

28 October 2024

## **ASX Announcement**

### **CEO's and Chairman's Address to Shareholders**

**Address by Chief Executive Officer, Swami Raote**

Healing. Redefined.

Two words, which unify clinicians and all of us at PolyNovo to push the boundaries of Plastic Reconstructive procedures for our patients. Since receiving FDA approval nine years ago, we have been able to reimagine the healing journey of over 50,000 patients globally. We now provide access to training and our products in over 42 countries, including many who have never had any access to advanced skin substitutes. With over 300+ independent articles and abstracts, relating to superior patient outcomes across multiple acute complex wounds indications, we are clearly seen as the new Standard of Care in the soft tissue reconstruction space in developed geographies.

The U.S. remains the driving force for our company, growing by 49% over prior year. As we expand into other trauma, infection and active complex wounds, the number of patients healed is expanding at a stronger pace. We are grateful for our partnership with BARDA, which has seen recruitment for our pivotal clinical trial conclude with 120 patients enrolled. Our conversations with the FDA are ongoing and we are looking forward to securing the PMA approval for third degree burns in our largest market.

In the U.K., Germany, and Australia & New Zealand markets, we are the overwhelming leaders in difficult burns as well as soft tissue reconstruction procedures. We hope to extend this leadership to the other three of the Top 5 European markets within the next eighteen months. In India, our efforts to develop the dermal substitute category continue at pace. In March, NovoSorb BTM received approval to be included in the Government-e-marketplace portal opening access to the use of product across all Defence, Railways and ESIC (Employee State Insurance Corporation) Hospitals. Although the market is complex and there are numerous bureaucratic processes to navigate, we are encouraged by orders from two prestigious hospitals including the largest burn centre in Asia. The momentum for geographic expansion continues with registrations obtained for Thailand, Peru, Bolivia, Ecuador, Nepal, Sri Lanka, and Bangladesh. Additionally, we have signed the commercial partner for Japan launch with an initial meeting with regulatory body scheduled in November 2024.

After a limited market release for NovoSorb MTX, we have started rolling product out across US, New Zealand, and Hong Kong. The appetite from our customer base is strong, with our US team reaching an impressive milestone of US \$ 1 M in product sales. We are looking forward to launching

multiple variants of NovoSorb MTX, including a particulate variant which has generated a lot of interest among clinicians for soft tissue reconstruction in difficult to access and undulating wounds.

Our R&D and clinical teams have worked with clinicians across the world to understand various soft tissue reconstruction pain points. With their help and a partnership with universities in U.S. and Australia, we are testing and refining a new product portfolio in burns, trauma as well as implantable products for hernia and other Plastic reconstructive procedures. We are grateful to the Victorian Government for a A\$2 M grant, part sponsorship funding for R&D lab expansion and new equipment purchase, subject to us meeting agreed milestones. With consistent rollout of new products over next three-year horizon, we are looking to expand our global reach and patient impact.

Our plans for manufacturing capacity expansion are on track for completion by December 2025. The new facility is designed for scale with focus on flexibility, modularity, and automation to service five times current volumes. This will be critical as we continue to advance into developed as well as developing geographies – well beyond the current reach of advanced skin substitutes.

As strong as our NovoSorb technology is, what truly fuels our success is our People, our Culture and our Partnership with clinicians seeking meaningfully differentiated patient outcomes. We are proud of having touched over 50,000 lives in our short commercial history, and acutely conscious of the need to reach millions more who seek it.

Our future is promising and your team at PolyNovo will stretch to deliver it responsibly.

### **Address by Chairman, David Williams**

The year just past:

- FY24 strong sales growth 54.5% and profitable.
- Ended FY24 with \$45.9m of cash on hand.
- Number of staff 218 to 254 (30 June 2024).
- Pivotal trial enrollment (120) complete.
- New executive leadership (APAC, Medical, HR, Legal).
- Supplying 42 countries.
- Conflict zones (Ukraine, Middle East) and humanitarian cases (Nigeria, Serbia).

Momentum:

- NovoSorb BTM in potential new indications (skin cancer, vascular wounds, limb salvage, free flaps). Surgeon-led innovation.
- Full market release of NovoSorb MTX in the U.S., Hong Kong, and New Zealand.
- Addition of Suprathel to product mix in UK, Australia, and New Zealand.
- Increased investment in R&D and pipeline development.
- Additional manufacturing facility intended to be operational Dec 25.
- Premarket approval (PMA) filing for an on-label indication supporting the use of NovoSorb BTM in full thickness burns in the U.S.
- Progress in Japan, China, India, and other new geographies.
- New alliances for product and distribution.

### **Videos**

Global Impact Video: <https://vimeo.com/1020789674/fdc2112efa>

Caitlin Cooper Patient Story: <https://vimeo.com/1023140695/92214d4080>

This announcement has been authorised by PolyNovo Chairman, David Williams.

### About PolyNovo®

PolyNovo is a disruptive ASX 200 medical technology company, based out of Melbourne, Australia. Its products simplify management of acute complex wounds, redefining healing with meaningfully differentiated patient outcomes across multiple wound etiologies. After treating 50,000+ patients across 42 countries, the company is investing for growth via new products, indications, and markets. For more 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.

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