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11 February 2016

### **Institutional Investors visit PolyNovo**

PolyNovo Limited (ASX: PNV) hosted a group of institutional investors on Wednesday afternoon.

Paul Brennan, the CEO of PolyNovo Limited, gave the attached presentation that was followed by a teleconference session with Professor John Greenwood and a guided factory tour.

Professor Greenwood elaborated on the development pathway and clinical experience of the BTM. He made further comments of the robust nature of the BTM in challenging clinical applications.

The material covered in the presentation is consistent with previously released investor presentations. In addition, the presentation contains images of patient 5 and further information in relation to PolyNovo's breast and hernia product development.

Viewer discretion is recommended as photographs are graphic.

#### **Further information:**

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# Vision

*We regenerate lost or damaged tissue through patented biodegradable medical devices.*

Investor presentation 10 February 2016

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# Board and Senior Executive

## David Williams – Chairman

David 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 possesses over 25 years' experience working with and advising ASX listed companies in the food, medical device and pharmaceutical sectors.

## Dr. David McQuillan – Non Executive Director

Dr McQuillan was appointed a Director of PolyNovo on 6 August 2012 and Joint Acting Managing Director on 15 July 2014. 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 of increasing responsibility, including Vice-President for Research and Development at LifeCell, and Senior Vice President of Advanced Research and Technology at KCI. Chief Science Officer for TELA Bio, a VC-funded development-stage biotechnology company from 2013 to 2015. He currently serves as an Operating Partner of 1315 Capital, a private equity partnership that provides capital to commercial-stage pharmaceutical, medical technology, and healthcare services companies

## Max Johnston – Non Executive Director

Max held the position of President and Chief Executive Officer of Johnson & Johnson Pacific, the world's largest Medical, Pharmaceutical and Consumer Healthcare Company for 11 years. During his tenure he also served as Director of Johnson & Johnson Research and was a member of their Research Review Committee. Prior to joining Johnson & Johnson, Mr. Johnston's career also included senior roles with Diageo and Unilever in Europe. Max has had extensive overseas experience during his career in leading businesses in both Western and Central-Eastern Europe, Africa as well as Asia-Pacific.

## Bruce Rathie – Non Executive Director

Mr Rathie is an experienced company director and lawyer holding degrees in law (LLB), commerce (BComm) and business (MBA) having practised 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. Bruce 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 company director. He is currently Chairman of eftpos Payments Australia Limited (6 years), Executive Chairman of DataDot Technology Limited (6 years) and a non-executive director of Capricorn Society Limited (7 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 (5 years). In addition, he was previously Chairman of Anteo Diagnostics Limited (3 years)

# Board and Senior Executive (continued)

## Philip Powell – Non Executive Director

Philip has over 15 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, 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. Philip has been involved in numerous IPO engagements, valuations and venture capital related raisings

## Leon Hoare – Non Executive Director

2015 Mr Hoare was Managing Director of Smith & Nephew Australia & New Zealand, which is one of the company's largest global subsidiaries outside the USA. Importantly, 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.

