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PolyNovo Market Update

Calzada's subsidiary, PolyNovo Biomaterials Pty Ltd (PolyNovo), continues to develop its proprietary medical grade polymers that can be utilised to manufacture novel medical devices designed to support tissue repair and then degrade in a safe manner. The following provides a summary of the current status of the company in developing and commercialising a number of products.

Topical Negative Pressure (TNP)[1]

TNP is a medical procedure to remove excess fluid from chronic wounds such as pressure sores. It inhibits infection, encourages new tissue to grow, increases the blood supply so nutrients and oxygen are delivered to the wound, keeping it moist and pulling the edges of the wound together. TNP consists of a sealed foam dressing over the wound, a suction pump, and a drainage tube from the dressing to a canister. Our NovoPore™ wound dressing provides the foam dressing component.

As previously announced, PolyNovo received CE Mark certification on 21 July 2014 and FDA 510(k) clearance on 6 March 2014 for NovoPore™. PolyNovo can now market NovoPore™ in the European Union (EU) and the USA. The registration of our foam product in the USA and EU is a significant step in the global regulatory status of PolyNovo material.

PolyNovo is investigating commercialisation opportunities and interest from companies who have established TNP therapy kits, whereby NovoPore™ would replace or supplement their existing foam components. It is unlikely that any deals will be finalised in this calendar year.

BTM for surgical wounds

Biodegradable Temporising Matrix (BTM) uses our NovoSorb™ technology to stabilise surgical and other wounds and promote new underlying skin formation as a precursor to a skin graft. Preliminary trials have indicated that BTM is safe and has strong medical benefits over existing treatment regimes.

On 4 February 2014, we advised that three Australian surgeons had received TGA Approval to use BTM in free flap donor sites (surgical wounds). The company had been advised that under this authorisation, eleven patients have had wounds treated with BTM and the preliminary results continue to confirm the positive outcomes from the clinical trial reported on 10 October 2013.

The company has announced it will seek registration of BTM with the USA FDA, that if successful, would allow the product to be marketed in the USA for surgical wound applications (including 2nd degree burns). A 510(k) submission is expected to be lodged with the FDA during the coming weeks.

The company has commenced assessing potential commercialisation options.

[1] In the USA TNP is referred to as Negative Pressure Wound Therapy or "NPWT".

BTM for treatment of 3rd degree burns

One of the strong potential uses of BTM is in the treatment of 3rd degree burns. However the pathway to registration is expected to require extensive clinical trials.

Adelaide Burn Trial

PolyNovo announced on 23 December 2013 that a trial of BTM in significantly injured burn patients had commenced recruitment. The trial is being conducted by Principal Investigator, Professor John Greenwood AM, at the Royal Adelaide Hospital. The performance of the BTM and data collected from this trial will be used to assist in the protocol design for larger clinical burn trials (see below).

As reported on 5 June 2014 a middle-aged patient that sustained flame burns to approximately 75% of his total body surface area (TBSA), with full thickness (3rd degree) burns affecting 45% TBSA became the first patient recruited in the trial. To date the performance of the BTM has progressed satisfactorily. No further patients have been recruited.

Planning for Future Clinical Trials

PolyNovo is planning clinical trials to initially satisfy EU, USA and Australian regulatory requirements for the BTM in 3rd degree burn applications. PolyNovo is working with an EU based Contract Research Organisation (CRO) to define the clinical trial requirements for regulatory submissions in Europe and Australia.

PolyNovo is assessing the funding required to undertake these trials. We are pleased to advise that PolyNovo has received a grant from the Victorian Department of State Development to prepare a feasibility study to conduct a trial in collaboration with the highly regarded Burns Unit at the Alfred hospital, Melbourne. A possible outcome of the feasibility study is that funding may be available from the Victorian Government for a clinical trial in 2015.

PolyNovo has applied to the Biomedical Advanced Research and Development Authority (BARDA) to fund a major burns trial in the USA that would assist in FDA approval. BARDA is a USA Government agency that provides medical countermeasures that address the public health and medical consequences of matters such as chemical, biological, radiological, and nuclear incidents. Following initial discussions, a revised proposal is currently being compiled by PolyNovo with its regulatory and clinical advisers to be lodged later this month. We will keep the market informed as to the outcome of this proposal, but this may be several months away.

Facial Aesthetics

On 9 July 2013 PolyNovo announced it had entered into an agreement with NovoPlastiq, LLC, a company formed by USA specialists to commercialise and distribute medical devices in the field of facial implant and aesthetic surgery. Under the terms of the agreement NovoPlastiq was responsible for raising the necessary working capital, gaining regulatory approvals, marketing and distribution of the finished devices. NovoPlastiq has so far been unsuccessful in raising the necessary working capital for the project to proceed to the next stage. The company is investigating the future of this relationship.

Hernia Repair

PolyNovo announced on 24 February 2014 it had completed a Feasibility Agreement with a specialist USA device company to evaluate the use of NovoSorb™ polymers in products for potential use in hernia repair.

The hernia market is broadly split between synthetic meshes for simple hernia repair and biologic meshes for the more complex repairs and each have their specific shortcomings and limitations. The company believes NovoSorb™'s biodegradability, biocompatibility, adjustable biophysical properties, and safety profile can provide advantages over existing devices.

PolyNovo continues negotiations with the USA device company to enter into a Licence and Supply Agreement which involves milestone payments and a share of royalties.

Other

There are a number of areas where PolyNovo's products are being tested and reviewed by third parties for a range of applications. These trials are conducted under confidentiality arrangements. Shareholders will be advised if and when trials by third parties result in commercial arrangements.

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