N8 Medical Is Awarded Almost $2 Million in Phase II SBIR Grant

Grant Funding will Support Further Development of Antimicrobial Pacemaker Envelope

PARK CITY, UTAH, UNITED STATES, June 22, 2022 /EINPresswire.com/ -- N8 Medical Is Awarded Almost $2 Million in Phase II SBIR Grant

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>
> *Robert D. Mitchell*

N8 Medical, Inc. (the "Company") announced today that the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) has awarded a SBIR Phase II grant to the Company in the amount of $1,995,642 to advance the development of a resorbable envelope to prevent infections associated with pacemaker implantation surgeries.

The team at N8 Medical will be working with researchers at DaVinci Biomedical Research Products, Inc. and with Dr. Paul B. Savage at Brigham Young University to develop the resorbable envelope. Dr..Georg M. Wieselthaler of UCSF and Mr. Michael John of MCRA, a leading medical device consulting firm, will be consulting on the project. Dr. Wieselthaler is a heart transplant surgeon and one of the world´s leading experts in mechanical circulatory support for end stage heart failure patients. He is a Professor of Surgery at UCSF and Director & Surgical Chief of Cardiac Transplantation and Mechanical Circulatory Support. Mr. John is MCRA's Vice President of Cardiovascular Regulatory Affairs and previously served as Chief of the Interventional Cardiology Devices Branch in the Division of Cardiovascular Devices at the US Food and Drug Administration. The grant application was reviewed and approved by a NIH panel of 25 of the nation's leading experts in this field.

The Company's proprietary CeraShieldTM coating technology is a platform technology applicable for many different medical devices to prevent dangerous biofilm bacterial growth on their surfaces. N8 Medical's first-to-market medical device is its CeraShieldTM Endotracheal Tube (ETT), which is designed to prevent potentially lethal infections in critically ill patients requiring mechanical ventilation. The Company's CeraShieldTM ETT was the recipient of Frost & Sullivan's 2019 Product Innovation of the Year award, and the FDA has designated the CeraShieldTM ETT as a "breakthrough device." The device has received regulatory approvals in Canada and Brazil, with approvals in other countries anticipated in the near future.

Surgical site infections are a serious complication of cardiac device implantation and are associated with significant morbidity. There are approximately 500,000 cardiac device surgical implants performed each year in the United States, and the number is expected to grow with the country's aging population. The potential worldwide market for the device exceeds $500 million annually.

With the emergence of deadly fungal pathogens such as Candida auris, there is a clinical need for devices that provide protection against both bacterial and fungal pathogens. The Company believes that its CeraShield™ pacemaker envelope, unlike others, has the potential to not only inhibit potentially deadly bacteria but the fungal pathogen Candida spp.as well. , to provide the broadestspectrum antimicrobial activity, and provide extended envelope activity duration at lower costs. The only FDA cleared antimicrobial pacemaker envelope in the market today is Medtronic's TyRx envelope which Medtronic acquired from TyRx Pharma for $165 milllion upfront in 2016.

Robert D. Mitchell, Chief Executive Officer of N8 Medical, stated, "We are pleased that the National Heart Lung and Blood Institute has recognized the need for more effective clinical solutions, and are we grateful for their assistance to further the development of our CeraShield™ technology in this promising and critically needed medical device application."

ABOUT N8 Medical
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 to address 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 ("ceragenins" or "CSAs") to existing medical devices for the purpose of transforming them into high value devices with unique antimicrobial, anti-inflammatory and other therapeutic properties that improve patient outcomes and lower the overall cost of care. The Company's first commercially-available product is its CeraShieldTM 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.
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