

13 November 2020

## ASX Announcement

### Chairman's, Managing Director's, and SVP of Sales US address to Shareholders

#### Address by Chairman – Mr David Williams

- Win for patients, the company, shareholders, and Australian technology
- Growth in the Core business and product
- Medium term growth in products
- Perspectives on Research and Development
- Implications for the Board and Management structure

#### Address by Managing Director – Mr Paul Brennan

Thank you for your attendance at this AGM. This has been a challenging year with the continued rapid growth of the business, building the new factory facility and juggling all the changes required by COVID. I would like to thank our staff at the outset for their flexibility, determination and perseverance. Thank you also to all investors for their support.

Sales revenue from NovoSorb BTM continues very strong growth, from \$9.3M in FY19 to \$19.06M in FY 20. This has been achieved even with H2 impacted by COVID travel restrictions, hospital access challenges and a head office lockdown for 120 days. The ability to pivot and conduct our business from a digital platform, supported by sales teams that made face-to-face visits whenever they could safely do so, has been fantastic. We stand-out amongst medical device companies for continued growth under such difficult market conditions.

What enables PolyNovo to achieve this?

- Talented and flexible staff
- Early and comprehensive action to protect our production facility and staff
- Earlier investment in upgrading our ERP system
- An established CRM system as central to how we conduct business
- Purchasing reimbursement data (US) to facilitate account prioritisation and access
- Established key opinion leaders with extensive NovoSorb BTM experience who were willing to share their experience via webinars
- Continued account acquisition and deeper account penetration and geographical expansion
- Good intellectual property that is well managed.

We continue to harness this momentum to double our revenues again in FY21.

Embracing change as an opportunity affords PolyNovo with continued growth and expansion.

## **Commercialisation of NovoSorb BTM**

### **US**

The US business continues to grow despite the disruption of COVID in H2. The team have continued to open new accounts and gain deeper penetration of existing accounts. These two strategies are not binary, as we can and must do both.

The revenue outside of burn continues to grow and many of these complex cases can be seen in the various webinars we have published.

The competitive response has been largely unchanged in the past year. We remain focused on our value proposition and execution of our sales and marketing strategies.

We continue to work on GPO/ IDN agreements and we have two signed to date. This has been interrupted by CoVid restrictions on the GPO side. They have now restarted however they are not at the normal pace so we do not have a definitive timeline for when we will achieve these.

Sales team expansion will continue throughout the year. We currently have 21 however we expect this number to grow to circa 30 by June 21. Our geographical reach has expanded and the existing sales teams have smaller territories to enable greater account penetration and we have added new accounts within the same state. We increased the regional sales managers positions from two to four which enables managers to coach and mentor their sales teams more closely to drive revenue growth. This approach also ensures we stay close to our customers and are able to respond quickly to any business initiatives or needs.

**Canada:** we have had several surgeries and sales in Canada under the exemption approval scheme. We are actively working on Canada regulatory approval and hope to have news on that in H2.

I will defer to Ed Graubart to give you a local sense of how the US team is responding to the challenges in the US market.

### **Australia/New Zealand**

Both Australia and New Zealand have had very good sales results and continue to.

The White Island volcano tragedy did have a H1 FY 20 impact. Our teams, logistics, sales, finance and management were highly responsive to the tragedy. The surgical teams did an awesome job caring for these people and continue to support them in their long-term recovery. It is humbling and motivating working with clinicians around the world who are so focused on the outcomes of their patients.

We have seen NovoSorb BTM use expand throughout the public and private hospital sectors. The wide range of use/ indications is especially encouraging.

One teaching hospital vascular department has recently presented to the PolyNovo team their experience of BTM on 35 patients with ischemic limbs, vascular wounds and diabetic foot ulcers. The outcomes have been extremely positive with many limbs saved. The savings to the health system and the quality of life benefits for these patients is enormous.

Our sales team expanded to four during the year and we will be looking to expand further within this FY. Valerie and her team are very customer service focused and great brand ambassadors for the company.

## Other markets:

### **DACH (Germany, Austria, Switzerland)**

Our CE Mark approval in December 2019 enabled us to sell in Europe, UK and Ireland.

In the DACH region we appointed Polymedics (PMI) as our distribution partner. They had an existing and extensive customer base ideal for NovoSorb BTM use. The first surgery was completed in January and sales have been very strong and building every month. Several surgeons in the region have also conducted their own private webinars with their peers extolling the benefits of BTM. We are very happy with PMIs performance to date.

### **UK/Ireland**

We expanded our UK/Irish team this year. We have three sales people, one European marketing person and one EMEA regional BDM to manage our distributor relationships and expansion.

NovoSorb BTM has been evaluated in more than 37 surgeries across 13 NHS hospitals through 22 surgeons. We have achieved modest sales to date however the wide range of use for NovoSorb BTM and the positive feedback augers well for significant lift in sales once the current CoVid lockdown eases in Britain.

We have appointed our first Irish salesperson, based in Dublin, and he will commence on 30 November this year.

Finland and Greece have been added to our new markets in the past month. There are several others in progress and we will announce these in due course. Suffice to say that our expansion through Europe, Mediterranean and the Middle East will be accelerating.

