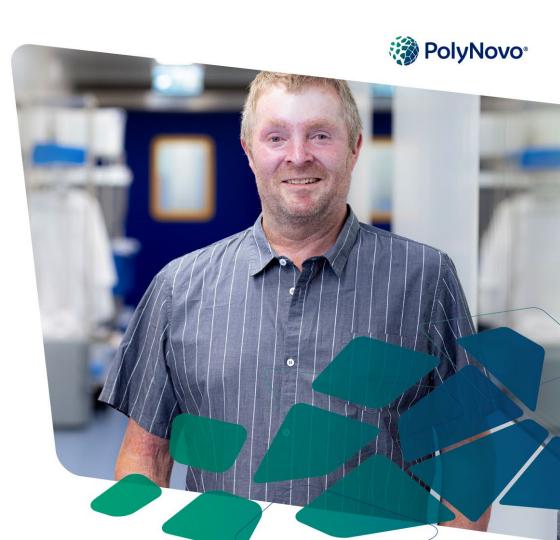
# PolyNovo FY22 Results

(in conjunction with Appendix 4E)

# Accelerating Global Impact

26 August 2022

Improving outcomes. Changing lives.



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# Picking up pace, post Covid

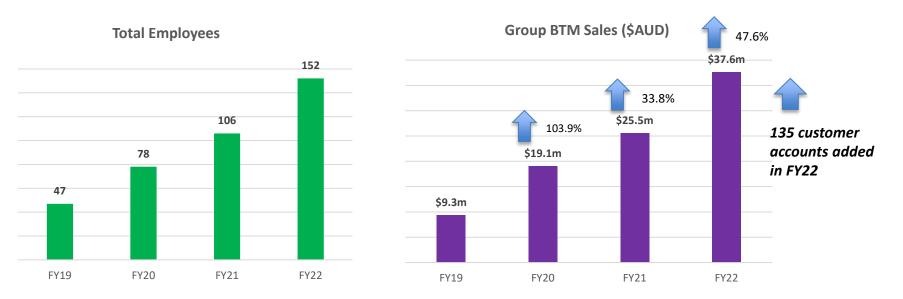
PolyNovo<sup>®</sup>



# **Investing for Growth**



- Investing in R&D, Sales & Marketing
- Increasing revenue and market share



# Marketing and Sales

Highlights by region



Improving outcomes. Changing lives.

# Highlights FY22 U.S.



## Profitability

- U.S. business is profitable on a standalone basis
- · Profitability continues to grow

## **Building the Team**

- Total U.S. headcount 67, up from last year 42
- Plans to increase the team further in FY23

## **Customer Account Acquisition**

- 75 new accounts added in FY22
- Rate of account acquisition is increasing, 11 recently added in July '22
- Large pipeline of new customers in development

## **Strong Sales Growth**

• FY22 BTM sales of AU\$32.1m up 55% on same time last year



# **Highlights Rest of World**

### **Building the Team**

- Total ANZ headcount 75, up from last year 58
- Total UKI headcount 9, up from last year 5
- · Expanded sales teams with additional sales reps and sales associates
- Clinical trainer hired in UK and NZ to support new and existing business

### **Customer Account Acquisition**

- Added 30 new accounts in ANZ for FY22
- Sold to every burn centre in Australia
- Further penetration of hospitals in ANZ
- Added 31 new accounts in UKI for FY22

### **Strong Sales Growth**

- ANZ had a strong recovery in 2H22 following long lockdowns in 1H22
- Since lockdowns lifted, 2H22 ANZ sales of \$AU1.9m were up 63% on 1H22
- UKI FY22 sales of \$1.3m up 184.9% on same time last year
- 2H22 sales in UKI improved up 144.8% on 1H22
- Distributor sales growth was flat YoY but improved in 2H22

#### **Geographic Expansion**

· First sales to Denmark, Greece, Cyprus, Poland and Turkey







## U.S. Burns Pivotal Trial (BARDA)

- Pivotal trial is a randomised controlled trial to assess NovoSorb BTM compared to FDA-cleared standard of care
- Trial is underway with 23 subjects enrolled as of July '22 out of a planned 120, across 30 sites (25 in U.S. and 5 in Canada)
- Expect to complete enrolment in Q4 2023
- Patients present with a deep dermal/full thickness burn injury.
- BARDA committed US\$15m towards the trial

## SynPath DFU Chronic Wound

- Randomised control trial comparing SynPath with standard of care (collagen alginate dressing)
- Trial is underway with first patient recruited out of a planned 138, across 8 sites
- Patients will present with a non-responsive chronic diabetic foot ulcer
- Anticipate U.S. market entry circa late 2023 with reimbursement (\$US400m addressable market)

## **Chronic Wound Study**

- Randomised clinical study comparing the use of NovoSorb BTM with negative wound pressure therapy
- Study will provide clinical evidence to support use of NovoSorb BTM for diabetic foot ulcers complicated by vascular insufficiency
- 8 out of 64 patients have been enrolled, completion of recruitment expected in late 2023

