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11 April 2017

ASX CEO Sessions, PolyNovo Presentation

PolyNovo Limited is pleased to release the presentation to be given by CEO Paul Brennan today at the ASX CEO Sessions in Sydney. The presentation provides an update on the Company's activities and development plans.

NB: There are some graphic surgical images contained within the presentation.

Further information: David Williams Chairman Mobile: +61 414 383 593

Paul Brennan Chief Executive Officer Mobile +61 427 662 317

About BTM

The BTM[™] is a tissue scaffold that facilitates the regeneration of the dermis when it has been lost or damaged through trauma, burns, surgery or wounding. The BTM has US FDA 510(k) approval for surgical wound application in the US Market with sales now in Australia, South Africa and New Zealand.

About PolyNovo

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



PolyNovo Market Update

Paul Brennan ASX CEO sessions April 2017

Improving outcomes. Changing lives.

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ASX : PNV

Corporate Overview



		Key Milestones			
-		2004 PolyNovo incorporated ex-CSIRO			
Share price 5 year graph				2006 NovoSkin feasibility study	
			2008 Port Melbourne facility established		
			2010 NovoSkin is incorporated		
			Bio-Innovation SA grant (\$217K)		
			2011 Feasibility study on NovoPore NPWT		
			2013 First BTM human study (Royal Adelaide Hospital)		
		Hernia feasibility study			
		Pelvic floor repair study			
		2014 NovoPore regulatory approval 510(k) and CE Mark			
		Royal Adelaide BTM burn trial			
		Key Milestones			
		2015 New CEO & 2 full-time regulatory staff, additional scientist			
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			Factory expansion to enable commercial production		
			BTM CE trials commence and patients enrolled		
				Successful capital raising of \$13.8M with in-flow of institutional investors	
				Successful capital raising of \$13.8M with in-flow of institutional investors	
				Successful capital raising of \$13.8M with in-flow of institutional investors Royal Adelaide Hospital patient trial enrolment concluded	
2013	2014	2015 2016	2017		
		2015 2016	2017	Royal Adelaide Hospital patient trial enrolment concluded	
	2014 <b>5A</b>	1		Royal Adelaide Hospital patient trial enrolment concluded US BARDA contract signed	
9	\$A	Major Shareholde		Royal Adelaide Hospital patient trial enrolment concluded US BARDA contract signed US FDA 510(k) clearance for BTM use in surgical wounds	
	\$A PNV	1		Royal Adelaide Hospital patient trial enrolment concluded US BARDA contract signed US FDA 510(k) clearance for BTM use in surgical wounds 2016 Established Direct US based sales & marketing team	
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ASX Code Share Price	<b>PNV</b> <b>27 cents</b> (31/03/17)	Major Shareholde 31.48% The Trust Company	e <b>rs</b> 11.05%	Royal Adelaide Hospital patient trial enrolment concluded         US BARDA contract signed         US FDA 510(k) clearance for BTM use in surgical wounds         2016 Established Direct US based sales & marketing team         Contracted Owens&Minor as 3PL provider to support logistics/sales in US         Established Australia & New Zealand distribution through Device Technologies         Entered South Africa through a distribution agreement with: Surgical Solutions	
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# NovoSorb



### NovoSorb

- Developed by the CSIRO and spun out as PolyNovo. Listed on the ASX 2004
- Unique attribute is that the Polyurethane is made with no aromatic isocyanates or solvents
- · Excellent biocompatibility, safety and toxicity profile
- Biodegrades through hydrolysis and excreted through urine, respiration and macrophage activity
- Patented platform technology of biodegradable polymer that can be utilised as:
  - a foam wound scaffold
  - thermoplastic extrusions
  - filaments for weaving or knitting
  - a solution for spray or dip coatings of other devices
  - patents on drug and antimicrobial elution

### **Purely synthetic materials**

- No organic remnants, sensitising proteins, no risk of rejection, no cross species risk, unique market proposition

### **Key Attributes**

- Excellent biocompatibility and harmless degradants
- Unparalleled range of mechanical properties and degradation times
- Versatile formats enabling many product development/application options
- Scalable manufacturing process
- · Fully manufactured in Port Melbourne

# **BTM Product Description**



BTM is a fully synthetic, biodegradable dressing with 3 layers:

