Department of the Navy SBIR/STTR Transition Program

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MCSC-PRR-3577

Topic # N171-002
Phase II: Intranasal Cooling for Encephalopathy Prevention in Combat Casualties (ICEPICC)
Vivonics, Inc.

WHO

SYSCOM: MARCOR
Sponsoring Program:
Transition Target:
TPOC:
sbir.admin@usmc.mil

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).

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.

Notes: The device could be stocked in FRSS facilities, in ambulances and medical evacuation (medevac) helicopters, and at Role 3-4 hospitals. To address DOD needs beyond the USMC, we will work with US Army Medical Materiel Agency (USAMMA) Advanced Development to introduce ICEPICC as part of the standard Army Medical Equipment Sets (MES) employed by medical personnel at each appropriate care Role from point of injury through to hospital settings.

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 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. The thermoelectric cooler (TEC) based system was selected as the approach that thoroughly meets the needs of the Marine Corps because it does not require a pressurized air source, specialized reactant, or circulating liquid, it can be powered by battery and/or via an outlet, it will run off the chosen batteries for a minimum (without control strategy) of 13 hours, and it fits in a (12.8 x 7.8 x 6 in.) box that is less than 20 lbs.

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. This number includes military personnel from the Army, Navy, Marine Corps, Air Force, and from the active duty and reserve components of the National Guard. To lessen the impact of TBI, the Navy would like to deploy brain cooling technology that could be applied at or close to the point of injury. However, 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 throughout an ambient operating temperature range of -32 to 52°C 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. ICEPICC will address this unmet need.

WHEN

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

Milestone	Risk Level	Measure of Success	Ending TRL	Date
Safety Animal Study Complete	Low	Proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.	TRL 4	4th QTR FY20
Dose Animal Study Complete	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	4th QTR FY21
FDA Pre-submission Meeting	Low	IDE review by CDRH results in determination that the investigation may begin.	TRL 5	1st QTR FY22
Human Subject Pilot Study	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 FY22
Human Subject Pivotal Trial	High	Clinical endpoints and test plans agreed to by CDRH.	TRL 7	1st QTR FY24

HOW

Projected Business Model: Licensing or partnering with an established medical device company for manufacture and delivery of ICEPICC is under consideration. Steve Weisner, Director of the Nihon Kohden's Innovation Center and Martin Waleij of BrainCool have both expersed interest in partnering. Mr. Waleij has said that the military market was not in their business plan but that BrainCool was interested in the potential market, potentially partnering with Vivonics to supply the military with novel devices like ICEPICC. Another possibility for distribution to the US Military is to supply the product 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.

Company Objectives: While Vivonics is highly confident in the system it is developing and the commercial need, we do not understand the transitioning process well in terms of identifying, communicating with, and selling product to a military customer. Ultimately, we believe that the Navy will be a core customer, but seek assistance in understanding this process.

Potential Commercial Applications: Tens of thousands of patients die each year in the US due to neurological complications after cardiac arrest alone and targeted brain temperature management has been shown to improve survival and neurological recovery after cardiac arrest. Other indications for use include traumatic brain injury (TBI). The equivalent of an icepack for the brain, the ICEPICC is expected to improve outcomes in many cases of brain injury. 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. TBI contributed to the deaths of more than 50,000 people and was a diagnosis in more than 280,000 hospitalizations and 2.2 million ED visits. These consisted of TBI alone or TBI in combination with other injuries. The ICEPICC has the potential for both prophylactic cooling and therapeutic cooling to improve outcomes for these patients.

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