

# PolyNovo

Half Year Results December 2019  
26<sup>th</sup> February 2020

**ASX: PNV**

Improving outcomes. Changing lives.



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# NovoSorb<sup>®</sup> polymer

## A unique platform technology

### NovoSorb<sup>®</sup>

- Base polymer developed by the CSIRO (Australian Government Research Organisation)
- PolyNovo developed the polymer further with foaming process and new formulations for medical devices
- Polymer that is programmable for re-absorption rate and product attributes.
- Excellent biocompatibility, safety and toxicity profile.
- Biodegrades through hydrolysis and excreted through urine, respiration and macrophage activity.

### Patented platform technology of biodegradable polymers that can be utilised as:

- A foam dermal scaffold
- Thermoplastic extrusions
- Filaments for weaving or knitting
- A solution for spray or dip coatings of other devices
- Patents on drug and antimicrobial elution
- 47 patents granted in the family all owned 100% by PolyNovo (4 new patents in process)

NovoSorb®  
**BTM**  
Sales Revenue H1  
**\$8.57M**

\$3.75 million 2018

Increase +129%

Cash on Hand  
**\$8.14 million 2019**

\$20.81 million 2018

Decrease -61%

R&D and New Capital  
Expenditure

**\$3.22 million 2019**

\$1.68 million 2018

Increase 92%

Total BARDA Revenue  
**\$1.61 million 2019**



\$1.92 million 2018

Decrease -16%

Inventory Value

**\$1.05 million 2019**

\$0.70 million 2018

Increase +50%

Total Employees  
**65 People 2019**

41 People 2018

Increase +59%

Net Loss

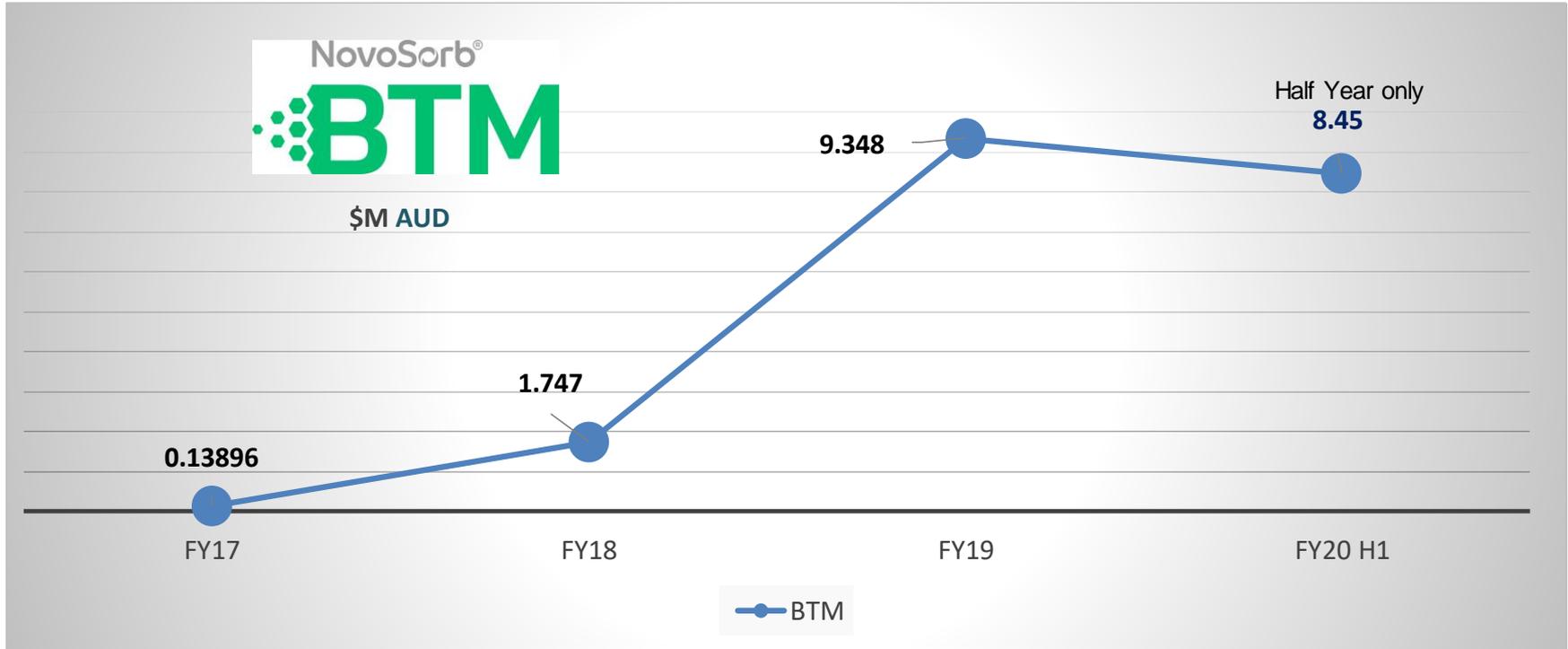
**\$2.42 million 2019**

\$1.92 million 2018

Increase +26%

Total Revenue H1  
**\$10.18M**

# NovoSorb BTM Commercial Revenues



**NB: Excludes all other revenues- only BTM sales**

- Expansion of the US sales team
  - Strong sales performance in US market with growing account penetration
- CE Mark approval December 2019
  - Allows for full Western European market entry
  - Initial markets UK/Ireland and DACH Region (Germany, Austria, Switzerland)
  - **UK/Ireland**- PolyNovo direct sales team **expanded** to 3 and 1 Marketer appointed
  - Further EU staff expansion in the H2 FY20
  - Surgeries and sales in DACH
  - Surgeries in UK
- Singapore/Malaysia
  - Appointed 1 direct PolyNovo salesperson with a third-party logistics (3PL) support
- PolyNovo response to White Island disaster (NZ)
  - Demonstrated supply capacity, logistics support and sales support of the surgical teams

#### Current staff distribution

Active recruitment in progress

US	26
Australia	39
UK/Ireland	4
Singapore	1

## Approved

Class III Medical device

- ✓ US FDA 510(K)
- ✓ CE Certification Europe, UK, Ireland
- ✓ TGA Inclusion
- ✓ NZ MedSafe
- ✓ South Africa
- ✓ India
- ✓ Malaysia
- ✓ Singapore
- ✓ Israel



## In Process

- South Korea
- Taiwan
- Mexico
- Kuwait
- Sri Lanka

- **Builder contracted**

- Foundation reinforcement
- Steel structure erected
- Electrical supply upgrade
- Cleanroom completion scheduled End May 2020



- **Production equipment delivered**