## Sealing membrane

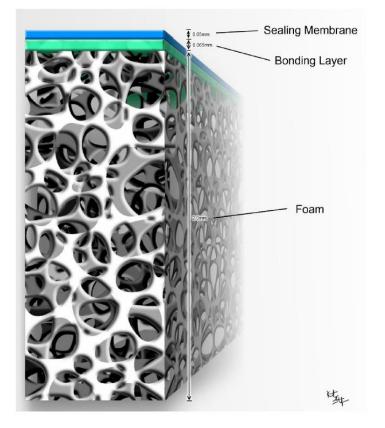
A temporary, transparent, polyurethane sealing membrane designed to physiologically 'close' the wound limiting water loss/evaporation

## Bonding layer

A temporary PU bonding layer designed to adhere the sealing polyurethane film/membrane

### • Foam

2 mm thick, white, open cell, high porosity, bio-degradable polyurethane foam provides a scaffold/matrix for dermal tissue integration



# **PolyNovo Resource Expansion**



- Cleanroom expansion will be complete June 2017. Provides 60% increase of space enabling improved process flow, higher production volumes, improved efficiency and waste reduction
- Melbourne team expanded to 24.2 FTE over past two years, with greater resources in:
  - Regulatory & Quality Management
  - Production
  - Marketing & Business Development
- US Team
  - Sales team of three plus two contract sales people. Further sales people will be added commensurate with sales revenues
  - Marketer
  - Regulatory Director
  - Program Manager (BARDA & Clinical Trials)

## **BTM on Sale**



## US

- BTM in use in 5 states of US, more to come on stream in coming months
- Progressing through the hospital procurement committees/process and staff education on use and care of the BTM. We anticipate a step change in sales in the coming months.
- Initial surgeon experience positive with the BTM showing robust performance in challenging cases. Five
  patients treated. Two patients absconded with their BTM newly implanted but have since had skin grafts
  with good results, demonstrating the robust nature of the BTM. All these surgeons have expressed an
  intention to use BTM again.
- · Logistics can reach all US hospitals with next day delivery
- Dedicated US PolyNovo website February 2017 <u>www.polynovo.com</u>
- Advertising campaign, Medical Journals, commenced February 2017
- Trade booths at major US medical conferences Boswick, NABS and ABA

### Photos: ABA Booth



#### Advertising BTM in US



### 1st Shipment to US, production team



## **BTM on Sale**



## Australia & New Zealand

- Device Technologies (DT) exclusive distribution agreement, sales made
- DT have a dedicated plastic surgery sales team, BTM has been used already
- NZ registration with sales available through all District Health Board
- Australia sales through the TGA exemption scheme
- Sales to date for necrotizing fasciitis, free flaps and burns
- New clinician focused website <u>www.polynovo.com.au</u>
- New marketing materials downloadable from the website
- Silver sponsor at the ANZBA conference , Adelaide October 2017



# **BTM on Sale**



## **South Africa and other African Countries**

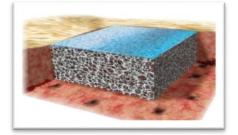
- SA health system transforming to full public access scheme over the next 2 years
- Ascendis Medical subsidiary, Surgical Innovations, is our exclusive distributor
- 5 dedicated BTM sales representatives, experienced in the plastic/burn surgery segment
- Initial sales focus is the private market sector
- Establishing trials in public system
- Initial sale to distributor with strong interest form hospitals and surgeons

## Other distributor markets for potential entry in CY 2017, work in progress

- Israel
- India
- Hong Kong
- Middle East: UAE, Saudi Arabia, Qatar, Bahrain, Jordan

# **BTM Application and Integration**





**BTM only applied to a surgically debrided wound bed** The wound is 'physiologically closed', limiting contraction and risk of infection.



## **BTM** fully integrated

The dermis is regenerated within the scaffold/foam. Once fully integrated, assessed by blanch test, the seal is ready for removal.





