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ASX Announcement

Paul Brennan CEO interviewed by Alan Kohler

PolyNovo CEO Paul Brennan was interviewed by Alan Kohler. Below is a transcript of the interview. Alan Kohler will have this interview on his website www.eurekareport.com.au and may appear in other publications Alan is connected with.

Well, Paul, you've had a spectacular start to the year. And before we get onto exactly what's going on with PolyNovo's treatment, tell us, you said on the 7th of January that you've had your first \$2 million month, does that mean that you made a cash profit that month as well?

Yes, we did make a profit in the month and we've made profit on various other months in the year as well, but in the overall state we've been shadowing our breakeven line. The reason we've been continuing to invest is that we have high gross margins and if we put the money back into the business of employing more sales people and driving the marketing activities it's better use of cash than to keep in the bank and at this stage announce a breakeven point. So it's about driving the business as aggressively as we can and expansion for the top line growth.

So are you going to announce a cash profit or even a net profit for the year, do you think, or not?

We haven't determined that at this point. The half year financial results are out on the 26th of February, so I can't go into those until they're out. But strategically from the business and the board's perspective is to, while we've got cash in the bank to keep driving the business quickly because we generate good revenues and gross profits and all of our cash projections show us paying cash rich in the near term. So we just need to continue to drive as aggressively as possible as we can towards that goal, the longer term goal.

I guess you've got to be careful about not permanently damaging your margins though?

No, our margins are very healthy, so I don't think we've got risk of having damaged our margin and the business is in good financial health.

And how much cash do you have in the bank? I must say, I don't understand, how you don't have to put out quarterlies, Appendix 4C quarterlies, you've actually said you're not going to do quarterlies, why don't you do it?

Well, that's a product of legacy that we haven't been required to and at this stage, while the business is in the early phases of growth we don't see it as a productive thing to put out a quarterly projection until we get less lumpiness in the business and solid, predictable sales targets and revenues.

Yeah. So you've been putting out some statements concerning sales in UK, Europe and the US, can you just bring us up to date with where you're at with all of those markets?

Yes, we launched in January in both the UK and in the DACH regions - Germany, Austria, Switzerland. We attended the DAV Conference, which is the DACH region burns conference and had a very successful launch there with the partners, PMI. The conference ended on the Saturday and the first surgery was done on the Sunday morning.

The surgeons in that region are extremely excited by the potential of what NovoSorb BTM offers and that's been very successful with surgeries being done throughout Germany and Switzerland. In the UK, we go direct there and I've made field visits with our sales manager in the UK and we've also employed an additional two sales reps to come on board effective as of today in the UK and we've had surgeries done in the UK as well. The surgeons there in the NHS are excited by a number of prospects. One is a competitive price point, which is always a very sensitive issue for the NHS, but also the robust nature of the product and the good clinical outcomes that it gives, I think give long term economic benefits. So in the longer term, we'll do some health economic studies to underpin that, but the surgeons are already seeing outstanding results.

Right. And what about the US?

The US is going very strongly. We've increased our sales team in the US we're effectively adding a sales rep per month at the moment in the US we've got a very good management team and we've had accelerating growth consistently in the US. So we're in a very good position. We've still got a lot of headroom for growth. It's a large market and certainly not tapped to any severe capacity there in the US at this point. But we do have large hospital names as regular customers and we're making significant inroads to key accounts there, so things are looking very positive for us in the US.

You mentioned in relation to the UK what was important or what was getting the surgeons excited was your price competitiveness. Can you just tell us about your competitive situation? What do you compete with and is there anything like NovoSorb BTM?

Well, there's no other synthetic dermal asking the scaffold so we're unique in the marketplace of being completely synthetic. All of our competitor products are animal sourced products. So when you have foreign animal proteins and collagen that you're laying into a wound you're providing potential food bacteria in a wound so you can turn a low infective risk into a high infective risk quite quickly. The other thing that the body needs to do is what's called re-model that foreign collagen. So new blood vessels have to effectively burrow their way into a product. When your cells try and move in there, they've got to move them out to get themselves in. So it's a little bit like moving into a fully furnished house with your furniture van, you've got to get all that stuff out while you get your new stuff in.

Whereas we're the empty build; you've got a completely vacant scaffold that blood vessels themselves just migrate completely into and it becomes the structure in which it provides a home for all the new cells to regenerate and repopulate, and then like sugar water, if you like, it dissolves away. So the product over the next 18 months or so will dissolve away into lactic acid, carbon dioxide and water and you'll just excrete that through your kidneys and breathe it off through your lungs. So it's quite a radical proposition compared to animal sourced products

And do you compete with AVITA Medical's spray-on skin regeneration product?

