

# SMALL-CAPS RECOMMENDATION



# PNV:ASX November 2024

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### SMALL-CAPS RECOMMENDATION

### Polynovo Limited PNV:ASX

Polynovo is a pioneering medical device company that has developed and commercialized innovative products using its proprietary NovoSorb bioabsorbable polymer technology. The company's flagship product, NovoSorb BTM (Biodegradable Temporising Matrix), is a synthetic dermal scaffold used in complex wound and burn treatments. This revolutionary product has redefined healing for over 50,000 patients globally across 42 countries since receiving FDA approval nine years ago. Polynovo's technology addresses critical unmet needs in the \$2.4 billion advanced wound care market, offering a synthetic alternative that eliminates risks associated with animal-derived products. The company is actively expanding its product portfolio, with recent launches including NovoSorb MTX for smaller wounds. Polynovo's global footprint is growing rapidly, with strong market leadership in key regions like the U.S., UK, Germany, and Australia/New Zealand. The company is also making inroads into emerging markets like India, where it recently gained approval for government hospital use. With ongoing research and development efforts, including partnerships with universities in the U.S. and Australia, Polynovo is poised to introduce new products for burns, trauma, and implantable devices for hernia and other plastic reconstructive procedures over the next three years.



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### **INVESTMENT CONSIDERATIONS**

### Leadership

Polynovo's leadership team is a key strength, combining deep industry experience with a track record of successful execution. CEO Swami Raote brings over three decades of experience in medical devices and pharmaceuticals, including senior roles at Johnson & Johnson.

This expertise has been crucial in driving the company's commercial success and global expansion. Under Raote's leadership, Polynovo has consistently delivered strong revenue growth, with a 50%+ CAGR over the past three years. The management team has successfully navigated regulatory challenges, expanded into new markets, and scaled manufacturing capabilities to meet growing demand. Recent additions to the executive team in key roles such as APAC leadership, Medical, HR, and Legal have further strengthened the company's ability to execute its growth strategy. Chairman David Williams provides strategic oversight and has been instrumental in guiding the company through its rapid growth phase. The leadership's focus on innovation, global expansion, and operational excellence positions Polynovo well for continued success in the competitive medical device market.

### **Financial Performance**



### **Highlights:**

- Total revenue including BARDA of A\$104.8m
- Up 57.5% on STLY of A\$66.5m
- NovoSorb product sales of A\$92.0m
- Up 54.5% on STLY of A\$59.6m
- BARDA revenue of A\$11.2m
- Up 96.9% on STLY of A\$5.7m (120 trial patients enrolled)





### **INVESTMENT CONSIDERATIONS**

### Valuation

At the current share price of \$1.99, Polynovo trades at 13.3x FY2024 sales, which we view as attractive given the company's strong growth trajectory and improving profitability. This valuation multiple is justified by Polynovo's impressive revenue growth, with FY2024 sales up 54.5% year-over-year to A\$92.0 million. The U.S. market remains the primary growth driver, with sales increasing 49% to A\$68.7 million. Rest of World sales grew even more rapidly at 73.1% to A\$23.3 million, demonstrating successful international expansion. Importantly, Polynovo achieved profitability in FY2024, with positive NPAT of A\$2.7 million in the first half. We expect this trend to continue, forecasting EPS growth of 40%+ annually over the next 3 years as revenues scale and operating leverage improves. The company's strong balance sheet, with A\$45.9 million in cash as of June 30, 2024, provides ample resources to fund growth initiatives. Given Polynovo's leadership position in key markets, expanding product portfolio, and large addressable market opportunity, we believe the current valuation offers an attractive entry point for investors.



### **Sociological Factors**

Polynovo's innovative NovoSorb technology is revolutionizing wound care, offering a synthetic alternative to animal-derived products for complex wounds and burns. This approach expands treatment options and improves accessibility to advanced wound care. The company's global expansion, including approvals in emerging markets like India, is bringing cutting-edge solutions to regions with limited access to advanced medical technologies. Ongoing research in skin cancer treatment, vascular wounds, and limb salvage shows potential for further expanding the technology's impact. By simplifying complex wound management and improving healing outcomes, Polynovo's products can reduce healthcare system burdens and enhance patients' recovery. The company's focus on innovation and expanding access to advanced wound care aligns with broader goals of improving healthcare outcomes and reducing costs. Polynovo's contributions to the field of wound care have the potential to significantly improve patient quality of life and transform treatment approaches worldwide.