**Sealing membrane removed** The neo-dermis is ready for final closure.



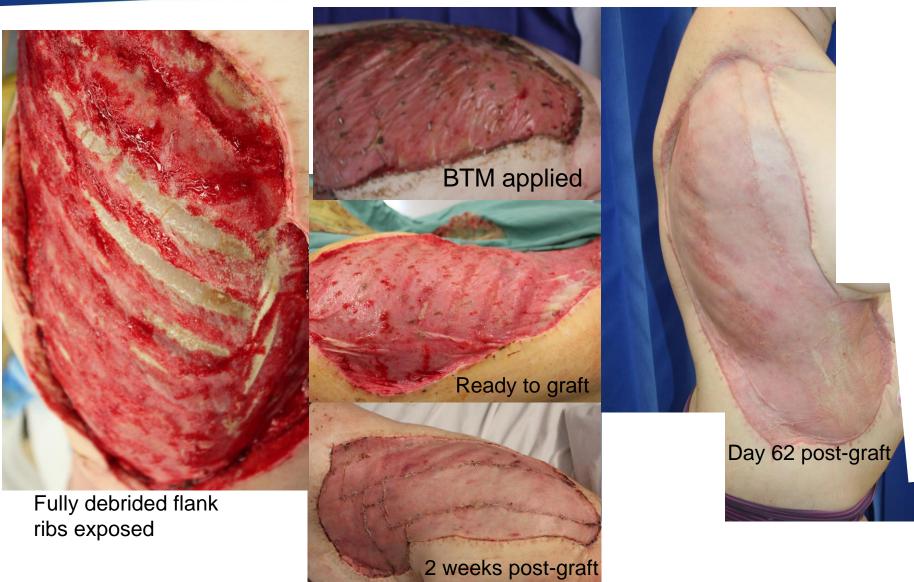
## Method of closure is the Surgeon's clinical choice:

- Large areas best closed with a split skin graft, meshed
- Small areas can be closed under existing moist wound healing dressings such as hydrocolloids or occlusive.
   BTM biodegrades in ~12 months.

4

# **BTM - Necrotizing Fasciitis**





# **Necrotizing Fasciitis, Neck**





Day 77, full range of movement; published ePlasty

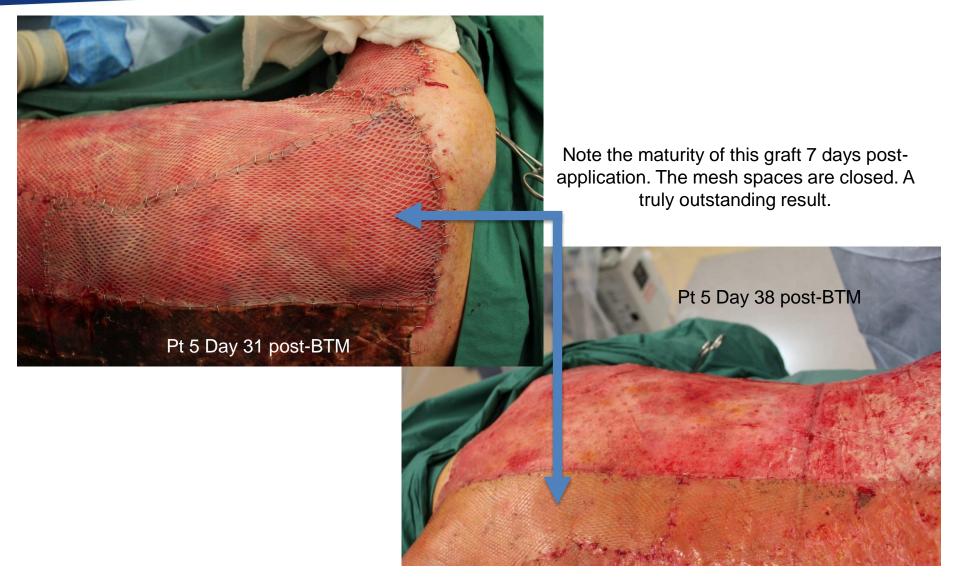
## **BTM Over Bone**





## **Allows for Staged Grafting**





# **Outcomes - the first 5 Burn patients**





Pt 1 Day 536

Pt 2 Day 368

Pt 3 Day 312

Pt 4 Day 171

Pt 5 Day 194

# **Outcomes- supple skin, elasticity**







A CE Mark is a regulatory standard/requirement for many countries eg: Europe, Australia, SE-Asia. Clinical trails are required as part of a Class III certification

- PolyNovo require 30 burn patients within the trial
- Outcomes:
  - BTM take, skin graft take, assessment through to 12 months post-graft application
- Current status 17/30 enrolled to date
  - Less three deaths unrelated to BTM and one exclusion
- Sites:
  - The Alfred Hospital Melbourne
  - Royal Brisbane & Women's Hospital
  - Royal North Shore Hospital Sydney
  - Concord Hospital Sydney
  - St. Anne's Hospital Toulon, France. One patient has completed follow-up and the site is now closed due to cost and slow recruitment.
- Estimate conclusion of recruitment August 2017 based on one patient per site per month
- Estimate CE application from burns trial November 2018
- Working concurrently on Priority Review pathway for CE application with the TGA. If successful, we may achieve CE certification in Q1 2018.

