PolyNovo Limited
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18 November 2016

Chairman and Chief Executive Officers Address

At today's Annual General Meeting the Chairman and the Chief Executive Officer provided the reports below.

Important information provided within these reports include:

- Reflecting on the past year noting a significant increase in the Company's share price, the additional organisational depth through the appointment of key staff, and cash at bank balance;
- The appointment of Device Technologies as the Sales and Distribution partner for the Company's products in Australia and New Zealand, and the Company's first ever commercial sale;
- Entering the US market directly following the lead of MiMedx, employing a US based sales team;
- Negotiations with potential distributors in South Africa and Hong Kong;
- Continued the CE Mark trials for burns and surgical wounds and added 3 Australian based sites to accelerate patient recruitment;
- Continued to provide BTM to the Royal Adelaide Hospital and have seen some impressive clinical outcomes;
- Progressed the contract with BARDA including an extension to fund a swine study;
- Obtained US FDA approval for the final Pivotal trial; and
- Continued Research & Development activities in breast and hernia applications.

Chairman's Address

Thank you for coming today and for supporting PolyNovo.

It is probably worth reflecting on the fact that only two AGMs ago we had no CEO and you were addressed by Director Phillip Powell as acting CEO.

Indeed only 18 months ago we had less than six staff. We had insufficient cash, a share price of 7.5 cents and an ill-defined path to market success.

In the short time since we sold AOD964, won a large BARDA contract, have bought our subsidiaries in-house, have $9.9m in the bank today, have 20 staff with at least three more positions to fill; have a well-defined clinical trial program with more to come, are well down the road on our planning for new products for hernia, breast and the like and have appointed people to sell our products in Australia, New Zealand and the US.

By anyone's standards new life has been breathed into a company with world-class technology… dare I say it, breathtaking technology that deserves to be, and will be on the world stage.

A company that risked dying by a thousand cuts like most Australian Pharma/Device companies with too little capital and too few staff now has an excellent chance of making it, and best of all relatively quickly.

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One year ago when I stood here our share price was 16 cents and today is 28 cents up from 7.5 cents 18 months ago. I judge this as proof that PolyNovo has real IP and a real chance of commercialising it in time frames our shareholders and investors can understand and can value.

There is no magic formula to this. All it takes is some unique IP, some capital, a properly resourced Board and Management, and bravery to pursue a development plan in the right and rigorous way. We will not die wondering if we can take PolyNovo's products to the world. At the same time we are not cavalier with your money, we will develop the IP we have properly and responsibly one step in front of the other, but time is of the essence.

I will leave it to Paul Brennan to outline in more detail the year just passed and the year ahead. However I did want to say two things about our commercialisation strategy.

First some shareholders were impatient with how long it took for us to settle our way forward for sales and marketing in the US. It sounds nice to partner with major Pharma but in this case we decided we could better do it ourselves by going direct. This was not a misplaced arrogance. The sorts of things that influenced us were margin leakage, speed to market and the concentration of likely buyers of our products. We looked at what MiMedx had done in the US and believe we can learn a lot from their approach and replicate some of their success. We have 3 excellent employees based in the US who have hit the ground running. They are experienced, know the market and know who to call. Paul will say more on their progress.

While it took us a while to make this decision do not think we were vacillating or uncertain of our position. The Board and Management are true believers and more than you can imagine are waiting for the first sales and confident they will come. We expect sales shortly and believe this will be the strongest signal yet that PolyNovo has a bright future and is on a different growth trajectory than it was 18 months ago.

Secondly we have invested heavily in Business Development and have recruited an excellent person from KPMG. He has already made some early contributions to our ability to support our US entry and to enter South Africa and other markets. Paul and the other 19 staff we have are a team (with a few more to add) who can take PolyNovo to another level and profitability showcase excellent Australian technology to the world.

I would now like to invite our CEO Paul Brennan to discuss the operations of the company.

Chief Executive Officers Report

A lot has happened in the past year. Externally, you may have seen significant progress but behind the scenes our expanded team have had a lot of work to deliver that progress.

I would like now to brief you on some of our achievements and foreshadow some of our work for the year ahead.

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Wound and burns applications

CE Mark Trial

The two CE Mark trial sites have experienced slower than expected recruitment. To address this we are adding 3 Australian based sites. The Alfred Hospital will be the Lead Investigating Site and their ethics committee is in the process of approving this step. We conducted the Principle Investigators meeting for the additional sites in November. We anticipate these sites will be open for recruitment from December/January.

The Alfred, to date, have recruited 12 patients with 3 deaths unrelated to PolyNovo BTM. They have indicated that the BTM is delivering excellent outcomes. We require 30 patients and our forecast is to conclude recruitment, with the assistance of the three additional sites, by June 2017.

