

21 July 2014

PolyNovo Receives CE Mark European Approval for NovoPore™

Calzada Limited (ASX:CZD) is pleased to announce that its subsidiary PolyNovo Biomaterials Pty Ltd (PolyNovo) has received CE (Conformité Européenne) Mark certification for its Topical Negative Pressure (TNP) foam wound dressing NovoPore™.

PolyNovo can now legally market NovoPore™ in the European Union and Canada. PolyNovo can also market in the USA after receiving FDA clearance for NovoPore™ on 6 March 2014. These territories represent the majority of the global market for TNP therapy.

NovoPore™ dressing can be used for the treatment of chronic wounds such as pressure sores. TNP therapy is designed to remove wound exudate and promote granulation to regenerate the dermal tissue by applying vacuum through a dressing placed in the wound cavity, sealed using an adhesive film and connected to a vacuum pump via a tube. The global TNP market is estimated to be around US\$2.53b. Current TNP foam dressings have previously raised concerns from the FDA in respect to complications associated with infection as a result of foam fragments remaining in the wound and bleeding upon removal of the dressing. Importantly, NovoPore™ demonstrated in its clinical trial completed last year (refer ASX trial announcement 17 April 2013) that it had the potential to improve outcomes through a reduction in: dressing fragmentation; risk of infection; trauma on dressing removal; and undesirable dressing retention in the wound.

PolyNovo's commercialisation strategy includes forming an alliance with a global partner, with an established TNP therapy solution, to market and distribute NovoPore™.

PolyNovo has also received ISO 13485 certification for the Company's Quality Management System. This certification is an important step for PolyNovo and demonstrates the Company's ability to manufacture medical devices that meet regulatory requirements applicable for medical devices sold in the European Union, Canada and elsewhere.

The CE Mark approval and ISO 13485 accreditation underpin the ASX announcement made last week that the Board was proposing to significantly increase its commercial, clinical, regulatory, quality and manufacturing staff to make the most of current opportunities and to generate other registrations, new intellectual property, and other opportunities.

David Williams, the Chairman of Calzada said "We have now received the necessary authorisations to market, in the USA, Canada and EU, a medical device based on our NovoSorb™ technology. This is important regulatory validation for our platform technology and an important commercial building block to generate strategic alliances."



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About Calzada Ltd

Calzada has 100% ownership of PolyNovo Biomaterials Pty Ltd and Metabolic Pharmaceuticals Pty Ltd. The Company is listed on the Australian Securities Exchange (ASX Code CZD).

About PolyNovo Biomaterials Pty Ltd

PolyNovo develops medical devices, based on its proprietary polymer technology NovoSorb™, that have clinical applications across numerous medical fields.

About Metabolic Pharmaceuticals Pty Ltd

Metabolic's asset is the AOD9604 peptide which has potential applications in the treatment of obesity, bone, cartilage and muscle diseases and repair.