# **BARDA PMA Trial Programs**

BARDA is a US Federal agency within the Department of Human & Health Services. They are charged with preparing for mass disaster management. BARDA awarded PolyNovo a contract which funds our US based clinical trials program. Success in these trials will lead to a US FDA PMA certification for treatment of full thickness burns with BTM.

- Feasibility trial
  - 10 patients in 3 sites Memphis, Sacramento and Tampa
  - All 2 of 3 sites actively recruiting, Memphis recruitment imminent
  - Current status 1/10 enrolment
  - Long timelines to activate sites with legal contracting, CRO processes and BARDA engagements/requirements
  - Conclude recruitment estimate November 2017
  - FDA approval to add an additional two sites, in progress
- Swine Study, degradation and toxicity
  - Concluded pilot trial
  - Conclude swine study November 2019 or earlier, dependent on the degradation rate and satisfying FDA requirements. Final report submitted to FDA February 2020
- Planning to submit a modular PMA that allows for FDA submission of data as it becomes available.





# **New Product Pipeline**



Product	BTM Wounds & Burns	Breast Sling	Hernia	Breast form	Skin Depots
Regulatory	FDA 510(k) <b>cleared</b> CE approval est 2018 US Burns PMA 2022	US FDA PMA clinical trials CE standard non-clinical & clinical TBD	US FDA 510(k) predicates CE- non-clinical study	US FDA510(k) CE Class III	PNV Polymer & BTM supplier. Regulatory submissions by partnered organisation
Total Market Opportunity	\$1B+ opportunity to expand the matrix market	\$500M+ of \$2b Expand the market through wider adoption	\$400M+ of \$1.5b	\$3b with opportunity to be determined	Drug to be defined BetaCell yet to be quantified
Clinical programs	CE Burns Trial conclude recruitment Aug 2017 PMA Feasibility recruitment close Nov 2017 Pivotal timeline to be defined	Biocompatibility, toxicology, non-clinical trial, clinical trial	Biocompatibility, toxicology, non- clinical trial	To be determined.	Each of the applications have specific non-clinical programs in progress
Resource requirements	CROs, engaged external consultants BARDA funding for PMA trials	CRO- clinical trial Likely third party manufacturer, IP retained by PNV	Likely third party manufacturer, IP retained by PNV	R&D and manufacturing resources	PNV R&D resources
USP	Only synthetic matrix scalable production, lower cost, excellent clinical outcomes, ease of use, less infection risk than biologics	Synthetic biodegradable, reduced contracture, simpler revision	High strength, novel material, biodegradable	Safety profile and degradation, growth PU breast forms in expanded global market	Safety profile and degradation/elution profile
In Market estimate	On sale now <b>US, NZ, SA,</b> Australia* Please refer to slide 8	US 2021 EU/Aust, SE-Asia 2019/20	US 2019 EU, SE-Asia 2019	TBD with partner	TBD with partners

# **Board and Senior Executive**



### David Williams – Chairman

Mr Williams was appointed as a Non-Executive Director on 28 February 2014 and Chairman on 13 March 2014.

Mr Williams is an experienced Director and Investment Banker with a proven track record in business development and strategy, as well as in corporate initiatives specialising in mergers and acquisitions and capital raising. He has more than 30 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), and is Managing Director of corporate advisory firm Kidder Williams Ltd. Mr Williams resigned as Non-executive Director of IDT (ASX:IDT) on 19 May 2015.

### **Bruce Rathie – Non Executive Director**

Mr Rathie was appointed a Non-Executive Director on 18 February 2010.

Mr Rathie is an experienced Company Director and lawyer holding degrees in law, commerce and business having practiced as a Partner in a large legal firm and then as Senior in-house Counsel to Bell Resources Limited from 1980 to 1985 in aggregate. He studied for his MBA in Geneva and then went into investment banking in 1986. Mr Rathie was Head of the Industrial Franchise Group at Salomon Smith Barney in the late 1990's and led Salomon's roles in the Federal Government's privatisation of Qantas, Commonwealth Bank (CBA3) and Telstra (T1). He now has over 15 years 'experience as a professional Non-executive Director.