No, there's no competition there at all. We regenerate the dermis, the underlying structure of the skin. So skin is made of two layers, the epidermis and the dermis. RECELL AVITA looks after the spread of the keratinocytes which are the cells of your epidermis. They do nothing for regenerating a dermal structure. So our job is to give a really good foundation for your skin with the blood supply, the ability to lay down fat again, the elastin for stretch and movement. And over the top of our product, when it's fully integrated, you then put a skin graft and if you choose to, you can also use RECELL in conjunction with skin graft on

top. In the US several surgeons have used RECELL over BTM as has Fiona Woods in Western Australia. And the good thing with our product is that we provide a highly vascular dermis that's also rough. So those keratinocytes that close the epidermis actually need a rough surface to be able to walk out into the empty space and re-proliferate. So we give that with our structure when you delaminate it, you get a micro-rough texture of the surface but you've got a very rich blood supply; all the things that those cells need to grow.

I obviously got it wrong. I thought you didn't need a skin graft after using your product, but obviously you're saying you do. So your product NovoSorb BTM actually exists under a skin graft does it?

Yes. So when you've got a large loss of dermis, say you've had an excision of a melanoma or you've had a road trauma or a de-gloving from an industrial accident or you've had a full thickness burn, when you've lost that dermis layer, which is the foundation of your skin, then that's where we come in to replenish and regenerate that and then you close the stage finally with skin grafts. So there's a film on the top of their product that when you're ready to do a skin graft, you can then peel that off and then you can close it with a skin graft and get a very good cosmetic result.

Macquarie put out a report in December that talked about a possible total market in the countries that you're selling in of more than \$200 million per year. And they were assuming a market share of about 10 per cent, \$19 million by 2024. That seems to be quite conservative to me. What do you think?

Yeah, 2024, it probably is conservative.

Does that sound right for the total market, \$200 million?

Well, the total market is actually \$1 billion, plus our models of \$1 billion is conservative, some of the competitors put the market over US\$1.5 billion in total size. There's \$400 million alone in chronic wounds in the US alternate care market. So the size of the market is significant. For us, we have penetration of the market. It's a matter of commercial execution as to how much of that total pie you own. And realistically we're never going to own 100 per cent, but obviously our goal is to get as close to that as we can. So in the longer term there's significant earnings potential within the space and then into that, you know, for us, we'll also be going into the hernia space and other spaces with this polymer as well. So the skin space is a very good space for us to get our start.

What do you mean hernia space?

Well we're developing a hernia product and so we'll be doing abdominal wall repairs for large hernias in calendar year 21 in the US market. We're in the process of building a factory here in Port Melbourne. There's a lot of building activity here today and that factory will be finished by the end of the day and then we'll make the commercial product within this facility and ship that to the US next year. So that's a \$2 billion market space that we'll be entering that's growing at over 7 per cent a year thanks to obesity and with class action lawsuits on permanent meshes, surgeons are looking for a device that can repair a hernia and then dissolve away, and that's our sweet spot. We've got a unique polymer that can be formatted into any number of medical devices. That's a true platform and NovoSorb BTM is the first product and it's proving to be very successful, but in the longer term, we'll be entering the markets of hernia and breast reconstruction and aesthetics and we'll go out into other markets with other devices in the longer term after that.

Right. So what do you think the total potential market is if there's \$1.5 billion of dermis, there's another \$2 billion of hernia. What else?

Well, the breast market's around \$2.5 to \$3 billion and then we can make a drug eluting polymers that can go underneath the skin and release a titrated dose of a drug per day. So for treating chronic conditions where compliance of patients with their medication taking is an issue that could be a good solution for those. So the scale of that market is yet to be determined. We've got the use NovoSorb BTM into a space where you can inject islet cells into it for the treatment of diabetes. We've got the St Vincent's Institute growing liver organoid cells in NovoSorb foam to study the mechanisms of actions of liver cancers. And longer term, there might be a possibility of doing some work with NovoSorb organ regeneration, but that's speculative and some way off at this point.

Could you tell us a bit about the history of PolyNovo? I think the substance, NovoSorb BTM was discovered or developed by CSIRO. Is that right? When was that and how did it become a listed company?

