23 October 2014

US Regulatory Update

- **PolyNovo files its 510(k) for surgical wounds with US Food and Drug Administration ("FDA");**
- **PolyNovo confirms submission of its Biomedical Advanced Research and Development Authority ("BARDA") Contract Application; and**
- **A Pre-Submission meeting with the FDA scheduled for 30 October 2014.**

Calzada (ASX:CZD) is pleased to provide an update on the following activities being undertaken by PolyNovo Biomaterials Pty Ltd.

BTM Wound Dressing - '510(k)' Submission

PolyNovo has filed a 510(k) submission to the US FDA for clearance to market its NovoSorb™ Biodegradable Temporising Matrix ("BTM") as a surgical wound dressing. A successful submission will allow the BTM to be marketed in the US.

The BTM Wound Dressing is indicated for the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.

The BTM Wound Dressing has been used clinically in 24 free flap donor site patients to date, including 14 under the TGA Authorised Prescriber Scheme. Treatment of these patients has generated encouraging results beyond those gained in the Free Flap trial (ASX 26 July 2013) indicating that the BTM is safe, easy for surgeons to use, and provides patients with medical benefits over existing treatment regimes.

PolyNovo expects the FDA to make a determination on the 510(k) submission in the first half of CY2015.

Biomedical Advanced Research and Development Authority (BARDA) Application

PolyNovo confirms lodgment of its BARDA contract application and expects to be advised of the outcome of the proposal by the end of this calendar year.

A successful BARDA contract will provide all funding required to undertake Pre Market Approval clinical trials required to gain FDA approval for the marketing of BTM for 3rd degree burns in the US.

A critical part of the BARDA application is the requirement to hold a Pre-Submission meeting with the FDA to agree on the path forward so further trials are constructed in a manner that ensures compliance for registration. This meeting has been scheduled for 30 October 2014 at the FDA offices. Associate Prof John Greenwood and Calzada Director Dr David McQuillan will be attending the meeting in person.

Advice on the outcome of the Pre-Submission meeting will be provided in due course.

David Williams, the Chairman of Calzada said, "These developments are significant regulatory steps towards the successful commercialisation of BTM for wounds and burns. These events have been underpinned by years of research to develop a product of significant market utility using our NovoSorb™ material."

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