# PolyNovo 1H22 Results

25 February 2022



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### **Trading Overview**





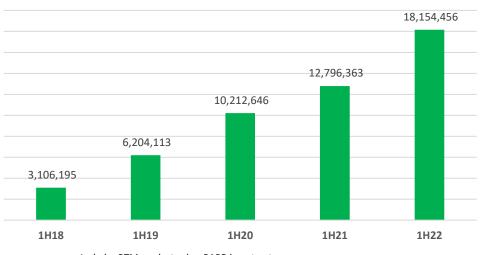






- > First ever \$3m BTM sales month (Dec 2021: \$3,791,952)
- > First ever \$4m BTM sales month (Jan 2022: \$4,051,542)

### 1st Half Total Group Revenue \*



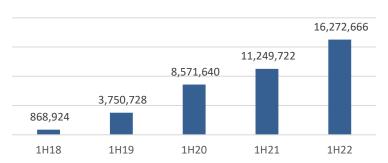
 Includes BTM product sales, BARDA contract revenue and Other Income

### **Trading Overview – Investing for Growth**



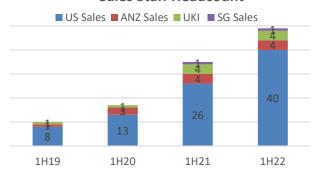
- Investing in sales & marketing teams
- Investing in R&D team for product innovation and commercialisation

### 1st Half Group BTM Sales (\$AUD)

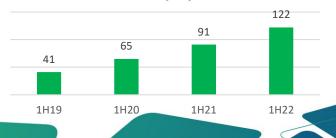




#### Sales Staff Headcount



#### **Total Employees**



# Marketing and Sales

Highlights by region



### **Highlights 1H22 USA**



### **Strong Sales Growth**

- 1H22 BTM sales of AU\$14.2m up 58% on same time last year
- BTM sales for December were a record \$AU3.4m up 76% on same time last year
- Monthly US sales for December significantly exceeded US\$2m for the first time
- Strong quarter on quarter momentum with Q2 sales AU\$8.1m up 31% on Q1 AU\$6.1m

#### **Further Update:**

Record results January 2022 with sales of AU\$3.7m up 96% on same time last year

#### **Building the Team**

- Hired 1 additional sales director, 10 sales reps and 1 sales associate, increasing the sales team to 40 (Dec '21)
- Additional recruitment underway to increase sales team to 54
- Added Director of Marketing, VP of US Sales, Director of Strategic accounts
- · Added roles focused on clinical and sales training, and development initiatives

#### **Customer Account Acquisition**

- 35 new accounts added in 1H22 brings total to 154
- Rate of account acquisition is increasing, 16 added in Q1 then 19 in Q2
- · Large pipeline of new customers in development

#### **Profitability and Expansion**

- US business is profitable on a standalone basis and profitability continues to grow
- Looking toward expansion into Canada

### **Highlights 1H22 Australia/New Zealand**



- Long lockdowns in 1H22 and cancelled elective surgery
- Strong recovery in Q3 with lockdowns lifted, January 2022 sales 6.5% above target and 72.5% up on January last year
- Return to in person meetings and attendance at conferences
- Large repeat customer base of 149 hospitals and selling into multiple verticals
- Increased usage of BTM in smaller burns which are more frequently occurring
- Sales of small devices now over 50% of total units sold, providing stability in orders and reducing reliance on burns
- Plans to add 3 additional sales personnel support and grow existing business

### **Highlights 1H22 UK/Ireland**



- 1H22 sales of \$369k up 254.6% on same time last year but less than target
- 1H22 sales impacted by Omicron, restricting hospital access and cancellation of surgeries
- Customer engagement maintained by digital and offsite meetings, resulting in strong account acquisition
- Increased UKI NHS accounts from 23 to 38 in 1H22
- Sales of small and medium BTM devices represents a large portion of sales and continues to increase with medical staff in new accounts gaining confidence in BTM use
- 2 sales reps added in London, and recruiting for Scotland
- A clinical trainer was also added in Q2 to assist with clinical support for new and existing business
- Increased focus ahead on generating more sales from the lucrative burns market

### **Highlights 1H22 Distributor Markets**



- Sales growth to distributors in 1H22 was flat compared to same time last year
- Omicron impacted Italy and the DACH region (Germany, Austria & Switzerland)
- Some markets such as Finland experienced reoccurring strong sales
- First sales to Denmark and Cyprus in 1H22 and to Poland in January 2022
- Both India and Taiwan placed orders in 1H22
- Initiatives to improve the effectiveness of our distributor model