Sure. NovoSorb is a polymer, was developed by the CSIRO and in 2004 they spun that out into a company called PolyNovo, which was then acquired by another company called Exceed Capital. And then it had a tortured pathway until it ended up as part of an entity called Calzada, which was publicly listed in 2014 and was having significant issues with the metabolic pharmaceuticals section. It had two products, one was NovoSorb, one was Metabolic Pharmaceutical. Metabolic Pharmaceutical didn't succeed in its clinical trials. And so after that, the shareholders rolled the board and then a new board came in and restructured the company in 2015 and when I joined, we divested the Metabolic and we rebranded as PolyNovo from Calzada. So changed the ticker from CZD to PNV and focused on being a pure play medical device company based on the NovoSorb polymers. So we've been focused on commercialisation since 2015.

In fact, I think the product that Metabolic was on about was AOD 9604, which is the peptide that Essendon Football Club got into trouble for?

Correct.

And the company was trying to develop it for osteoarthritis and obesity and God knows what and it didn't work.

Yes, that's right. That's now been sold off to the previous CEO and he's got a company called Lateral Pharmaceuticals and he's developing that for other uses. But that has nothing to do is PolyNovo. I mean the new board in 2014, and when I joined in 2015, made the strategic decision that it had no role in PolyNovo and that's why we divested it off to David Kenley and focused specifically on the polymer and until we got NovoSorb commercialised as a polymer because this is a radical technology and there are so many devices we could make out of it that change people's lives.

So AOD 9604 not only has caused a lost decade for the Bombers, it caused a lost decade for your company. I mean, it was basically 10 years that was distracted by that. You could have been doing NovoSorb BTM for years until you came along. I mean, and you had to fix the place up, didn't you?

Well I wouldn't say that it's just me, it takes a significant team to get things happening. We still have the board who are a very active board and very supportive. So when I started, one of the comments from the chair was Australian companies tend to die from a thousand cuts. And in his vernacular, "let's put some serious money into this and let's see if we can get this thing to work". So with that commitment is where you then build a team that can then execute on a commercial strategy of building a world class production facility. In 2015 I was the sixth employee and now we're close to 70 employees.

In fact Paul, you came from Smith & Nephew where you'd been for five or six years, but had you been dealing with this company at Smith & Nephew? Because I think that there was some kind of distribution arrangement for NovoSorb with Smith & Nephew.

Yeah, the NovoSorb polymer had been licensed to Smith & Nephew Orthopaedics as a bone void filler and Smith & Nephew still haven't really progressed that into any commercial device. When I was at Smith & Nephew, I came across the animal studies that were being done on the NovoSorb BTM and was fascinated that you could get a square wound because there was so little contraction in these wounds that whatever shape you cut out was the shape that was healed with NovoSorb BTM. So I'd suggested to Smith & Nephew that they should acquire PolyNovo. But they decided that it was too early in development and highly speculative. So when the 2014 situation developed here, when it was Calzada, and they were looking for a CEO, I thought, well, I'll put my money where my mouth is and let's go commercialise it and in hindsight, a great decision.

Did you put much money into it at the time? When you say put your money where your mouth is, how much money went where your mouth was?

Well I had to buy the share options at each tranche as I've gone and that's been at times, a financial stretch for myself and my wife and also personally bought shares as well at the time and so have various family members. So, you know, it's the belief that head down, bum up, do the hard yards and this could maybe make it.

It's interesting because when you were telling Smith & Nephew to buy PolyNovo, back in 2014, the stock was about 6 or 7 cents and now it's \$2.80 and it capitalised at \$1.8, 1.9 billion – goodness me.

Yeah. It's been a journey, but a very positive one but there's still a long way to go for this company. We've got a large potential footprint to be made with many medical devices. So it's a diverse polymer. We've got 47 patents covering the IP and it's fields of use and manufacturing processes and we've got further patents that will be issued shortly to add to that family of IP protections. So we've got a lot of development potential ahead of us and it's really limited by our scope of imagination and investment in the R&D as to how we execute.

And I suppose, do you think at some point Smith & Nephew will come back and take up your suggestion?

Look, personally I hope not. I think Australia has a very rich history with, you know, ResMed, Cochlea, CSL and many others, medical developments and several other medical companies. I think there's no reason we can't be a very successful Australian multinational on our own. Now everything on the share market is obviously for sale every day, so if somebody makes a play for PolyNovo then, and you know, that happens, but you never run a business with the view to selling, you run a business to be commercially viable, innovative, disruptive, and successful. So we're completely focused on doing nothing other than running our business as a very successful commercial enterprise.

Good to talk to you, Paul. Appreciate it. Thanks.

No problem, Alan, enjoyed the conversation.

That was Paul Brennan, the CEO of PolyNovo.

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

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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.

About PolyNovo®

PolyNovo is an Australian based medical device company that designs, develops and manufactures dermal regeneration solutions (NovoSorb BTM) using its patented NovoSorb biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopaedic applications. For further information and market presentations see www.polyново.com.au