## 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 in NSW, General Nursing and Midwifery Certificates.

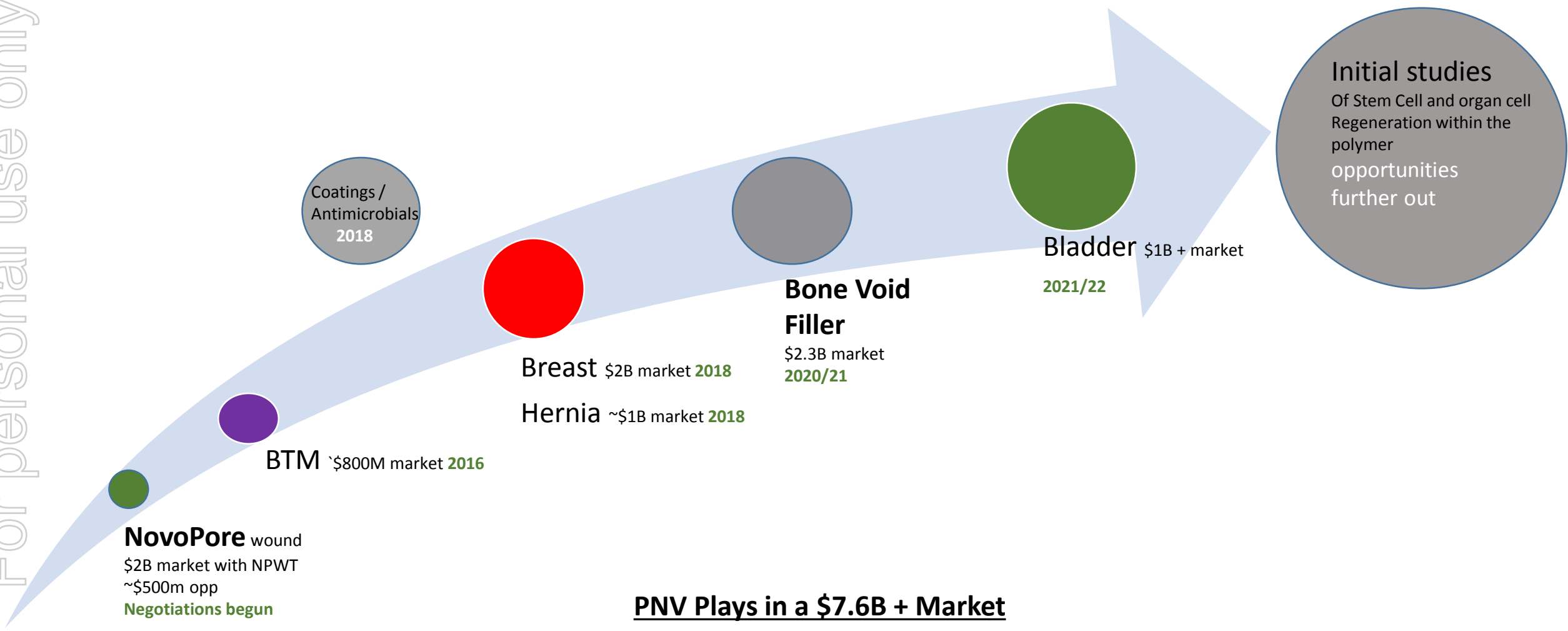
## Ms Andrea Goldie CPA - CFO and Company Secretary

Ms Goldie was appointed Company Secretary and Chief Financial Officer (CFO) of PolyNovo on 28th October 2015.

Ms Goldie has over 13 years corporate governance experience with multinational companies within the Pharmaceutical and Health-care industries. Areas of expertise include financial accounting, statutory reporting, auditing and tax compliance. These skills have been applied across a number of geographic regions including Europe, Middle East, Africa, Asia Pacific and North America. Ms Goldie is a Chartered Accountant; Chartered Tax Adviser and holds a Bachelors of Economics, Finance and a MBA.

# Projected Developments & Markets

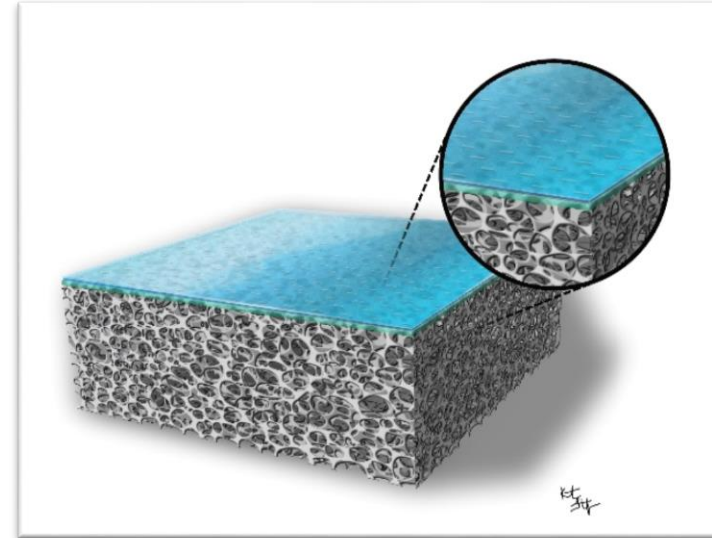
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# What makes NovoSorb Unique?