### **New Products**



### **Matrix**

- Broad applicability for single-stage grafting in burns, chronic, surgical and deep tunnelling wounds to provide increased treatment options and better outcomes
- Total addressable US market comprising in and out-patient settings of US\$750m
- · Product comprises of BTM foam only without the temporising film in various sizes
- 510k submission is expected to be lodged with the FDA in CY22



- Unique sizes and shapes of NovoSorb BTM for the US Alternate care US\$400m market (outpatient).
- DFU/VLU reimbursement study in progress, first patient 10 patient trial completed with good results.
- Next phase to commence in April 2022 will recruit 138 patients
- Launch once reimbursement is established circa late 2023

### **New Products**





- 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
- We anticipate filing for FDA clearance in CY24

### NovoSorb®

- The project to develop products to aid in breast reconstruction is being conducted in-house
- Employed dedicated marketing resource
- Project team established and surgeon engagements underway
- Expect to leverage the processes developed for hernia devices

### **Partnerships**

- PolyNovo will supply Beta-Cell with NovoSorb BTM for use in their trials.
- Beta-Cell are ready to commence human trials in Adelaide

### Clinical Trials - BARDA Pivotal Trial



- Pivotal trial is open for recruitment, screening of eligible patients in progress
- During 1H22 5 patients were recruited, and this has increased to 10
- 25 US sites and 5 Canadian sites being enrolled, and we expect patient recruitment to increase as more sites are activated. Total trial patients 120.
- 2H22 and FY23 will see higher BARDA income commensurate with the patient recruitment activities
- BARDA committed US\$15m towards the trial
- BARDA is a valued partner, and we maintain a strong relationship







### Clinical Trials – SynPath DFU Chronic Wound



- 10-patient diabetic foot ulcer (DFU) pilot study has been completed with SynPath applied to chronic wounds between 1 to 25 cm<sup>2</sup>
- Mean time to closure was 6.25 weeks, with the fastest being 2 weeks
- 7 out of 10 ulcers had complete wound closure at 12 weeks. The 3 remaining ulcers did not achieve wound closure but did show a significant reduction in wound size.
- Results will be submitted to The Symposium on Advanced Wound Care (SAWC) Fall in October 2022
- Study protocol for a RCT comparing SynPath with collagen alginate dressing (SOC) has been finalized with the goal of 138 patients in two equal groups. Recruitment to commence in April 2022.
- Results of this study will be used to support US reimbursement for use of SynPath to manage chronic wounds in the outpatient setting, a \$US400m total addressable market in the US
- Anticipate US market entry circa late 2023 with reimbursement

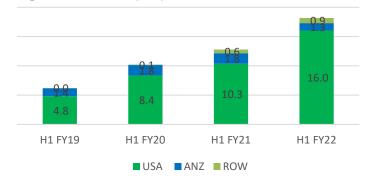




### Total Revenue (\$m)



### Regional Revenue (\$m)



### **Group Highlights**

- Total revenue +41.9%
- BTM product sales +44.6%
- Total BTM product sales \$16.3m
- Record monthly BTM product sales:
  - \$3.79m (Dec 2021)
  - \$4.05m (Jan 2022)

### **Market Highlights**

- US BTM product sales +57.9%
- ANZ BTM product sales -25%
  - o Result impacted by lockdowns, less burn, trauma and elective surgeries
  - Recovery in January 2022, 6.5% up on target and 72.5% up on January last year
- UKI BTM product sales +254% but less than target, impacted by Omicron
- · Distributor sales growth was flat with mixed results
  - o DACH region (Germany, Switzerland, and Austria) impacted by Omicron
  - Finland had strong reoccurring sales
- o First sales to Denmark and Cyprus in 1H22, and to Poland in Jan 2022
- 1H22 increased new customers (hospitals) in direct markets by 66 from 295 to 361



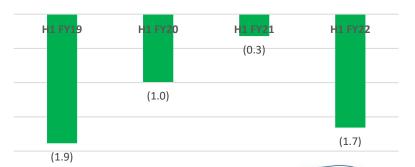
### **Operating Expenses (\$m)**

(excl. Share Based Payments & Unrealised Forex)



### Net Profit / (Loss) after Tax (\$m)

(Excl. Non-Cash Items)



### **Operating Expenses**

(excl. Share based payments, unrealised forex loss)

- Operating Expenses +53%
- · Continued investment in growth
- Increase headcount by 34% from 91 to 122
- Annualised impact of prior year hires
- · One off expenses such as recruitment fees
- Expanded regional operations in the US, EU and Australia

