

03 November 2023

## ASX Announcement

### Chairman's and CEO's address to shareholders

Patient story, Faliha – <https://vimeo.com/880407425/08b18fc16b?share=copy>

#### Address by Chairman – David Williams

##### The year just past:

- FY23 strong sales growth 58.3%
- US profitable and growing
- Ended FY23 with \$46.8m of cash on hand
- Number of hospitals 470 to 638 (30 June 2023)
- Number of staff 152 to 218 (30 June 2023)

##### Momentum continues:

- Sales teams expansion: US 56 to 76, UKI 5 to 6, ANZ 5 to 9, HK 1
- First ever AUD \$7m sales in May 2023 (May 2022: \$3.3m)
- R&D expanded team and pipeline development
- BTM in new indications (skin cancer, vascular wounds, limb salvage, free flaps). Doctors lead the way
- BARDA additional \$US10m funding
- Pivotal trial 76 of 120 enrolled

##### The year ahead:

- Sales team expansion Eastern Canada
- Progress Japan and China
- New channels of distribution: plastics, outpatient
- New alliances for product and distribution
- New leadership in IT and other important positions
- Complete enrollment for pivotal trial

#### Address by CEO – Swami Raote

Thank you, David. Good afternoon, everybody.

2023 marks ten years since NovoSorb BTM was first implanted in a patient. Since then, over 33,000 patients have seen the benefit of our simple, elegant and transformative technology.

One of these is John Weeks, the first burn patient to receive NovoSorb BTM after an accident left him with burns to 75% of his body. With the persistence of his surgical team, John recovered, started a family, created a life with partner Jade, and now works to support other burns survivors. In John's words, "I have gone from flat lining to living life flat out".

Stories like John's and Faliha's, which was shared a moment ago, are fuel for PolyNovo's ambition; the people who have suffered trauma and bear the scars. NovoSorb BTM can improve form and function, but most importantly returns the patient to live a life full of possibilities and reach their maximum potential. Our objective is to bring this life saving technology to the world.

Continued sales growth and geographic expansion reflect NovoSorb BTM's acceptance by surgeons as the next generation dermal substitute. NovoSorb BTM is fast becoming a standard of care in complex wound management across many countries. Surgeons are excited by the potential of NovoSorb technology: its simplicity, versatility, and ability to transform patient outcomes, while reducing pressure on health systems. We stay inspired to learn from our clinicians and provide solutions to their surgical problems.

Thank you to all those who have joined us on this journey.

Earlier this week, the senior leadership team of PolyNovo came together to reflect on the achievements of the past twelve months as we gear up for FY24 and beyond. We are building on a solid foundation. We are outpacing the dermal implant category by a factor of ten and winning market share across all geographies we operate in. Additionally, insights and talent gathered over past twelve months have led us to promising new product pipeline projects helping us expand our impact beyond our original indications.

Group sales continued to accelerate in FY23, with global NovoSorb BTM sales of \$59.6m up 58% on the prior year. The U.S. market continued its impressive performance, up 45% in AUD. The Rest of World was up 134%, with Australia increasing sales by 84% and UK/Ireland by 169%. Distributor performance has also been strong, with Germany growing by 193%.

In addition to Australia and New Zealand, where NovoSorb BTM enjoys market leadership, we now enjoy market leadership in the United Kingdom and Germany. These results demonstrate the disciplined effort and focus of our commercial teams, along with the ingenuity and enthusiasm of clinicians who are now contributing to innovation, new applications, and the education of their colleagues. We are extremely grateful for the continued support and partnership of our clinicians.

Total FY23 revenue of \$66.5m was up 58.8% on the prior year which includes revenue from the BARDA pivotal trial. With additional funding of \$US10 million announced in October 2023 and 76 enrolled patients, we are past the mid-point in the trial, with recruitment expected to be completed in FY24. BARDA has been a decade long partner of PolyNovo, supporting and guiding our efforts with numerous regulatory agencies to accelerate PMA approval.

NovoSorb MTX received 510(k) FDA clearance during the year and has already received strong support from surgeons. Our limited market release in the US and NZ will develop the clinical evidence to support a full commercial launch, planned for FY24. The innovation pipeline is exciting, with the extension of the NovoSorb MTX and BTM portfolio, to include surgeon-led innovations, planned in FY24.

We continued to invest in building our capacity to drive revenue with personnel growing from 152 to 218. The majority of this expansion reflected increases in headcount in the U.S. sales team, manufacturing, research and development and clinical support teams. The capital raise has allowed us to accelerate these efforts, with a new manufacturing facility design in progress and scheduled for completion in CY26.

Year on year sales momentum has continued, and in May, monthly sales exceeded \$7 million with total revenue exceeding \$8 million for the first time. This trajectory has continued into the current financial year, with August revenue of \$7.7M, up 119% vs. August prior year.

## **Accelerating Global Impact**

### **1. Geographic expansion:**

The title of our FY23 Annual Report was “New Horizons” and true to that, we have increased our footprint in the U.S., entered Canada, Hong Kong, and India, and very recently, Spain and France.

Each region warrants excitement for different reasons; Hong Kong as a precursor to a China market entry, India to prove our market development credentials by satisfying economics of a large, middle-income economy, together with its contribution to the BARDA trial, and Canada as an opportunity to leverage the success of the U.S. We aim to achieve market leadership in these new geographies within eighteen to twenty-four months.

Launching in India, we are ensuring that our simple, transformative, and cost-effective technology is available to patients who need it most and were previously constrained by cost, availability, and professional education. We are working with Indian surgeon networks to build the dermal implant category, underpinned by professional education programs, and working closely with federal and state governments on tenders.