- Custom built production machines have been delivered with only a couple of machines outstanding
- All machines installed in an off-site facility to accelerate timeline to market
- Will move machinery into Port Melbourne new facility ~ June 2020



- Significant engagement with key opinion leaders
- Marketing plan refinement
- Once machinery installed in Port Melbourne commercial validation processes will run till end of 2020
- Regulatory dossier on track for US FDA filing
- US Market entry ~ June 2021

- **Breast product**
  - Working with Establishment Labs for first product design
  - Regulatory strategy being finalized, which will determine timeline
- **IP- Patent filings**
  - 4 new patents in “contestable phase” we will announce these once this phase is concluded
- **BetaCell**
  - The team at BetaCell have repeated pig studies utilizing stem cell derived Islet cells. Once the data is complete, they anticipate human trials sometime in 2020
- **Drug elution, Organoids and other opportunities utilizing NovoSorb polymer continue to be explored and will get greater resources once hernia transfers to manufacturing**

- CE Burn trial is complete publication March 2020
- BARDA funded Feasibility trial publication March 2020, sites were
  - Wake Forest Baptist Health, Winston-Salem,
  - University of Tennessee Medical Centre, Memphis
  - University of California Davis Medical Centre, Sacramento
  - Tampa General Hospital, Tampa
  - Arizona Burn Centre, Phoenix
  - Lehigh Valley Hospital, Allentown
- Granted US FDA “Break through technology” assessment pathway for NovoSorb BTM which will accelerate US FDA feedback, guidance and support of the trial program
- BARDA funded Pivotal burn trial will commence once US FDA approves protocol. This will determine the finalised number of centres, budget and timelines with announcements made in due course



# Offices Refurbishment & Expansion complete

- **Port Melbourne**

- Combined Unit 1&2 office areas and refurbished
- Allows for future team expansion
- Collaborative areas and meeting rooms



- **San Diego**

- Moving into enlarged area, in the same building, to accommodate expanded team
- Additional resources in Marketing, HR, Clinical Research and Administration



- **England/EU**

- Team currently work from home
- Will look at establishing an office in response to revenue generation and team resource expansion





**Mr David Williams** (*B.Ec (Hons), M.Ec, FAICD*)

Non-executive Chairman Mr Williams was appointed as a Nonexecutive Director on 28 February 2014 and Chairman on 13 March 2014. Mr Williams is an experienced Director and investment banker with a proven track record in business development and strategy, as well as in mergers and acquisitions and capital raising. He possesses 35 years' experience working with and advising ASX-listed companies in the food, medical device and pharmaceutical sectors. Mr Williams is currently Chairman of ASX-listed Medical Developments International Ltd (ASX: MVP), Chairman of RMA Global Limited and is Managing Director of investment bank Kidder Williams Ltd.