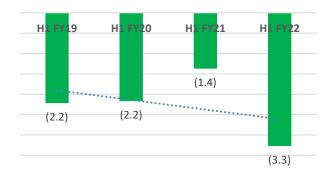
### Net Profit / (Loss) after Tax (excl. non-cash items\*)

- NPAT -\$2.5m (excl. share-based payments & unrealised forex gain)
- NPAT -\$1.7m (excl. all non-cash items)
- EBITDA -\$1.4m (excl. non-cash items)
- Following achieving an underlying break even result for FY21, an acceleration of sales rep hiring occurred in 1H22 mainly in the US
- Increased headcount is having the desired impact on sales with record US sales results in Dec '21 and Jan '22
- Expect profitability and cash flow to significantly improve in 2H22

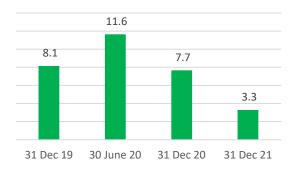
<sup>\*</sup> Non-cash items comprise of unrealised forex gain/(loss), depreciation & amortisation, and share based payments (refer to reconciliation on p.20)



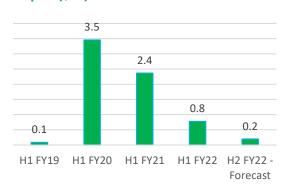
### Net cash flow from operations (\$m)



### Cash on hand (\$m)



Capex (\$m)



### **Highlights**

- Cash from operations of -\$3.3m
- 1H22 investment increasing sales reps in US and other regions, R&D team and supporting business expansion
- \$3.3m cash on hand
- Capex reduction due to completion of new cleanroom in CY21
- 2H22 forecast discretionary capex of \$0.2m

#### **Subsequent Event in Feb 2022**

- An offer of \$6.35m was signed on 21-Feb-22 for the sale and leaseback of Unit 1 / 316-320 Lorimer St, Port Melbourne
- Property purchased for \$4.6m in (Feb/2019)
- Conditional on due diligence ending the earlier of 14 business days from 28-Feb-22 or exchange of contracts
- Lease term is 10 years with two 5-year options at a circa 4.3% yield. Our existing lease on Building 2 will be synchronised with the new lease.
- \$3m of the proceeds will be used to reduce debt
- · Balance of proceeds for working capital



(\$m)	1H FY22	1H FY21	Change %
Revenue	18.2	12.8	41.9%
Expenses			
Changes in inventories & WIP	(0.9)	(8.0)	12.2%
Employee-related expenses	(11.4)	(7.8)	45.3%
R&D Costs	(2.4)	(1.3)	86.3%
Corp, administrative & overhead expenses	(5.1)	(3.1)	62.1%
Total Expenses	(19.7)	(13.0)	
Operating Profit / (Loss)	(1.5)	(0.2)	626.6%
Include Share Based Payments	3.8	(1.2)	-404.1%
Unrealised Forex Gain/(Loss)	0.4	(1.4)	-126.2%
EBITDA	2.6	(2.9)	-189.7%
Depreciation & Amortisation	(0.7)	(0.5)	62.7%
EBIT	1.8	(3.3)	-154.9%
Interest Costs	(0.1)	(0.2)	-14.6%
NET PROFIT BEFORE TAX	1.7	(3.5)	-148.2%
Income Tax Benefit	(0.1)	(0.0)	0.0%
NET PROFIT AFTER TAX	1.6	(3.5)	-145.8%
Add Back Non-Cash Items			
Include Share Based Payments	3.8	(1.2)	
Unrealised Forex Gain/(Loss)	0.4	(1.4)	
Depreciation & Amortisation *	0.9	0.5	
UNDERLYING LOSS	(1.7)	(0.3)	419.9%

### **P&L Highlights**

- Product sales +44.6%
- Revenue (incl. BARDA) +41.9%
- Product sales gross margin +1.5% (manufacturing efficiency gains)
- Employee related expenses +45.3% (increased headcount)
- Corp, admin & overhead expenses +62.1% (business expansion)
- R&D spend +86.3% (team expansion, DFU trial, hernia and breast)
- Net profit after tax \$1.6m
  - Includes reversal of \$4.7m in share-based payments (expensing of share options)
- Net underlying loss after tax -\$1.7m (Excl. non-cash items)

<sup>\*</sup>Includes depreciation from movement in inventories

### Focus Points 2H22 & FY23



- Increase sales teams to intensify sales effort in direct markets
- Optimise distributor model and emerging markets model
- Expand geographic footprint
- Expand Key Opinion Leader program (especially UK & EU)
- Focus on product development and faster commercialisation