# Advanced Wound Care – Increasing Indications & Geography



# NovoSorb®

- Bilayer biodegradable synthetic matrix used when the dermis has been lost or removed.
- Temporarily closes a wound and provides a scaffold for generation of a neodermis.
- Indications are for full or deep partial thickness burns and wounds, surgical and reconstructive wounds, and traumatic wounds.
- Increasing indications where surgeons have elected to use for skin cancer excision, scalp reconstruction, hidradenitis, and over free flap soft tissue reconstruction.
- Entering new markets Canada and Hong Kong in 2H22
- Increased focus on emerging markets such as
  India

# NovoSorb<sup>®</sup>

- MTX is a synthetic dermal substitute comprised of NovoSorb foam providing a scaffold for wound healing across deep, complex structures such as bone and tendon.
- MTX is indicated for wounds that do not require temporising or protection from contraction, and there is a clear clinical need for NovoSorb MTX.
- It is indicated in cases where wound contraction and reduced time to healing are preferred, such as diabetic and venous ulcers, and smaller traumatic or post-surgical wounds.
- MTX promises clinicians ease of use and simplicity.
- Total addressable U.S. market of AU\$500m (in and outpatient)
- 510(k) submission was lodged with the FDA on 1 August 2022



- SynPath is designed to promote organised healing by providing a porous network of biodegradable synthetic polymers which act as a template to support the proliferation of vital cells involved in tissue repair.
- SynPath is indicated for chronic wounds such as diabetic foot ulcers and venous leg ulcers which can advance quickly, and if not treated promptly may necessitate amputation.
- Total addressable U.S. market of US\$400m (in and outpatient)
- Launch in U.S. market once reimbursement is established circa late 2023



## Implantable NovoSorb based Devices:

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- Expanded approach to hernia market
- In the process of validating 4 design options for various hernia types
- The 4 designs are being developed simultaneously
- Expect to have more than one product

## **Tissue Reinforcement**

- PolyNovo previously announced that it has taken the breast development program in-house
- Design concepts continue to be developed
- Surgeon engagements underway
- Dedicated marketing resource
- Expect to leverage the processes developed for hernia devices

## NovoSorb Dermal Beta Cell Implant:

- PolyNovo will supply Beta-Cell Technologies (a 3<sup>rd</sup> party group) with NovoSorb BTM for use in their trials to explore the potential of integrated NovoSorb BTM to host pancreatic Islet cells in the skin.
- This treatment holds significant promise for treating Type I diabetes with reduced reliance on a donor pancreas.

## NovoSorb Drug Elution Depot (pellet)

Therapeutics:

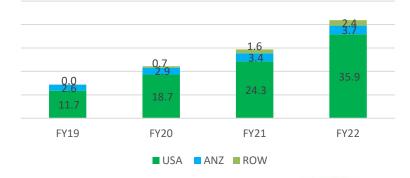
- PolyNovo produced polymers with up to 45% of the weight being a bound drug.
- Our initial work is focused on low temperature extrusion for optimal drug stabilisation.
- Further development will continue with the addition of further research and development resources.







#### **Regional Revenue (\$m)**



## **Group Highlights**

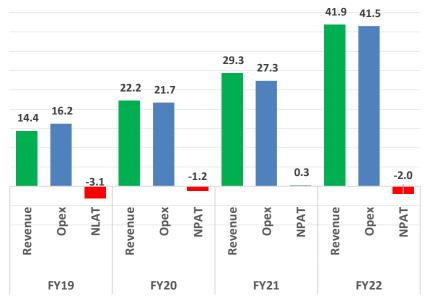
- Total revenue \$41.9m up 42.8% on last year
- Total BTM product sales up 47.6% on last year

## **Market Highlights**

- US BTM product sales +55.1%
- ANZ BTM product sales -1.1%
  - Result impacted by lockdowns in 1H22
  - Strong recovery in 2H22 up 63% on 1H22
- UKI BTM product sales +184.9%
  - 1H22 impacted by Omicron
  - Strong recovery in 2H22 up 144.8% on 1H22
- Distributor sales growth was flat YoY but improved in 2H22
- First sales to Denmark, Greece, Cyprus, Poland and Turkey
- Added 135 new customers (hospitals) in FY22







#### **Operating Expenses** (excl. non-cash items)

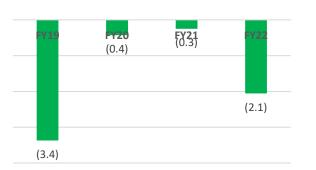
- Operating Expenses +52%
- · Continued investment in accelerating growth
- Increase headcount by 43% from 106 to 152
- · Business expansion in the U.S., EU and Australia
- · Investing in clinical trials
- · Investing in improving scalability

