

SBIR PHASE-I FINAL SUMMARY REPORT

Developing An Ideal Wound Care Platform To Prevent Sepsis In Trauma Wounds During Care Under Fire

The Challenge: Sepsis is the greatest danger after hemorrhage in both civilian and combat-related injuries with mortality rates ranging between 19.5 - 23%. Early intervention with appropriate antibiotics, hemodynamic optimization, and supportive care are particularly vital in preventing trauma related sepsis. Treatments to prevent trauma sepsis may be confounded by the uncontrolled bleeding which often attends severe traumatic injuries and is responsible for 40% of trauma deaths, the majority of which occur in the prehospital period. Both sepsis and hemorrhage can trigger deadly inflammatory responses causing fatal injury to tissues and organs. Rapid interventions which control bleeding while reducing contamination to diminish the high mortality and morbidity rates associated with sepsis in traumatic injuries are a critical need. Remote austere environments at point of injury often delay delivering essential medical care. In military trauma wounds, this may be further exacerbated by the hostile environment.

Project Objective and Solution Description: The primary purpose of the work performed in this SBIR Phase I Research project was to test and advance a wound and drug delivery system under conditions that simulated the material's ability to (1) transform and form a dressing that will act as a primary material to provide benefits of moist wound healing, (2) contain a clotting agent and demonstrate that the dressing combined with clotting agents performs the same or better than current standard of care, and (3) provide controlled antimicrobial release profiles over periods of up to 72 hours. A sustained release of antimicrobials will provide protection in the deep tissue planes of the wound and skin surface for at least 72 hours under care-under fire conditions when delivered using this wound dressing.

Our project tested the in vitro performance of several such prototypes which allow dynamic release of active agents to prevent hemorrhage and sepsis with extended wear time to improve current standard of care during care under fire and prolonged field care. The base materials are light, easy to use, transportable and shelf-stable.

Scope of Work: During the 6-month project period, over 60 different prototypes of wound dressings were manufactured by combining the base materials with a number of antimicrobial and clotting agents at varying dosages. Each sample was tested for its physical properties and ability to maintain a moist environment. Antimicrobial effectiveness of the antimicrobial combinations was tested in-vitro with gram positive and gram negative bacteria. The viability of a controlled release of embedded drugs over an extended time period was also tested. The clotting capability in the case of the hemostatic combinations was tested in an in-vitro test and compared to current standard of care.

Project Results: Our research indicated that a dressing solution with various active therapeutic agents can be successfully formulated to provide a moist wound healing solution that can deliver highly effective clotting or antimicrobial agents beyond a 72-hour period.

Technical Transition Strategy: The proposed formulations will be produced and marketed using our Company's existing marketing and distribution networks. The base prototype is already manufactured

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using a network of FDA-registered and GMP-compliant facilities and successfully sold in prominent government (including military) and commercial hospital systems in the United States and internationally by our sales personnel and distribution partners. While the products described in this proposal are innovative, they do not pose manufacturing complexities that exceed the expertise of our existing manufacturing resources. The raw materials are widely available, and the cost of materials and manufacturing processes are commercially viable.

Anticipated Benefits: The availability of a portable, simple yet comprehensive wound management system to prevent sepsis in contaminated and open combat or civilian trauma injuries is a global need. With over 5.8 million deaths related to trauma injuries, such a solution will have significant impact in several market segments including military, public and private emergency medical services and all commercial and consumer first aid kits. Our research presents a novel dressing solution capable of delivering actives for extended periods of time. The proposed solution provides cost-effective, shelf-stable, easy to apply, high performing, extended wear, first-use agents to help prevent hemorrhage and infection that may otherwise lead to excessive loss of blood and ultimately to septic shock and potential death, thereby saving lives and helping trauma victims globally.

Photo Attachment: Base powder formulation aggregates into a moist dressing material upon hydration.