**Dr Robyn Elliott** (*BSc (Hons) Chemistry PhD Inorganic Chemistry*)

Dr Elliott is currently Senior Director for Strategic Expansion Projects at CSL Behring, previously she was the Managing Director at IDT Australia and commenced her career at DBL Faulding. Dr Elliott has a proven track record in product development, clinical trials, regulatory affairs, audits, quality management and operational strategy. At CSL, her worldwide experience in new plant development and strategy, regulatory affairs and audit will be invaluable to PolyNovo as the company scales its operations globally.



**Mr Philip Powell** (*B.Comm (Hons), ACA, F.Fin, MAICD*)

Non-executive Director Mr Powell was appointed a Director of PolyNovo on 13 May 2014 and was Acting Managing Director from 15 July 2014 to 13 February 2015. Mr Powell has many years' experience in investment banking specialising in capital raisings, Initial Public Offerings (IPOs), mergers and acquisitions and other successful corporate finance assignments across a diverse range of sectors including utilities, IT, pharma, financial services, food and agriculture. He spent 10 years in senior financial roles at OAMPS Ltd, a former ASX-listed financial services group, and 10 years in audit with Arthur Andersen & Co in Melbourne, Sydney and Los Angeles. Mr Powell is currently a Non-executive Director of Medical Developments International Ltd (ASX: MVP), RMA Global Ltd (ASX: RMY) and BARD1 Life Sciences Ltd (ASX:BD1).



**Dr David McQuillan** (*PhD*)

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



**Mr Bruce Rathie** *(B.Comm, LLB, MBA, FAIM, FAICD, FGIA)*

Non-executive Director Mr Rathie is an experienced Company Director with a finance and legal background. He practised as a partner in a large legal firm and acted as Senior Corporate Counsel to Bell Resources Limited in its early years. He then studied for his MBA in Geneva and embarked on his 15 year investment banking career. When Head of the Industrial Franchise Group at Salomon Smith Barney he led Salomon's roles in the Federal Government's privatisation of Qantas, Commonwealth Bank (CBA3) and Telstra (T1). He now has over 17 years' experience as a full time professional Non-executive Director. He is currently Chairman of Capricorn Mutual Limited and a Non-executive Director of Capricorn Society Limited and Australian Meat Processors Limited. In the medical device space, he was previously Chairman of ASX listed Anteo Diagnostics Limited and a Director of Compumedics Limited and USCOM Limited. He has been a Non-executive Director of PolyNovo since February 2010.



**Mr Max Johnston** Non-executive Director. Mr Johnston was appointed a Director of PolyNovo on 13 May 2014. Mr Johnston held the position of President and Chief Executive Officer of Johnson & Johnson Pacific, a division of the world's largest medical, pharmaceutical and consumer healthcare company for 11 years. Prior to joining Johnson & Johnson, Mr Johnston's career also included senior roles with Diageo and Unilever in Europe. Mr Johnston has also held several prominent industry roles as a past President of ACCORD Australasia Limited, a former Vice Chairman of the Australian Food and Grocery Council and a former member of the board of ASMI. Mr Johnston has had extensive overseas experience during his career in leading businesses in both Western and Central-Eastern Europe and Africa as well as the Asia-Pacific region. Mr Johnston is currently a Non-executive Director of Medical Developments International Ltd (ASX: MVP), CannPal Limited (ASX: CP1), ProLife Foods NZ, BARD1 Life Sciences Ltd (ASX:BD1) and Non Executive Chairman AusCann (ASX: AC8) and was a former Non Executive Director of Enero Group Limited (ASX: EGG), and Non-executive Chairman of Probiotec Ltd (ASX: PBP).



**Mr Leon Hoare** *(GradDipBus, AssocDipAppSc(Ortho), GAICD)*

Non-executive Director Mr Hoare was appointed a Director of PolyNovo on 27 January 2016. He is the Managing Director of Lohmann & Rauscher, Australia & New Zealand (ANZ), a private EU based medical device company. Previously he was Managing Director of Smith & Nephew ANZ (all divisions) until the end of 2015, one of Smith & Nephew's largest global subsidiaries outside the USA. He served as President of Smith & Nephew's Asia-Pacific Advanced Wound Management (AWM) businesses for 5 years and was a member of the Global Executive Management for the AWM Division. In his 24 years with Smith & Nephew, he also held roles in marketing, divisional and general management. His career also included a senior role at Bristol-Myers Squibb in surgical products, and as Vice Chair of Australia's peak medical device body, Medical Technology Association of Australia. He is currently a Non-Executive Director of Medical Developments International Ltd (ASX: MVP).