The Toulon site has only recruited 1 patient and given the high cost of keeping this site open we have suspended further recruitment in Toulon.

Our primary end point is 2 weeks post graft to assess performance of the BTM and we then monitor safety for twelve months. We are exploring the possibility of an earlier CE submission during the twelve month monitoring phase. Our goal is still to achieve a CE Mark in early calendar 2018.

Royal Adelaide Hospital (RAH)

RAH continue to utilise the BTM on the TGA prescriber's exemption scheme. To date we have more than 50 free flap grafts, 1 necrotising fasciitis of the neck and continued use in Burn care. The clinical outcomes of these patients are excellent.

The previously announced pig study into the use of BTM as a depot for beta Cell injection (Diabetes Type I) is BetaCell IP position is in the process of being resolved. BetaCell estimate that the pig study will commence early 2017. This has no impact or relation to PolyNovo's IP of the BTM. We have the specialized shapes of BTM manufactured and ready for supply.

BARDA US based clinical trials

The Feasibility trial has been approved by the US FDA. We are limited to 10 patients from 3 sites in this phase of the program. Once the last patient has been closed we can submit the preliminary data to the US FDA 3 months later. This will initiate the review process of the final pivotal trial. The BARDA funding contract for the Pivotal trial will be negotiated concurrently. This pivotal trial will build the clinical evidence required for a Pre-Market Approval (PMA) submission.

Dr Marcus Wagstaff acts as our Clinical Director in the CE Mark and PMA trials. His contribution to PolyNovo has been significant and Marcus is a valuable asset to the team.

As we previously announced BARDA have exercised the option to fund a swine study to map the full bio-reabsorbsion of the BTM. This trial is underway and full conclusion of the swine studies is expected in mid-2019.

Commercialisation

US

We announced our establishment of a direct sales team to sell our US FDA 510(k) approved BTM. We planned to introduce Mr Jay Bodet, National Sales Director of PolyNovo North America LLC, to you today. However Jay had a personal matter that precluded attending today.

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Jay and his team have been fully inducted into PolyNovo and have been actively calling on Plastic, Reconstruction, Trauma and General Surgeons in the US. We have many sites doing BTM evaluations and expect this to translate into sales in the coming months.

The appointment of our third party logistics partner will deliver a seamless supply chain to our US customers. They will call a dedicated PolyNovo order centre and receive their product and invoices branded as PolyNovo. We are in the final days of contract negotiations and expect to sign this contract next week. They are a sophisticated healthcare logistics company in the US with many sites across the US.

The sales team are attending various trade shows and conferences in addition to their site call cycle.

ANZ

Corporate:

We have renewed our branding in order to build a strong brand image, culture and value for our ongoing success.

Device Technologies were appointed to distribute our BTM in New Zealand and Australia, they have a strong surgical team representing our product. We are pleased to announce that our first commercial sale of the BTM was achieved on 4 November for use in another necrotising fasciitis case at The Alfred under the TGA prescriber's exemption scheme.

Other markets

We are in advanced discussion with a South African distributor to represent us in that market. We anticipate signing an agreement within weeks.

In Hong Kong we are in discussion with a number of potential partners and hope to have an arrangement in place early in CY'17.

To support this market growth we have commenced a factory expansion project. This will more than double our cleanroom space and allow for a higher production volume with improved quality and waste reduction. We have employed additional product staff including a process engineer to look at continuous improvement and cost reduction.

In June 2016 we added a Business Development Manager to the team. He has been instrumental in developing our commercial partnerships and establishing our agreements. We are now looking at adding a Marketing person to the business to increase our capacity to service the sales teams and develop our key opinion leader resource base. Further sales and marketing roles may be added in the coming year.

Research & Development - New Products

We have been looking at various fabric constructs utilising our unique NovoSorb Polymer platform technology and we have made several fabrics to be utilised in breast sling and hernia applications. Each indication requires different tensile and rebound strengths. We will now seek Key Opinion Leader feedback to refine the design inputs. Once these are finalised we will progress into various test programs before any clinical applications. Our goal is to have these products in clinical evaluations by 2018.

PolyNovo is happy to be a commercial supplier of the NovoSorb sheets to Dr Greenwood's business in his development of Cultured Composite Skin Bioreactor. This could be a future revenue stream if full validation of their product and processes is achieved.

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Regulatory & QA

We will be establishing a US based regulatory function to support our commercial sales and PMA trial program. We are currently recruiting for this role. Our Melbourne based regulatory team will work closely with this person.

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