Department of the Navy SBIR/STTR Transition Program

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MCSC-PRR-4045

Topic # N171-002

Phase II: Intranasal Cooling for Encephalopathy Prevention in Combat Casualties (ICEPICC)

Vivonics, Inc.

WHO

SYSCOM: MARCOR

Sponsoring Program: Portfolio Manager Logistics Combat Element Systems (PfM LCMS) - PM Supply and Maintenance Systems (PM SMS)

Transition Target: Medical - Force Health Protection Program (FHPP) FNC

TPOC:
sbir.admin@usmc.mil

Photo courtesy Vivonics, Inc.

Other transition opportunities: The key Department of the Navy customers include Battalion Aid Station (BAS), Shock Trauma Platoon (STP), Forward Resuscitative Surgical Suite (FRSS) and En Route Care System (ERCS) Authorized Medical Allowance Lists (AMALs).

Notes: Conceptual rendering of the Intranasal Cooler for Encephalopathy Prevention in Combat Casualties (ICEPICC) system that delivers tympanic membrane feedback brain cooling through the nasal cavity. Photo courtesy Vivonics, Inc.

WHAT

Operational Need and Improvement: Brain cooling can prevent encephalopathy during events like traumatic brain injury, stroke, cardiac arrest, and respiratory failure, where blood oxygen availability is low, swelling is prevalent, and intracranial pressure is high. Cooling of the vessels within the nasal cavity as well as the barrier between the nasal cavity and the brain is a minimally invasive technique used to reduce brain temperature back to normal (normothermia) or even below normal body temperature (therapeutic hypothermia) without requiring cranial access.

Specifications Required: Vivonics, Inc. has been developing a portable system to provide a level of cooled airflow (<10C @ 25 liters per minute) shown conducive to lowering pig brains to both normo- and therapeutic hypothermic temperatures for over 4 hours from Role 1 through En Route Care.

Technology Developed: The patent protected Intranasal Cooler for Encephalopathy Prevention in Combat Casualties (ICEPICC) is a portable device which will enable intranasal cooling to be performed by a combat medic or paramedic, by affixing a nasal cannula and temperature probe to the patient and setting the desired brain temperature on a simple user interface.

Warfighter Value: According to a Defense and Veterans Brain Injury Center (DVBIC) analysis of surveillance data released by the Department of Defense (DoD), 375,519 U.S. military personnel were diagnosed with a TBI between 2000 and 2017, with a peak of 33,149 in 2011 alone. There is currently no robust fieldable technology that can achieve the Dept. of the Navy's goals of an intracranial temperature range of 33 - 35°C to within ±1°C in military field conditions and therefore the Dept. of the Navy currently does not attempt to cool the brain after TBI, despite the significant potential in lessening the degree and impact of TBI. The thermoelectric cooler (TEC) based system does not require a pressurized air source, specialized reactant, or circulating liquid, it can be powered by military battery and/or via an outlet, it will run off the chosen batteries for a minimum (without control strategy) of 13 hours, and is designed for Role 1 through definitve care, including En Route care.

WHEN

Contract Number: M67854-19-C-6502 **Ending on:** August 31, 2022

Milestone	Risk Level	Measure of Success	Ending TRL	Date
Safety and Effectiveness Animal Study Complete	N/A	Proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.	TRL 4	3rd QTR FY21
FDA IDE Submission	Med	Investigational Device Exemption (IDE) review by Search Results Web results Center for Devices and Radiological Health (CDRH) results in determination that the investigation may begin.	TRL 5	1st QTR FY22
Human Subject Pilot Study: In-hospital	Med	Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and supports proceeding to clinical safety and effectiveness trials.	TRL 6	1st QTR FY23
Human Subject Pilot Study: Pre-hospital	High	Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and supports proceeding to clinical safety and effectiveness trials.	TRL 6	3rd QTR FY23
Human Subject Pivotal Trial: Pre-hospital	High	Clinical endpoints and test plans agreed to by CDRH.	TRL 7	1st QTR FY26
FDA De Novo	Med	The medical device may be distributed/marketed.	TRL 9	3rd QTR

HOW

Projected Business Model: Vivonics seeks to minimize time to market for ICEPICC and additional capital will be the linchpin behind achieving such a goal. Licensing or partnering with an established medical device company for manufacture and delivery of ICEPICC is under consideration and multiple parties have expressed interest as a landing spot once certain inflection points are achieved. Alternatively, capital raise through distribution to the US Military could take place through our CranioSense, LLC subsidiary, which was established to commercialize our non-invasive intracranial pressure (ICP) monitoring system called IPASS. Commonality of the target users and patient population for ICEPICC and IPASS makes it logical to establish joint marketing and distribution. A direct salesforce will focus on sales to relevant medical providers, including EMS, ERs, and NeuroICU, among others.

Company Objectives: Vivonics is highly confident in the system it is developing and the civilian and military market need. We believe that the USMC will be a core customer but seek additional partners within the DoD. Ultimately, we are seek further financial support to bridge the road to private money, FDA clearance, civilian launch, and transition to the military.

Potential Commercial Applications: According to the CDC, in 2010, about 2.5 million emergency department (ED) visits, hospitalizations, or deaths were associated with TBI—either alone or in combination with other injuries—in the United States. The ICEPICC has the potential for both prophylactic cooling and therapeutic cooling to improve outcomes for these patients as well as patient experiencing other ischemic events, such as those experiencing a stroke or cardiac arrest.

Contact: Ryan Myers, Lead Engineer and Director of Technology and Business Development
rmyers@vivonics.com (781) 373-1930 x270