturing facility which is not currently being depreciated. On completion of the facility, the related assets will be depreciated.

Impairment

Impairment expenses of $nil were recognised by the consolidated entity during the half-year ended 31 December 2019 (2018: $nil).

12. Right of Use Assets

Leases

The note provides information for leases where the group is a lessee.

	Right-of-use assets			
	Property $	Office Equipment $	Manufacturing Equipment $	Total $
Reconciliation of carrying amounts				
Transition adjustment at 1 July 2019	2,461,155	16,395	22,374	**2,499,924**
Additions	–	21,011	–	**21,011**
Depreciation expense	(146,660)	(4,659)	(4,351)	**(155,670)**
As at 31 December 2019	**2,314,495**	**32,747**	**18,023**	**2,365,265**

13. Contributed Equity

	31 December 2019		30 June 2019	
	No. of Shares	$	No. of Shares	$
Fully paid ordinary shares	**661,088,044**	**139,070,502**	661,088,044	139,070,502

During the Period under review the Company did not issue any new shares.

14. Reserves

	31 December 2019 $	30 June 2019 $
Share-based payments reserve (i)	**4,036,580**	3,157,986
Foreign currency translation reserve	**(413,711)**	(375,939)
Acquisition of non-controlling interest reserve	**(9,293,956)**	(9,293,956)
Balance at end of period	**(5,671,087)**	**(6,511,909)**

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

	31 December 2019		30 June 2019	
	No. of options	$	No. of options	$
Share-based payments reserve	**5,300,330**	**4,036,580**	1,000,000	3,157,986

During the period under review no options were exercised. Options on issue as at the beginning and at the end of the reporting period are detailed in the following table.

Date of Issue	6/3/2019	13/8/2019[1]	1/10/2019[2]	Total
On issue at beginning of the period	1,000,000	–	–	1,000,000
Granted during the period	–	1,000,000	3,300,330	4,300,330
Exercised during the period	–	–	–	–
Expired unexercised during the period	–	–	–	–
Forfeited/forfeited during the period	–	–	–	–
On issue at balance date	1,000,000	1,000,000	3,300,330	5,300,330
Issued subsequent to balance date	–	–	–	–
Exercised subsequent to balance date	–	–	–	–
Forfeited/Forfeited subsequent to balance date	–	–	–	–
On issue at date of Directors' Report	–	–	–	–
Current number of recipients	1	1	1	

1. On 13 August 2019, the Group issued a share option award to a senior executive under the PolyNovo Employee Option Plan. The exercise price of the option plan of $1.55 was equal to the market price of the shares on the date of grant. The options vest if the share price maintains $1.55 for a 3-month continuous period and the employee achieves a 2 year service anniversary. The fair value of the grant was estimated using the Monte Carlo simulation, taking into account the terms and conditions upon which the options were granted. There is no cash settlement of the options.
2. On 1 October 2019, the group issued a share option award of up to $10 million in shares to the Chief Executive Officer as a Long Term Performance Plan. The award was granted on 1 October 2019 and is subject to the group's market capitalisation reaching and maintaining $2 billion for a minimum period of 3 consecutive months across a 3 year service period from 1 October 2019, with the shares being allocate in three equal tranches from 1 October 2020 should they vest. Any shares that do not initially meet the market capitalisation hurdle will be available for retesting with the next tranche. All tranches then receive an additional and final retest in the financial year ending 30 June 2024. The awards each vest on 1 October after the end of the financial year. If the employee leaves before the 1 October vesting date they will not receive their allocation.

For the six months ended 31 December 2019, the group has recognised a share based payment expense of $878,594 (2018: $40,128) in the Statement of Comprehensive Income.

15. Contingent Liabilities and Contingent Assets

The Directors were not aware of any contingent liabilities or contingent assets as at 31 December 2019.

16. Capital Commitment

As at 31 December 2019, the Group had capital commitments of $4.5 million.

17. Corporate Information

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

18. Related Party Disclosures

Dr David McQuillan, a Non-Executive Director of the Group, received payments in the amount of $24,274 (2018: $34,506). These payments were in respect to consulting services provided to PolyNovo North America LLC for the R&D Hernia Project on normal and arms length commercial terms. This engagement has now ceased.

19. 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 2019

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 2019 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
26 February 2020

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 consolidated statement of financial position as at 31 December 2019, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated 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 2019 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 controls 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 31 December 2019 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.

Independent Review Report to the Members of PolyNovo Limited continued

Building a better working world

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.

Independence

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

Ernst + Young

Ernst & Young

Jlonergan

Joanne Lonergan
Partner
Melbourne
26 February 2020

Corporate Directory

ABN 96 083 866 862

Non-Executive Chairman

Mr David Williams

Non-Executive Directors

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

Chief Executive Officer

Mr Paul Brennan

Company Secretary

Mr Jan Gielen

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Australian Securities Exchange

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