### **Asia**

We appointed our own salesperson in Singapore to commence our Singapore/Malaysia sales. We have achieved sales in Singapore and surgeries have been conducted in several hospitals on a wide clinical indication base. NovoSorb BTM is again proving itself to be different to biologic products and readily accepted.

We announced **Taiwan** regulatory approval and the appointment of Evermed as our distribution partner. This will be an exciting market for us.

We have indicated our entry into **Korea** in the Annual Report. The Korea regulatory authority has conducted their audit of PolyNovo and we are now awaiting approval. This has been slowed by CoVid so we now expect approval in H2 this FY.

### **India**

Our distributor, Myovatec Surgical Systems, have achieved sales throughout the year. Some of the Indian surgeons have presented at conferences and even conducted online presentations highlighting the benefits of NovoSorb BTM. We are currently looking at appointing additional distributors in India to enable a greater geographical reach.

### **Africa and Middle East**

Surgical Innovations continue to support NovoSorb BTM in South Africa. It is a difficult market without reimbursement. We have provided clinical data to the insurance bodies however this is proving to be a protracted process for the private hospital network. In the public system we have had sales and continue to see BTM used in the worst clinical cases with good results.

### **Saudi Arabia and Israel**

We are reconsidering our distribution partnerships in these markets due to poor responses and sales.

**Kuwait and UAE** are anticipated to be new markets for PolyNovo in H2 this FY.

### **New markets**

We are actively pursuing further market entry opportunities for the year ahead. Further expansion throughout Europe and Asia will be announced in due course.

### **Manufacturing Facilities**

We completed the new cleanroom facility within Unit 1 that will manufacture hernia and breast products. We have also built into the factory redundant capacity to manufacture BTM. This gives us back-up capacity for maintenance periods in Unit 2 and further production capacity if required in the years ahead.

The final stage of the factory is the film extrusion and stretching facility which will be conducted in a controlled environment versus a cleanroom. This section will be completed by March and will allow us to move the equipment housed at UBI in Scoresby to Port Melbourne.

CoVid has caused some delays in machinery delivery and commissioning however we have had proactive workarounds for many of these issues. It is estimated we have added around four to five months to our timeline for hernia. We anticipate having our first Syntrel available for surgical use around Christmas 2021.

Our US office near San Diego has expanded and now houses our sales, marketing, clinical and HR support teams for the US. We will be adding a finance function to the local team shortly.

We had a capital intensive FY20 however the forecast for FY21 is significantly reduced as these factory facility works conclude.

### **BARDA US based clinical trials**

The US feasibility clinical trial results for full thickness burns has concluded. This morning we received approval of our pivotal trial IDE from the US FDA. We will recruit 150 patients in 20 sites once we have the local IRB approvals. We anticipate recruitment of patients will begin early 2021 and take approximately 3 years. Further details will be shared in the coming weeks.

We have announced the generous support of BARDA with a \$15M USD contract to support this program.

We have brought in-house many of the clinical supervision roles to ensure PolyNovo has a close relationship with the trial sites and we can optimize our recruitment of patients through excellent site support.

### **NovoSorb SynPath Reimbursement Chronic Wound study**

We have contracted a CRO to conduct this clinical and health economic study of chronic wounds. We will announce full details of this program once we have IRB approval that will enable sites to begin recruitment. We anticipate recruitment to begin January 2021. Once complete, the data will be used to apply for private health insurance reimbursement coverage. This will enable PolyNovo to expand into the alternate care market with a TAM of circa \$400M USD. Forecast for CY 2023.

### **Research & Development - New Product Pipeline**

Syntrel Hernia devices have been covered elsewhere in this speech.

## Breast

Drawing on PolyNovo's increased in-house research and development capability PolyNovo has the opportunity to accelerate the Breast device development.

This development will draw on other in-house programs, and focus on products that have more direct pathways to market.

## Others

Drug elution and sports medicine devices are in proof of concept phase. Some early laboratory and animal work has been done however we will accelerate these programs with the further expansion of our R&D team. We recently appointed a dedicated development project manager, in addition to our new COO Dr Anthony Kaye who commenced this week and a new scientist. Further recruitment in the R&D group is in-process.

PolyNovo added four new patents in the past year and filed several brand/ trademarks in multiple jurisdictions. We are well placed to drive these programs with the conclusion of the Syntrel R&D phase fast approaching with its impending transfer to manufacturing in early 2021.

## BetaCell – Diabetes program

This is a program that utilises NovoSorb BTM as a dermal implant to support islet cell implantation that may result in insulin production negating the need for Type 1 diabetics to require regular insulin injections.

The Adelaide team have been working through some technical aspects with stem cell derived islet cell sourcing. They have applied for additional funding grants to support their human trial program. We are ready to support the team once they secure funding.

I am happy to take questions at the end of this segment.

## **Address by Senior Vice President of Sales US – Mr Ed Graubart**

- The US business structure
- Size and geographical coverage of the business
- Growth of the team, geographical coverage, and sales for FY'21
- The reaction of surgeons and marketplace to our product
- CV-19 impact, Military, GPO and Hospital VAC

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

## **Further information:**

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### About NovoSorb®

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 programmable bio-resorption profile. NovoSorb® BTM is a dermal scaffold for the regeneration of the dermis when lost through extensive surgery or burn.