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- **Purely synthetic matrix**
  - No organic remnants, sensitising proteins
- **Competitors are biological based**
  - Animal sourced: Pig, Cows, Shark, Sheep, Combinations
  - Human: Cadaver skin, Placenta /Amniotic
  - Complex manufacturing and expensive to scale up
- **Developed**
  - Burn and wound repair
    - Biodegradable Temporizing Matrix (BTM)
  - Negative Pressure Wound Therapy
    - NovoPore negative pressure wound dressing
- **In-Development**
  - Hernia repair – Mesh & Foam or reinforced foam
  - Pelvic Floor repair – combination device
  - Breast Reconstruction – considering 3D concepts
  - Breast Augmentation – foam coating, non-resorbable
  - Breast Slings – combination device



# BTM in use

## Current standard of care

- Note the scarring and the tendons in this example of the traditional approach



- Note tendons and poor skin quality

## BTM - Innovates the standard



- Note the lack of scar/contracture and topography.



# Tendon is free to move

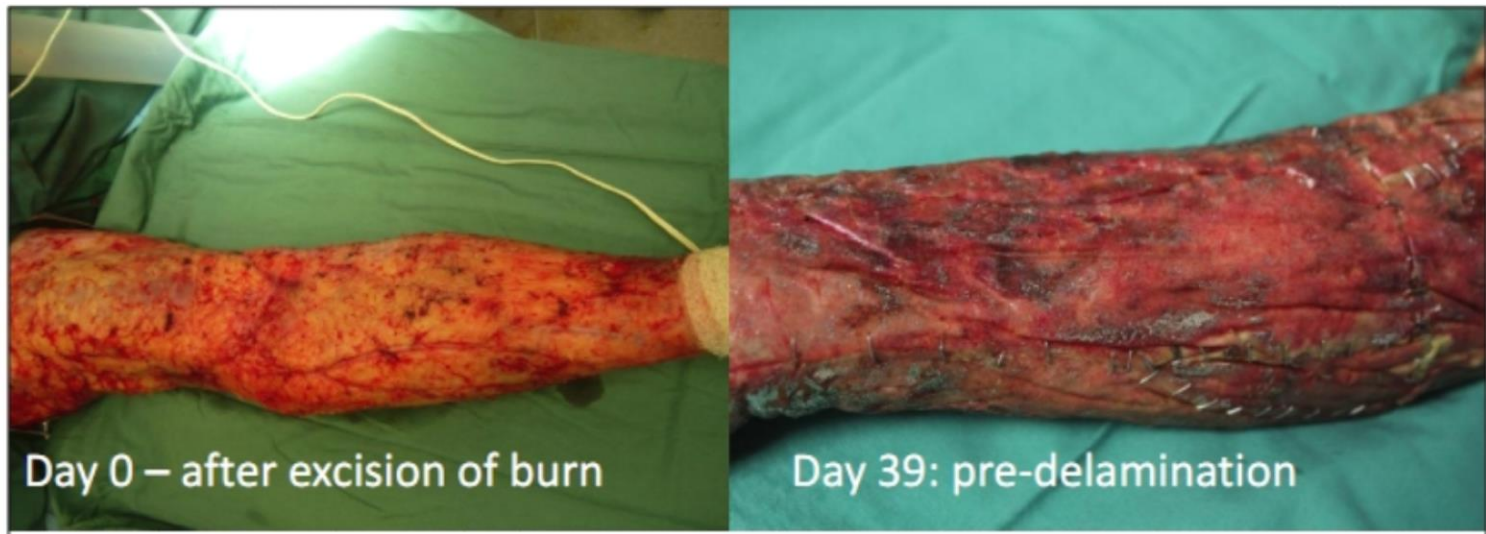
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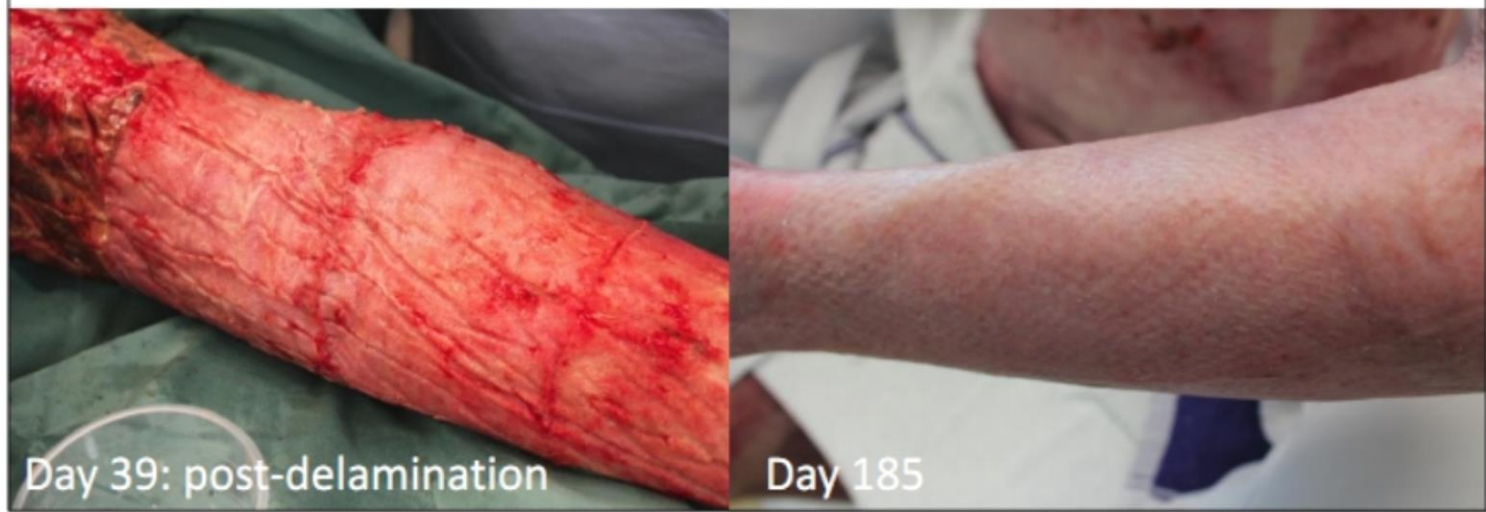
Video

