

NIH Awards N8 Medical Two Additional SBIR Grants to Develop CeraShield™ Coated Hemodialysis Catheters and Pedicle Screws

[Park City, Utah, December 6, 2022] – N8 Medical, Inc. (the “Company”) announced today that the NIH has awarded two Phase 1 SBIR grants for the development of CeraShield™ coated hemodialysis catheters and pedicle screws in the amounts of \$299,155 and \$258,455 respectively. The NHLBI had previously awarded a \$1.95 million Phase II SBIR grant to further development of a CeraShield pacemaker envelope for reducing surgical site infections associated with pacemaker implantations.

The team at N8 Medical will be working with researchers at UNC and USC and with Dr. Paul B. Savage at Brigham Young University to develop the hemodialysis catheter and pedicle screw, respectively. Drs. Roy-Chaudhuran (UNC) and Jeffrey Wang (USC) will provide consultation on hemodialysis and pedicle screw projects, respectively. The grant application was reviewed and approved by a panel of the nation’s leading experts in this field.

The Company’s proprietary CeraShield coating technology is a platform technology applicable for many different medical devices designed to prevent dangerous biofilm bacterial growth on their surfaces.

The constantly increasing number of hemodialysis patients (2% increase every year in the United States) creates a subsequent increasing burden of catheter-related infections, with direct and indirect hospitalization costs ranging between \$17,000-\$32,000 per episode and a mortality rate at 30 days of 18%. There is an urgent need for an effective way to prevent and treat these catheter-related infections. We believe that our CeraShield technology can effectively meet this challenge.

Surgical Site Infection (SSI) is one of the major complications of implant surgery, especially in spinal surgery, where SSI leads to unfavorable health and functional outcomes. Antimicrobial coatings have been explored as a way to prevent microbial colonization on the surface of pedicle screws. However, current strategies to generate antimicrobial coatings do not show broad-spectrum antimicrobial activity; in fact, they can engender bacterial and fungal resistance. N8 Medical proposes a pedicle screw with a novel anti-infective coating based on ceragenins (CSAs), which mimic antimicrobial peptides (AMPs) thereby possessing the ability to eradicate both bacterial and fungal populations (including resistant strains) and prevent the formation of biofilms without engendering resistance. The market for pedicle screws is approximately \$2 billion annually.

N8 Medical is a clinical-stage medical device company focused upon commercializing antimicrobial medical devices and coatings to address the multi-billion dollar public health market and with it, the economic burden associated with medical device-related hospital acquired infections (“HAIs”). N8 Medical’s business is based on the application of a novel, proprietary class of compounds known as ceragenins (or “CSAs”) to existing medical devices for the purpose of transforming them into high value devices which exhibit unique antimicrobial, anti-inflammatory, and other therapeutic properties meant to improve patient outcomes and lower the overall cost of care. The Company’s first commercially available product ex US is its CeraShield ETT (Endotracheal Tube), designed to prevent potentially lethal infections in critically ill patients who require mechanical ventilation. Other infection prevention applications in development include wound closure devices, vascular access products, and women’s health products. For more information, visit www.n8medical.com.

###