**Overview**

Stratatech is a regenerative medicine company focused on the commercialization of novel skin substitute products for therapeutic and research use. The company was founded in 2000 to commercialize an extraordinary discovery made at the University of Wisconsin-Madison. The discovery of NIKS® cells – a human keratinocyte cell line that produces living tissue nearly identical to native human skin – has the potential to revolutionize wound care.

Keratinocytes are the cells that make up approximately 90 percent of the epidermis, the outer layer of human skin. NIKS keratinocytes are a consistent source of pathogen-free, non-tumor-producing, long-lived adult progenitor cells. These cells faithfully reproduce normal skin tissue architecture and barrier function when cultured appropriately.

Technically and strategically, this discovery has profound implications. Traditional allogeneic skin substitutes utilize donated primary keratinocytes that must be periodically replenished and requalified at significant cost. Moreover, this may impact product consistency, performance and safety.

The NIKS progenitor cell line avoids these issues, providing a consistent, well-characterized technology platform. Importantly, having a clonal cell source enables Stratatech to create genetically enhanced, wound healing products that heretofore have been impossible.

**StrataGraft®**

The company’s flagship product, StrataGraft tissue, is a viable, full-thickness skin substitute being developed as a treatment for severe burns and other complex skin defects. It was designed to mimic natural human skin, with both dermal and fully differentiated epidermal layers. Unlike first generation skin substitutes, this resorbable tissue is easily sutured and remains intact in the wound bed, providing critical barrier functionality during the natural wound healing process.

A Phase I/IIa clinical trial of StrataGraft tissue has been successfully completed, providing important safety and immunological insights. A proof-of-concept trial focused on wound healing endpoints is anticipated to start in the second half of 2011.

There is an urgent need for new treatment options for burns. Currently, patients with severe 2nd and 3rd degree burns must endure painful skin transplants called autografts, and frequently are treated with cadaver skin as a temporary wound covering prior to autograft procedures. StrataGraft tissue has the potential to provide a safer, less painful and more effective alternative in a single surgical procedure.
ExpressGraft™
The company is developing a suite of next-generation, genetically enhanced tissues that produce elevated levels of natural wound healing and anti-microbial factors. Delivered this way, these therapeutic proteins are available where and as needed, at no incremental cost. This strategy creates a targeted, biological mechanism through which to protect and modulate the local wound microenvironment, fight infection, and accelerate healing.

The lead product in this class, ExpressGraftAM tissue, expresses elevated levels of cathelicidin, an innate host defense peptide known to play an active role in wound healing and having broad anti-microbial properties. In research models, these tissues produced 140-fold greater levels of cathelicidin protein in vitro versus unmodified control tissues, and in vivo showed a 100-1,000 fold reduction of a clinical isolate of the multidrug-resistant nosocomial strain, Acinetobacter baumannii. Data published in Molecular Therapy elicited independent commentary by German surgeons hail this capability as a “paradigm shift in the management of skin pathologies”.

The second product in this class, ExpressGraftPRO tissue, expresses VEGF, a pro-angiogenic growth factor that plays a central role in controlling angiogenesis and enhancing blood supply. Because many chronic wounds are associated with insufficient tissue oxygenation, boosting local levels of VEGF may favorably enhance the frequency and rate of wound healing. Results to date are promising, supporting further preclinical development. A number of additional ExpressGraft products have also achieved discovery proof-of-concept, demonstrating the versatility and potency of this platform.

Clinical development for ExpressGraft products will focus on large, underserved markets in chronic, non-healing ulcers, including diabetic foot ulcers, venous leg ulcers and sclerotic digital ulcers. It is anticipated that ExpressGraftAM will enter a Phase I clinical study in diabetic foot ulcers in the second half of 2012, contingent on funding. The NIH Recombinant DNA Advisory Committee has already endorsed its clinical progression.