# Burn progression with BTM

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Patient 1 from the burn trial



# Delamination of the BTM

## Note:

- Neo-Dermis regenerated
- Quality and elasticity of the new tissue
- No "pie dish" effect
- One piece easy removal



Video

# Patient 5 Adelaide

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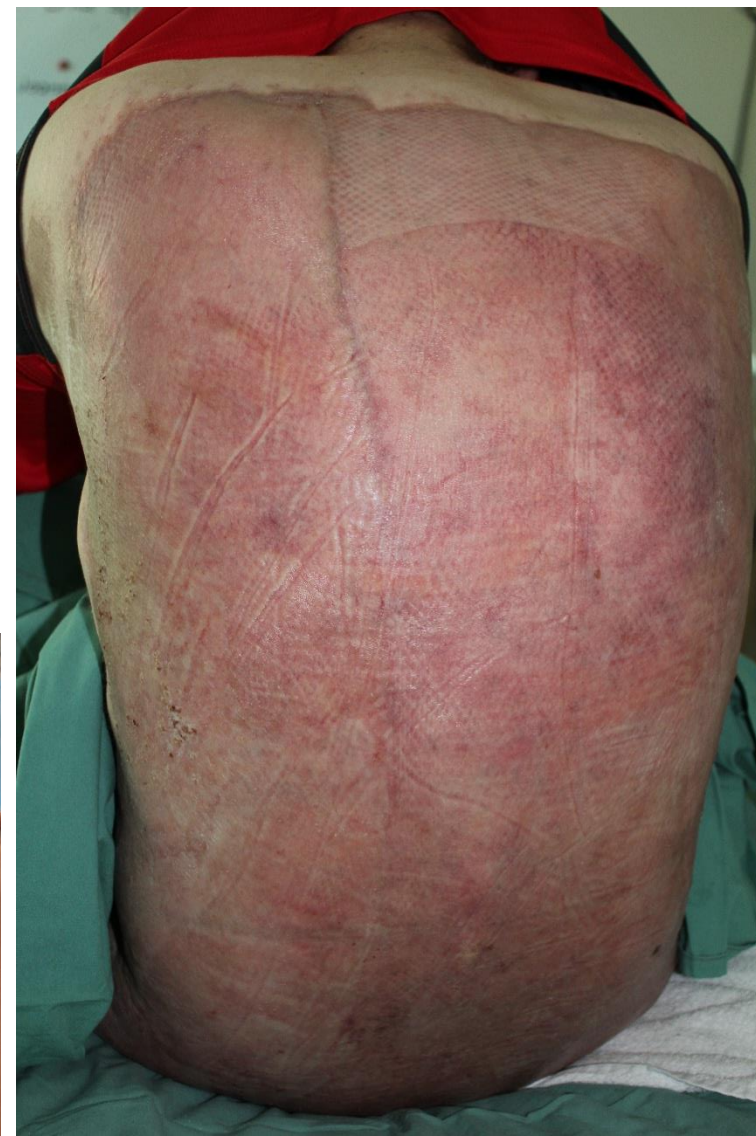