**Mr Paul Brennan** (MBA, BSc (Nursing) RN RM)

**Chief Executive Officer**

Mr Brennan was appointed Chief Executive Officer (CEO) of PolyNovo Ltd on 13 February 2015. Mr Brennan has extensive knowledge, exposure and understanding of the health system through his clinical background and commercial exposure with various multinational companies. He has coordinated the marketing, global strategy development, new product development and regulatory processes for the Asia-Pacific region for industry-leading organisations in relation to medical products and devices.

Mr Brennan has an intimate knowledge of the manufacturing and production processes. Previously he was Marketing Director Australia and New Zealand and Sales Director New Zealand for Smith & Nephew Healthcare from 2008 to his commencement with PolyNovo in February 2015. Mr Brennan holds a MBA from Swinburne University, a Bachelor of Science (Nursing) from the University of New England in NSW, Certificate in Midwifery Central Coast Area Health Service NSW, and General Nursing certificate from St Vincent's Hospital Darlinghurst NSW.



**Mr Jan-Marcel Gielen** (CA, Bachelor Bus (Acc))

**Chief Financial Officer and Company Secretary**

Mr Gielen joined PolyNovo on 13 December 2018. Mr Gielen holds a Bachelor of Business (Accounting) degree from Monash University, is a member of the Institute of Chartered Accountants and commenced his career with Pitcher Partners. Since then Mr Gielen has held senior finance roles for various businesses across a range of industries such as retail, ICT, logistics (3PL) & medical, both locally and internationally. Mr Gielen has extensive experience in CFO and Finance Director roles for fast growing PE and VC backed businesses and played an important part in expanding these businesses globally, both from a financial and operational perspective. Mr Gielen had a long involvement from inception with ICIX, a leading SaaS platform supporting global retailers and manufacturers where he served as Finance Director in Silicon Valley. Mr Gielen's most recent role was CFO of CardioScan for 6 years, Australia's largest cardiac reporting provider, which during his tenure the business expanded to HK, Singapore & North America.



## **Dr. Tim Moore**

### **Principle Scientist**

completed a Bachelor of Applied Science (Chemistry) degree at Swinburne University of Technology, followed by an honours degree and PhD degree. Dr. Moore's PhD dissertation was in the field of biodegradable polyurethanes; the title was 'Design and Synthesis of Biodegradable Thermoplastic Polyurethanes for Tissue Engineering'. Dr. Moore has been involved with PolyNovo since its inception and is a co-inventor of some of the variants of NovoSorb™. He has been working on the development of biodegradable polymers for medical devices for over ten years. His main area of expertise is in polyurethanes and the development of biomaterials for use in medical devices. He developed a novel range of biodegradable chain extenders which is included in several of PolyNovo's patent applications. Dr. Moore is involved in project management and product development in PolyNovo's leading applications. Dr. Moore is also responsible for the maintenance of PolyNovo's extensive Intellectual Property Portfolio. He is co-author on a number of peer-reviewed papers and patent applications. He was a co-recipient of the CSIRO Molecular Science Divisional Strategic Action Plan Award for Innovation (2004) and of the CSIRO medal in Research Achievement category (2005).



## **Mr Gordon Fleming** (BSc (Hon) Industrial Chemistry, MBA)

### **Director of Operations**

Gordon's career spans three decades in Australia, Asia, and Europe including more than 20 years best-in-class manufacturing experience in the Chemical, FMCG, Food and Packaging sectors. After completing his degree in Industrial Chemistry at the University of NSW, Gordon began a 15-year stint in food sciences, during which time he held a range of operational leadership positions with Australian and Asian food manufacturers including Meadow Lea and Don Smallgoods.

Aside from a two-year stint in the commercial packaging industry, Gordon's career has been with BASF, the German chemical giant. Following four years as BASF-Australia's Manufacturing and Operations Manager, Gordon was made the global Head of Intelligence and Synergies, based in Ludwigshafen, Germany and in which capacity he introduced best practice manufacturing processes at 25 major sites across the world. He returned to Melbourne in 2013 as Head of Technology and Operational

