Overview

Chronic or non-healing wounds are wounds that have not made significant improvements after several weeks or fail to respond to medical or surgical management. They are wounds that do not undergo the normal healing process that includes inflammation, proliferation and matrix deposition and remodeling.¹ They can be caused by diabetes, poor circulation, burns, pressure and other conditions, and are characterized by redness, warmth and pain, increased drainage or drainage with an odor, tenderness and swelling.² Therefore, they can be found in patients with issues and conditions that inhibit tissue repair, including diabetic wounds, vascular insufficiency ulcers, compromised amputation sites, radiation necrosis and gas gangrene.³

In the United States, approximately five to seven million people are affected. People with diabetes are especially at risk to develop chronic wounds, usually in the form of foot ulcers. The incidence of chronic wounds is highest among the eight percent of the total United States population that have diabetes, with approximately 15-25 percent of diabetic patients eventually developing them.⁴ Because the number of diabetic patients is expected to swell to 425 million people worldwide by 2030, the number of patients afflicted with chronic, non-healing wounds is also expected to increase in the coming decades.⁵

Non-Healing Wounds

Non-Healing Wounds and Regenerative Medicine

Although traditional wound care often aids the healing process of chronic, non-healing wounds, as many as one-third of these wounds fail to heal.⁵ Regenerative medicine technologies thus have great potential to bridge the success rate gap for treatment of these ailments. The field of regenerative medicine has been focusing next generation technologies to help heal cutaneous wounds. One successful approach is the creation and use of three-dimensional scaffolds as extracellular matrix analogs that mimic the natural extracellular matrices. These scaffolds, when seeded with a range of molecules, including fibroblasts (the cells that synthesize the extracellular matrix and collagen), help foster cell adhesion, growth and differentiation to form skin functional and structural tissue. Stem cells, growth factors, chemokines, cytokines and other molecules are also being explored as regenerative medicine products to renew endogenous healing processes in chronic, non-healing wounds.

Organogenesis has commercialized a living cell-based product. Apligraf is a bi-layered cell based technology, composed of a layer of differentiated keratinocytes and a layer of fibroblasts seeded in a collagen matrix, which has been proven to close wounds faster and to reduce amputations. In 2012, the company announced that it had shipped over 500,000 units of Apligraf, making it the most widely used regenerative medicine product in the world to date. In April 2012, the product also established improved coverage from multiple healthcare contractors and payers.

Shire Regenerative Medicine’s lead product, Dermagraft, utilizes human fibroblast cells derived from newborn foreskin tissue seeded into a bioreabsorbable scaffold. The product is on
the market in the United States, and expected to be available in Canada in the first quarter of 2013. Another Shire Regenerative Medicine product, ABH001 (derived from neonatal dermal fibroblasts), recently initiated a Phase 3 study for patients with non-healing wounds stemming from epidermolysis bullosa (EB), a family of genetic skin fragility disorders.

Cytomedix’s product for non-healing diabetic, pressure and/or venous wounds, the AutoloGel System, utilizes autologous platelet rich plasma (PRP) to produce a gel for wound application. The PRP gel contains growth factors, cytokines and chemokines that help reestablish the body’s endogenous healing processes. In February 2013, Cytomedix announced that physicians can use AutoloGel to treat Medicare beneficiaries with chronic wounds and receive reimbursement for the product under the Coverage with Evidence Development (CED) program.

Avita Medical’s product, ReCell Spray-On Skin, is an autologous cell technology that when sprayed onto a skin wound accelerates healing, minimizes scar formation, eliminates tissue rejection and reintroduces pigmentation to the skin. The product is on the market in Europe, Canada, and Australia, and is under clinical investigation in the United States.

Cytori Therapeutics’ technology employs adult stem cells, endothelial progenitor cells, leucocytes, endothelial cells and vascular smooth muscle cells found in adipose tissue taken from the patient’s own body fat (known as adipose-derived stem and regenerative cells or ADRCs). In March 2012, the company published the favorable results of its RESTORE-2 trial, which used ADRCs in partial mastectomy patients. Cytori was recently awarded a contract valued up to $106 million by the Biomedical Advanced Research and Development Authority for preclinical and clinical development of the company’s cell therapy for the treatment of thermal burns.

Healthpoint Biotherapeutics, which was recently acquired by Smith & Nephew, is a company using acellular matrix scaffolds to treat diabetic foot ulcers. Their Oasis Wound Matrix is a matrix derived from porcine small intestinal submucosa (SIS). The SIS technology is proven to help the body repair and replace damaged tissue. The Oasis Ultra Tri-Layer Matrix is made from the same structural SIS/ECM components as the Oasis Wound Matrix, but Oasis Ultra has three layers of the SIS structure to target more problematic wounds.

### Non Healing Wounds: Economic Impact

**$35 Billion**

The estimated cost of healthcare for individuals suffering from chronic, non-healing wounds.¹

**$200 Billion by 2020**

Projected additional cost for treatment of diabetic foot ulcers.²

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