# Patient 5 Adelaide

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- Day 46 seal removal/grafting
- Day 96 healed



# In Market Projection

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## BTM

- Regulatory Approvals
  1. USA FDA 510(k) achieved
    - USA Surgical Wounds approval Dec 2015
    - Currently discussing US/Canada distribution with a few interested parties- Under NDA
    - Future geography rights negotiated as Regulatory approvals achieved
  2. Europe CE Mark anticipated late 2017
    - Anticipating Europe Sales end 2018
    - We will negotiate geographic licencing rights
  3. South East , Australia, New Zealand & India end 2017 with CE Mark
- BTM other regions
  - Mapped several markets where the US 510(k) can be used to facilitate market entry. Currently in the process of building those dossiers and looking at prospective commercial partners.

## NovoPore

- Have US & EU Regulatory approvals
  - Currently in discussion with an interested wound care multinational



# Breast Sling

## New Product **NovoSling**

Combination technology of our polymer in fibre bonded with NovoPore providing low profile, strength and proven cellular matrix interface specific for the breast sling application

## Opportunity

- FDA have challenged all current suppliers to stop hernia products being used in this application. No breast sling specific product currently on offer
- Large market looking for specific and biodegradable sling. Biodegradable is highly attractive for surgeons when revising breast

## Rationale

- Market opportunity is significant with high margins
- We exploit our polymer investment. Foam process established. Fibre process initially outsourced but using our polymer
- We would have a novel product within the segment which will be highly attractive to commercial partners

## Market access

- Currently working with two outside manufacturers to refine fibre component manufacturing, making rolls of material
- CE and USA 510K File once dossier is complete
- Will require clinical evidence and new biocompatibility work, PNV funded

## Commercialisation

- Several potential partners
- Work with KOLs to refine product, conduct clinicals and generate interest from leading commercial parties

# Hernia Repair

## **Product**    **NovoFlex**

- Design of fibres bonded to NovoSorb foam, similar in concept to Breast Sling however a different strength profile
- Implantable defect support to challenge hernia meshes and matrix products

## **Opportunity**

- Answers the challenge of abrasive non-degradable hernia mesh that causes erosion or infection
- Provides a novel biodegradable solution that is specific to hernia repair

## **Rationale**

- Large market segment with few differentiated products offered. Biodegradable is an attractive proposition
- Expands the application of our technology (polymer), leverages production process and enters an attractive commercial segment

## **Market access**

- USA 510K process
- EU requires CE Mark process , we will leverage US clinical evidence in building the dossier

## **Commercialisation**

- Several corporations are looking for new biodegradable products. Competitive segment.
- Establish a commercial agreement for distribution once we have a US FDA 510(k)



# Capabilities & Team

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## Facilities

- Cleanroom for production and product conversion
- Dedicated R&D and QC Labs

## Accreditation Standards

- TÜV-SÜD quality audit February 2016
- EN ISO 13485 (2012)
- ISO 10993 Biocompatibility testing



## Key Staff current 14 FTE

- 3 Full time Regulatory Managers
- 2 Full time Development Scientist
- 1 Full time Clinical Programs Manager
- 1 Full time, USA based contractor, Project Manager- for BARDA
- 1 Full time Quality Manager
- 2 Production Staff
- Office & Administrative support team



## Product Formats & Patents

- Polymer Foams
- Polymer Foam Laminates
- Thermoplastic Polymers – thermoset, injection moulding, filament extrusion
- Polymer solutions for spray on or dipping applications
- Eluting Polymers

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