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## ASX Announcement

### Chairman's and Managing Directors address to Shareholders

#### Address by Chairman – David Williams

- FY21 strong sales growth
- Momentum building despite COVID
- Hospital trials lead to strong sales in the UK and Germany
- New distributors and first sales in the EU with more to come
- New accounts up
- Despite COVID, US conferences start and new sales staff on the road
- Use of BTM in new indications
- Cash up/neutral 31 December – 30 June '21
- Profits emerge after non-cash items
- Reflections on the PNV share price

#### Address by Managing Director – Paul Brennan

Thank you for your attendance at this AGM. Virtual AGMs lack the personal interactions I enjoy with many of you, but we are hopeful next year we will be back face to face.

The past year has been challenging for everyone in society and it is certainly challenging to run a global business via remote access. Despite these challenges we have a lot of positive news, achievements, and team growth. We have made rapid and significant changes in ways of doing things and found new opportunities to address restrictions impacting product development.

In FY21 sales in the US were up 49%, Distributor sales up 53%, doubled our US sales team, in the process of doubling our UK/Ireland team, completed the Unit 1 factory, commissioned new production machinery, expanded the R&D and production teams, and manufactured several thousand Syntrel hernia devices for use in laboratory and animal studies. Capping this off we returned our first profit, excluding non-cash items. By any measure that is an outstanding result during a global pandemic!

Sales revenue from NovoSorb BTM in FY21 was \$25.5M and BARDA revenue an additional \$3.7M, total revenue \$29.3M.

Revenue first quarter of FY22 started strongly, \$8.05M for the group. Further we are having high volume growth in purchase orders for small and intermediate sizes. This indicates wider account penetration and a broadening of our sales base outside of the burns segment. I will cover the regions separately however the projection of revenue growth for the remainder of FY22 is strong. This is based on increased number of accounts and raising trend of purchase orders, geographical expansion, and continued sales team expansion. FY22 will be a stronger sales growth year than FY21.

It has been a rapid journey over the past five years with significant need for constant change and improvement. Our teams have grown, the depth of talent expanded and our capacity to drive forward forever improving.

### **Commercialisation of NovoSorb BTM**

#### **US:**

The US business achieved strong growth in FY21 against a challenging COVID environment, bearing in mind this time last year the US was experiencing ~4,000 COVID deaths per day! The impact on the hospital system was significant and yet we grew the US sales by 49%, doubled our sales team, signed three General Purchasing Organisations (GPOs), and opened 44 new accounts.

What these numbers do not show is the pivot our teams made in digital approaches: recruitment, induction, training, surgeon/customer interactions, clinical support, tradeshow on-line and webinar development.

These activities remain staples of the ongoing business practices and the environment that we work in. This pandemic is abating however there is still some way to go. Hospital access is steadily increasing yet some regions (southern) are challenged today by the Delta variant impacting the unvaccinated.

July and August were good performing sales months in the US with September being impacted by low burn incidents. The number of purchase orders is growing strongly with sales of small and intermediate sizes rising significantly.

In Q1 'FY22 the US team opened 16 new accounts and saw record number of purchase orders of 131 in September. We have signed with three General Purchasing Organisations (GPOs) and have dedicated resources appointed to manage the GPO relationships and drive sales top down. Concurrently the sales team are pulling sales through. We are actively pursuing further GPO agreements.

#### **US: DFU trial (chronic wound reimbursement)**

The initial 10 patients completed the trial with seven completely healed within six weeks and the remaining three demonstrating significant wound closure within six weeks. The sites involved have been very impressed with BTM's performance in these challenging wounds. The next phase of the trial will begin as soon as the protocol adjustments are approved by site ethics committees. We anticipate having results submitted to insurers for reimbursement in 2024.

#### **BARDA pivotal trial**

Two patients have been enrolled in the trial to date. 16 US sites have been contracted with the remaining four US and five Canadian sites in various stages of induction. The trial is anticipated to take three years to conclude.

#### **Australia/New Zealand:**

Our Australian and New Zealand sales continue to build strongly. Boarder closures and hospital capacity challenges have impacted sales however we have seen good recovery each time lockdowns have been lifted.

Our growth in the Australian private hospital market has also been encouraging with a wide range of elective surgical indications.

We increased the sales team with the addition of salespeople in Victoria and Western Australia and we anticipate further expansion this year in response to sales growth.

#### Other markets:

##### **Asia:**

**Singapore:** We are seeing regular elective surgery use of NovoSorb BTM throughout eight hospitals in Singapore. We are currently looking to add an additional salesperson to the Singapore team.

Taiwan has achieved sales and we see good growth potential with an excellent distribution partner. We are introducing smaller 5X5 size to Taiwan in response to chronic wound demand.

**India:** Myovatec Surgical Systems, as our distributor, have delivered sales throughout the north. We are working closely with them to look for accelerated opportunities. We are also looking at additional distributor opportunities in regions currently not serviced directly by Myovatec.

We are currently looking at opportunities to enter further countries in the region with various distributors. Once we have regulatory approvals, we will announce these market entries.

##### **Distributor sales**

In FY21 distributor sales were up 53%. We have seen strong performance from our partners throughout Europe during very difficult COVID conditions. Life is returning slowly to more normal patterns in Europe with hospital access improved and face to face interactions in hospitals and at trade shows. We see some good growth opportunities in the year ahead in our current markets and further expansion with France, Spain, and Portugal as high priority markets.

Our distributor markets are profitable for PolyNovo allowing us to support the expansion of our direct markets.

##### **Manufacturing Facilities:**

We have completed the factory build at Unit 1 Lorimer St and we are now working through the operational validation processes that allow transfer of hernia manufacturing from R&D to manufacturing. There will be no requirement for any major capital works in the near term as we bring these new manufacturing machines online.

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

##### **Hernia**

SynTrel VP. We have manufactured several thousand Syntrel VP devices as part of our validation processes. We currently have a large animal (pig) study in progress. The data generated from this study will support not only hernia devices but breast and many other devices that can be made from a NovoSorb film and NovoSorb foam combination.

Research and development is not a straight forward process. The purpose of these studies is to identify all possible performance aspects of products against intended use and misuse clinically. We may also discover possible new applications as data is assembled.

### **Breast**

The breast product development path will benefit from the hernia study. We have employed a dedicated marketer to assist in gathering end user design input for this and other product developments. At this stage we do not have a finalised estimate of time to market however we may provide an estimate at the half year results.

### **Other Devices**

#### **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 need regular insulin injections.

The Adelaide team inform us that the first human trial will begin in Adelaide by November this year. They have secured their funding from the JDRF.

NovoSorb Foam for cavities, wounds and tissue layering: We are in the process of defining the range of clinical applications for the use of NovoSorb Foam with no sealing membrane for use in a wide range of complex wounds and tissue reinforcement/ regeneration applications. This will greatly expand our commercial opportunities and surgical applications across existing and new accounts.

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.