He is currently Chairman of DataDot Technology Limited (7 years), Vice Chairman of Capricorn Society Limited (2 years) and Chairman of Capricorn Mutual Limited (2 years). In the medical device space, he was previously a Director of Compumedics Limited (2 years) and USCOM Limited (5 years) and has been a Non-executive Director of PolyNovo Limited since February 2010 (7 years). In addition, he was previously Chairman of Anteo Diagnostics Limited (3 years).

### Dr. David McQuillan - Non Executive Director

Dr McQuillan was appointed a Non-Executive Director on 6 August 2012.

Dr McQuillan possesses extensive technical, medical, scientific and regulatory knowledge as well as merger and acquisition expertise. Dr McQuillan was with LifeCell Inc/Kinetic Concepts Inc for 12 years, and served a number of roles increasing responsibility, 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.

### Max Johnston – Non Executive Director

Mr Johnston was appointed a Non-Executive Director on 13 May 2014.

Mr Johnston was a former senior executive with Johnson & Johnson, the world's largest Medical, Pharmaceutical and Consumer Healthcare company. He was President and CEO of Johnson & Johnson Pacific until retirement in 2009. He also lead several Asia Pacific and Global Franchise and Functional working groups. Mr Johnston has also served as a past President of ACCORD Australia, Vice Chairman of the Australian Food and Grocery Council (AFGC) and board member of the Australian Self Medication Industry (ASMI). Prior to joining Johnson & Johnson Max held senior local and international executive positions with Unilever and Diageo and was Non-Executive Chairman of Probiotec and a Non Executive Director of ENERO until 2016. He brings extensive overseas and local experience of leading businesses and franchises in Asia-Pacific, Western and Central Europe and Africa .Other current Directorships including ProLife Foods NZ Pty Ltd and Medical Developments International (ASX:MVP).



### **Philip Powell – Non Executive Director**

Mr Powell was appointed a Non-Executive Director on 13 May 2014.

Mr Powell has over 18 years' experience in investment banking specialising in capital raisings, 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 has been involved in numerous IPO engagements, valuations and venture capital related raisings. Mr Powell is currently a Non-executive Director of Medical Developments International Ltd (ASX:MVP).

#### Leon Hoare – Non Executive Director

#### Mr Hoare was appointed a Non-Executive Director on 27 January 2016.

Mr Hoare is 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, which is one of the company's largest global subsidiaries outside the USA. Until 2014 he served as President of Smith & Nephew's Asia Pacific Advanced Wound Management (AWM) business for 5 years. He was also 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. Mr Hoare's career also included a senior role at Bristol-Myers Squibb in surgical products, and Vice-Chair of Australia's peak medical device body, Medical Technology Association of Australia. Leon is currently a Non-executive Director of Medical Developments International Ltd (ASX:MVP).

#### Paul Brennan – Chief Executive Officer

Paul has extensive knowledge, exposure and understanding of the health system through his clinical background and commercial exposure with various multinational companies. He has co-ordinated the marketing, global strategy development, new product development and regulatory processes for the Asia-Pacific region for industry leading organisations in relation to medical products and devices. Paul has an intimate knowledge of the manufacturing / production processes. Previously he was the Marketing Director Australia and New Zealand and Sales Director New Zealand for Smith and Nephew Healthcare from 2008 to his commencement with PolyNovo in February 2015. Paul holds a Masters of Business Administration (MBA) from Swinburne University and a Bachelor of Science (Nursing) degree from the University of New England.

### Mr Gavin Smith CPA - CFO and Company Secretary

Mr Smith was formally appointed as a Joint Company Secretary on 20 January, 2017. He is a CPA and a member of the Australian Institute of Company Directors and is contracted on an interim basis during Ms Andrea Goldie's maternity leave period. Mr Smith has extensive experience as a Public Company CFO and Company Secretary across multiple industry sectors including industrial, agribusiness, mining and financial services. He has had involvement in a number of businesses in other regions including North & Central America, Europe and many parts of Asia and has a special interest in linking supply chain activities to financial outcomes.

In recent times, Mr Smith has been involved in a number of CFO and company secretarial roles on an interim and/or part-time basis. Prior to this, he was engaged in senior commercial finance roles for a number of major companies including BTR Nylex, Elders, Incitec Pivot, IOOF, ION, Orica and Sunrice.

# **PolyNovo - The Australian Team**





# **PolyNovo - Triathlon Team**



