

## Poraderm: A Fully Degradable Synthetic Cutaneous Wound Treatment

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**Technology:** We are PEURegen Inc. and we are developing **Poraderm**, an implantable, degradable, synthetic skin substitute designed for application in full thickness wounds such as diabetic foot ulcers (DFUs) or pressure ulcers (PUs). As an implantable scaffold, Poraderm presents a compelling opportunity for wound repair and restoration to healthy skin functionality. Poraderm is a prefabricated skin substitute, made of a porous polymer (polyurethane), which can be designed to have structural properties similar to those of native skin. Polyurethane (PUR) is a synthetic polymer that has been utilized in medical devices and resorbable scaffolds for tissue regeneration<sup>1-4</sup>, and has a history of U.S. Food and Drug Administration (FDA) clearance for a variety of indications. Poraderm can be manufactured as a three-dimensional foam and customized post-hoc. The customizable size of the material will allow clinicians to completely fill the entire defect in one easy application. The porous structure of Poraderm provides a scaffold for skin regenerating cells to infiltrate, remodel, and replace with healthy skin. Additionally, the fully degradable synthetic chemistry naturally dissolves into non-toxic small molecules that are easily cleared from the body. This has been proven in preclinical porcine excisional wound studies, shown in Figure 1, where Poraderm provides advanced wound healing compared to controls. Poraderm's synthetic nature makes it an attractive material in that it has no potential of transmitting infectious diseases, does not induce a prolonged immune response, and subsides regulatory constraints that accompany biologics-based therapies. Current treatment options have disadvantages that affect the clinicians applying the grafts, the patients, and the insurance providers. The key technical/economic hurdles that have limited the uptake and effectiveness of current wound care products are the ability to 1) be easily handled by clinicians, 2) fill full-thickness voids with material that has structural rigidity that will 3) stay in place and 4) be incorporated into the healing process, while being offered at a 5) reasonable price. Poraderm is currently being developed to address these issues.

**Market:** Full-thickness, deep, cutaneous wounds include both acute surgical or trauma-related wounds as well as chronic wounds such as DFUs or PUs (also known as bed sores). If left untreated, chronic wounds can lead to infection, amputation and increased chance of mortality. Most chronic wounds are ulcers that are associated with ischemia, diabetes mellitus, venous stasis disease, or pressure. Non-healing wounds affect about 6.5 million people in the United States alone, with persons 65 years and older accounting for 85% of these events<sup>5</sup>. Chronic wounds result in enormous health care expenditures with the total cost estimated at more than \$30B per year<sup>5</sup>. The cost of healing a single DFU with currently available treatments is \$8K-\$17K, while the cost of healing a PU can be even higher, exceeding \$100K when additional

hospital stays are considered<sup>5</sup>. If treatment fails, amputation may be required, with costs of up to \$38K before considering the significant loss of productivity and quality of life<sup>6</sup>. Successful development and commercialization of a low-cost, high-performance treatment for full-thickness cutaneous wounds would reduce the cost of wound treatment, aid in the healing of initial full-thickness wounds, prevent the need for amputation, and thus improve quality of life for patients.



**Figure 1.** Poraderm prototype scaffolds result in less wound contraction and a more controlled healing compared to empty defects. Wounds are illustrated at d0 (upper panels) and d15 (lower panels). Untreated wounds (left panels) undergo extensive distortion compared to either Poraderm prototypes (center) or (right).

**Commercialization Strategy:** PEURegen Inc., a small business started by experienced researchers from Vanderbilt University, will develop the proprietary product Poraderm initially for the full thickness chronic wound market, specifically DFUs. Our projected path to commercialization first focuses on obtaining preclinical animal model data directly comparing Poraderm to clinical relevant predicates. This preclinical data will allow us to optimize the Poraderm formulation and obtain data to strengthen government regulatory approval applications for the DFU indication. We anticipate seeking government approval both in United States, through the FDA 510(k) regulatory pathway. Pivotal preclinical studies and ISO 10993 testing are ongoing in preparation for a 510(k) regulatory filing. In order to market and sell Poraderm, we will pursue a contract partnership with a medical device distribution company that has an established sales force in the U.S. (and/or international market) in the relevant medical fields for diabetic patients, mainly endocrinology, dermatology, and general surgery. Although the distribution company will lead these efforts, we anticipate focusing initial marketing efforts on building product awareness with thought leaders in these medical fields through direct communication, advertising at scientific conferences, printed advertisements in clinical journals, and scientific publications in peer-reviewed clinical journals.

**References:** <sup>1</sup>Adolph EJ, et al. (2012). *JBMR:A* 100A(2):450-461. <sup>2</sup>Hafeman AE, et al. (2008). *Pharm. Res.* 25(10):2387-2399. <sup>3</sup>Gorna K, et al. (2006). *JBMR:A* 79A(1):128-138. <sup>4</sup>Guelcher SA, et al. (2008). *Tissue Eng:B* 14(1):3-17. <sup>5</sup>Sen CK, et al. (2009). *Wound Repair Regen.* 17(6):763-771. <sup>6</sup>Shearer A, et al. (2003). *Diabetes Care* 26(8):2305-2310.