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## POLYNOVO LIMITED PNV:ASX



### RISKS

### Risks

investors should be aware of several key risks:

- 1. **Competitive pressures:** The advanced wound care market is highly competitive, with established players and potential new entrants. Polynovo must continue to innovate and demonstrate superior clinical outcomes to maintain its market position.
- 2. **Execution risks:** Rapid global expansion and new product launches require careful execution. Any missteps in manufacturing, quality control, or market entry could impact growth and profitability.
- 3. **Regulatory hurdles:** Obtaining approvals for new products and indications, particularly the pending PMA for full-thickness burns in the U.S., is critical for future growth. Delays or setbacks in the regulatory process could affect the company's expansion plans.
- 4. **Geographic expansion challenges:** Entering new markets, especially in developing countries, involves navigating complex regulatory environments and establishing local partnerships. Success in these efforts is not guaranteed.
- 5. **Potential patent expirations:** While Polynovo has a robust IP portfolio, future patent expirations could expose the company to increased competition.
- 6. **Reliance on key products:** NovoSorb BTM currently drives a significant portion of revenue. Diversifying the product portfolio is important for long-term growth.
- 7. **Currency fluctuations:** As an Australian company with significant international sales, Polynovo is exposed to foreign exchange risk.
- 8. **Healthcare policy changes:** Shifts in reimbursement policies or healthcare regulations in key markets could impact adoption and sales of Polynovo's products.
- 9. **Manufacturing capacity constraints:** While the company is expanding manufacturing capabilities, any delays or issues in scaling production could limit growth.
- 10. **Clinical trial outcomes:** The success of ongoing clinical trials, particularly the BARDA-sponsored pivotal trial for burns, is crucial for expanding indications and market opportunities.



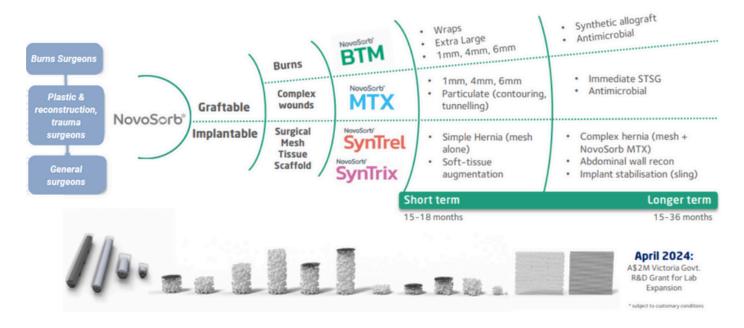


### WHY HOLD THE COMPANY?

### Why hold the Company?

We recommend investors buy PNV shares based on the following key factors:

- 1. **Strong revenue growth outlook:** Polynovo has demonstrated consistent high growth, with a 54.5% increase in sales in FY2024. We expect this momentum to continue, forecasting a 40%+ CAGR over the next three years, driven by further U.S. market penetration and global expansion.
- 2. **Improving profitability:** The company achieved profitability in FY2024, with positive NPAT in the first half. As Polynovo scales its operations, we anticipate significant operating leverage, leading to expanding margins and strong earnings growth.
- 3. Large addressable market opportunity: The \$2.4 billion advanced wound care market provides ample room for continued expansion. Polynovo's synthetic products address key limitations of existing biological alternatives, positioning the company to capture increasing market share.
- 4. **Innovative product portfolio:** NovoSorb technology has demonstrated superior clinical outcomes across multiple indications. The recent launch of NovoSorb MTX and ongoing R&D efforts in new applications provide multiple growth avenues.
- 5. **Experienced management team:** The leadership's track record of successful execution in commercialization and global expansion instills confidence in the company's ability to capitalize on its growth opportunities.
- 6. **Geographic expansion:** Strong momentum in key markets like the U.S., UK, and Germany, coupled with entry into new territories, provides a clear path for sustained growth.
- 7. **Potential for strategic partnerships:** Polynovo's innovative technology and growing market presence make it an attractive partner for larger medical device companies, potentially accelerating growth or leading to acquisition interest.



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