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4 February 2013

PolyNovo Concludes Recruitment for the NovoSorb™ VAC Clinical Trial

- Final patient recruited in the NovoSorb™ Vacuum Assisted Closure (VAC) Clinical Study,
- Results expected within 75 days,
- Positive results will support PolyNovo's application for Marketing Approval in the United States of America (via a 510(k) Clearance Pathway),
- PolyNovo expects to file for 510(k) clearance in the USA in Q3, 2013.

Calzada Limited (ASX: CZD or "the Company") is pleased to report that the clinical team, supervised by Associate Professor John Greenwood AM, has concluded recruitment of the required patients for PolyNovo's NovoSorb™ Negative Pressure Wound Therapy (NPWT) dressing human clinical trial (VAC trial). Results from the trial are expected within approximately 75 days.

Fifteen patients have completed their eight weeks of treatment, two (2) were withdrawn (one in each group, for issues unrelated to the treatment) and three are currently undertaking their treatment in the trial.

Calzada's 100% subsidiary PolyNovo intends to file a 510(k) application seeking FDA clearance of the NovoSorb™ dressing product in the USA. A 510(k) application is a pre-market submission made to the FDA to demonstrate that a device, to be marketed, is as safe and as effective as an existing predicate device being sold in the US. In 98% of cases[1], devices seeking 510(k) clearance are approved for sale within 150 days after filing a marketing submission. A device that receives a 510(k) clearance can be marketed in the US.

The NovoSorb™ dressing was tested in hard to heal pressure sores (also known as decubitus ulcers or bedsores). Primarily due to the aging population, the incidence of difficult to treat pressure sores is growing. In the United States alone, it is estimated that 2.5 million patients per year are treated for pressure ulcers, with the more advanced and challenging ulcers costing upwards of US$70,000 per patient, and costing the healthcare system around US$11 billion per year[2].

NovoSorb™ NPWT dressings represent an innovative approach in the field of wound care with the potential NPWT market alone being valued at over US$400 million per annum.

Currently Granufoam™ (Kinetic Concepts Inc.) is the market leader in NPWT, with an estimated market share of about 80%. Importantly, PolyNovo's NovoSorb™ has several key advantages over Granufoam™ which potentially offer major productivity improvements for nurses and enhanced clinical outcomes and experiences for patients.

[1] Source FDA website

[2] Colorado Foundation for Medical Care

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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 owns and develops a suite of state of the art biodegradeable polymers that have potential applications across numerous medical fields. PolyNovo has licence agreements and alliances with a number of the world's leading medical device companies and also has joint venture arrangements with local experts in the areas of skin repair.

About Metabolic Pharmaceuticals Pty Ltd

Metabolic's major asset is the AOD9604 peptide which has potential applications in the treatment of obesity, bone, cartilage and muscle diseases and repair. AOD9604 is a small 16 amino acid peptide modelled on one active segment of human growth hormone. It has proven to have an excellent safety and tolerability record from testing in a total of six human clinical trials involving 925 humans. In June 2012 AOD9604 received a self-affirmed GRAS status, conditional only on publication of the peptide's existing safety data. AOD9604 is being sold in the market as one of the key components of Phosphagenics' cosmetic anti-cellulite cream called BodyShaper™. Metabolic receives royalties from Phosphagenics on worldwide sales of this product and a share of any sub-licensing revenue that may be received.