### Net Profit / (Loss) after Tax (excl. non-cash items\*)

- NPAT -\$2.0m (excl. non-cash items)
- EBITDA -\$1.6m (excl. non-cash items)
- · Loss continues to be minimised compared to business expansion
- · Increased headcount is having the desired impact on sales growth
- Continue to reinvest cash flows to grow revenue and market share in FY23

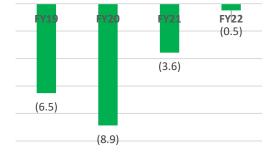
\* Non-cash items comprise of unrealised forex gain/(loss), depreciation & amortisation, share based payments and impairment loss (refer to reconciliation on p.16)



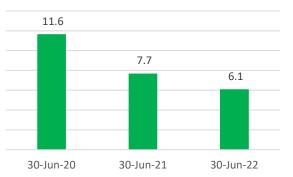


Net cash flow from operations (\$m)

Capex (\$m)



Cash on hand (\$m)



#### Highlights

- · Cash outflow from operations of -\$2.1m
- Significant investment increasing sales reps in all direct markets particularly the U.S., R&D team and supporting business expansion
- \$6.1m cash on hand
- \$0.5m incidental capex purchases for manufacturing and R&D
- Capex in FY23 is expected to be approx. \$0.8m of which \$0.6m will be funded by the Victorian Government Medtech Manufacturing Grant

#### Asset Sale

- Sold and leased back Unit 1 / 316-320 Lorimer St, Port Melbourne
- \$6.35m sale price
- \$3m of the sales proceeds was used to reduce debt
- · Balance of sales proceeds used for working capital
- Lease term is 10 years with two 5-year options at a circa 4.3% yield.





(\$m)	FY22	FY21	Change %
REVENUE			
Product Sales - BTM	37.6	25.5	47.6%
BARDA	3.8	3.7	4.0%
Other Income	0.5	0.2	148.5%
TOTAL REVENUE	41.9	29.3	42.8%
Changes in inventories & WIP	(2.2)	(1.6)	41.6%
Operating Expenses			
Employee-related expenses (excl. share based payments)	(24.9)	(16.7)	48.7%
R&D Costs	(5.7)	(3.6)	57.6%
Corp, administrative & o'head expenses (excl. unrealised forex gain)	(10.9)	(6.9)	56.7%
Finance Costs	0.0	0.00	0.0%
Impairment Loss**	(1.4)	0.00	-100.0%
Total Operating Expenses	(42.9)	(27.3)	56.9%
Operating Profit / (Loss)	(3.2)	0.4	-834.1%
Share Based Payments - non-cash	3.5	(2.6)	-232.5%
Unrealised Forex Gain/(Loss) - non-cash	0.5	(1.1)	-144.4%
EBITDA	0.8	(3.3)	-122.8%
Depreciation & Amortisation	(1.6)	(0.9)	72.6%
EBIT	(0.8)	(4.2)	-80.2%
Interest Expenses	(0.3)	(0.3)	-1.9%
NET PROFIT / (LOSS) BEFORE TAX	(1.2)	(4.6)	-74.7%
Income Tax Expense	(0.0)	(0.1)	-23.8%
NET PROFIT / (LOSS) AFTER TAX	(1.2)	(4.6)	-74.1%
Add Back Non-Cash Items:			
Share Based Payments	(3.5)	2.6	
Unrealised Forex Gain/(Loss)	(0.5)	1.1	
Depreciation & Amortisation *	1.8	1.1	
Impairment Loss**	1.4	0.0	
NET PROFIT / (LOSS) - Excluding Non-Cash Items	(2.0)	0.3	-871.6%

\* Includes depreciation included in movement of inventories (manufacturing cost)

\*\* Impairment loss on sale and leaseback of building

#### P&L Highlights

- Product sales +47.6%
- Total Revenue (incl. BARDA) +42.8%
- Employee related expenses +48.7% (increased headcount)
- R&D spend +57.6% (team expansion, clinical trials)
- Corp, admin & overhead expenses +56.7% (business expansion)
- Net loss after tax -\$1.2m
- Net underlying loss after tax -\$2.0m (Excl. non-cash items)

# **Accelerating Global Impact**

#### Accelerating Adoption, Prudent Geography Expansion:

- Doubling down on US, ANZ expanding beyond Burns
- · Investing in Clinical & Health Economic packages vs. Standard of Care
- Expanding our KOL network, Selling infrastructure
- Accessing select Emerging markets & Developed Economies

#### Steady Cadence of New Product Pipeline:

- MTX for single-stage procedures
- SynPath for Diabetic Foot Ulcers
- · Continued investment behind Breast & Hernia

#### Capacity Expansion, Building Flexibility and Scale:

Modifying Process for scale & flexibility

#### Purpose Driven Organization, Engaged Organization

- Creating, Communicating and Reinforcing, Vision, Values & Integrated Goals
- Building a culture of Transparency, "Speak-up", culture enrolling Partners in our mission

#### To be a Global Standard of Care in Soft Tissue Reconstruction



PolvNovo



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