We will continue to expand the dermal substitute category in Australia, UK, Ireland, and Germany. The team maintains a patient focus as they outperform the category to accelerate our growth. Our commitment to our communities is strong, and in the U.S. alone, approximately 63,400 sq cm of product was donated for charitable use.

Our U.S. team are energised by NovoSorb MTX and a richer product suite to guide patient care. In FY24, we plan to put more tools and products into their hands, and we expect to see a swift payoff in customer account value.

### **2. Indication expansion**

Last year I spoke of our strategy of going beyond burns in our mature markets, and I'm pleased to report that use of NovoSorb BTM is increasingly the dermal substitute of choice in trauma and other complex reconstruction cases where we can have significant impact for our patients, surgeons, and hospital systems.

In Australia and New Zealand, we maintain our leadership of deep dermal, full thickness burns, with all Burn Centres using NovoSorb BTM. Revenue outside of burns is accelerating with our successful shift to trauma, plastic reconstruction, vascular, pressure ulcers, limb salvage and other indications, with the number of patients treated increasing by approximately 70% year on year.

### **3. Innovation and product pipeline**

We have redesigned our innovation process to capture the voice of multiple healthcare stakeholders. In addition to our established polymer chemistry expertise, we continue to build out a robust product development team, with package engineering and pre-clinical sciences (encompassing animal models and implant evaluation). We are also glad to share that we have engaged with world leaders in textile engineering, hernia mesh development and manufacturing, as well as experts in breast reconstruction, who are contributing to our internal development programs.

In September 2022, NovoSorb MTX received FDA 510(k) clearance, with broad applicability in burns, chronic and surgical wounds. NovoSorb MTX and NovoSorb BTM are complimentary, and the addition of

NovoSorb MTX to our product suite offers clinicians increased flexibility, for situations where the sealing membrane is not required.

By tapping into the voice of clinicians to get their insights on how and where NovoSorb technology can impact, we aim to accelerate rollout of our Advanced Wound Care portfolio with additional 510(k) submissions. A submission for the extension of the NovoSorb MTX product range was recently submitted, with further submissions planned in 2024.

We have focused our approach to hernia repair and are developing a targeted solution for ventral hernia and complex abdominal wall reconstruction. This novel NovoSorb-based textile will expand the clinical application of the NovoSorb polymer technology, with other implantable applications to follow. We also continue to support our partners with novel drug-device and cell-device combinations, which could have substantive impact on the treatment of Type I diabetes and other cell-based therapeutics.

The core NovoSorb technology can support other clinical needs and we are open to partners to help co-develop, commercialize, or distribute innovative new products. We recognize that building successful partnerships is vital for PolyNovo to reach more patients faster, amplifying the impact of our technology.

#### **4. Capacity expansion**

We are investing in scaling our production facilities in Australia as we scale globally. In late FY23, manufacturing capacity was doubled, and efficiencies gained when our second facility, adjacent to the existing facility became operational.

The capital raising of \$53 million in November 2022 further amplifies these efforts, with a new co-located manufacturing facility currently being designed, estimated to be operational in CY26. Employing state-of-the-art process and manufacturing capability along with R&D labs, the new facility will produce around 500 M devices/ approximately 5 times current production volumes.

A new office space has been completed, supporting enabling functions for global growth including IT, Legal and HR. We will invest in digital and information technology, to ensure that we stay connected and agile as we scale globally. The recent hire of a Chief Information Officer has seen the rapid advancement of projects including CRM, website, cyber security and document management systems.

#### **Capital Efficient Profitable Growth:**

PolyNovo, has a history of driving capital light growth. Our path to profitability is clear and we will remain prudent and responsible in investing capital in areas providing the maximum impact for our customers and patients, and superior results for our shareholders.

Before I make my final comments and hand back to David, I would like to reflect upon Faliha and the transformative potential of NovoSorb technology.

Burns can be devastating injuries, leaving scars long after the original trauma. What should be celebratory and joyful; a birthday, adding a few centimeters in height, can be accompanied by declining mobility, discomfort and pain caused by scar contracture. Faliha's journey with NovoSorb BTM marked a turning point, relieving 7 years of pain and discomfort and offering an improved quality of life. She has started playing with her friends and begun dreaming of becoming a Doctor. With the highest rate of burn injury across the globe, we know there is much to do in India.

PolyNovo has touched and healed over 33,000 patients since its inception: 13,000 including Faliha in FY23. As proud as we are of our efforts and results, we are not satisfied. All of us at PolyNovo know we need to reach and heal many more.

This announcement has been authorised by PolyNovo Company Secretary Jan-Marcel Gielen.

### About PolyNovo®

olyNovo is a disruptive medical device company, focused on Advanced Wound Care that designs, develops, and manufactures dermal regeneration solutions (NovoSorb BTM, NovoSorb MTX) using its patented NovoSorb biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopaedic applications. For further information see [polynovo.com](http://polynovo.com)

### About NovoSorb®

NovoSorb® BTM is a dermal scaffold for the regeneration of the dermis when lost through extensive surgery, trauma or burn. NovoSorb® is a novel range of bio-resorbable polymers that can be produced in many formats including film, fibre, foam, and coatings. NovoSorb's unique properties provide excellent biocompatibility, control over physical properties, and a programmable bio-resorption profile.

### Reach

PolyNovo supplies approximately 638 hospitals directly in Australia, Canada, Hong Kong, India, Ireland, the Middle East, New Zealand, Singapore, the United Kingdom, and the United States. Other countries, such as Germany, France, and Spain are serviced by a distributor.