Department of the Navy SBIR/STTR Transition Program

STATEMENT A. Approved for public release; distribution is unlimited. ONR Approval # 43-2203-16

Topic # N14A-T019 Miniature Integrated Circuits Reporting Overall Status (MICROS) Vivonics, Inc.

WHO

SYSCOM: ONR

Sponsoring Program: Code 30

Transition Target: Marine Corps (MARCOR) Program Manager for Training Systems (PM TRASYS)

TPOC:

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Other transition opportunities: Army Program Executive Office for Simulation, Training, & Instrumentation (PEO STRI); also adaptable for operational troop monitoring by MARCOR and Army PEO Soldier

Notes: MICROS provides a wearable sensor for electophysiology signal acquisition in an adhesive patch format



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WHAT

Operational Need and Improvement: Continuous physiological monitoring can provide invaluable insight into the status of the person monitored. The right sensors can provide important information related to both the physical and mental state of the subject. The DOD requires an integrated system for biosignal data fusion with sufficient precision, analytical capabilities, scalability, and energy efficiency to enable long-term monitoring and robust operation from limited energy supplies. Data will be obtained from a wearable sensor under a variety of situations, such as sleep deprivation, physically stressful activities, and during sleep.

Specifications Required: A compact, low power dynamic system built on an integrated circuit (IC) serving as a common and scalable platform for multi-modal current detection sensing at the 1 picoAmp (pA) level is needed for Electrocardiogram (ECG), Electroencephalogram (EEG), and Electrodermal Response (EDR) biosignal detection. The system should be packaged as a miniature wearable device with non-contact electrodes. The signal processing should compensate for movement and be useful for medical monitoring to assess a subject's stress, fatigue and resilience.

Technology Developed: The MICROS system measures physiological parameters using ruggedized miniaturized sensors worn directly on the skin via an adhesive patch. MICROS includes power scavenging capabilities to augment an on-board battery, providing extended operating time, and wireless data transmission. Combined with monitoring and analysis software on a mobile platform, MICROS will provide comprehensive, real time data on the physical and mental readiness of personnel for military and commercial applications.

Warfighter Value: MICROS provides data measurement and analysis to assess the physical and cognitive status and resilience of the warfighter. It can be used to optimize training by allowing trainees to be pushed aggressively without causing injury or lasting adverse cognitive effects. In operational settings, MICROS provides an inward-looking input to a commander's situational awareness by assessing the warfighter's stress, fatigue and resilience, thereby adding troop readiness to the external battlefield picture which is the usual focus of situational awareness systems.

WHEN Contract Number: N68335-16-C-0117 Ending on: September 25, 2019

| Milestone | Risk Level | Measure of Success | Ending TRL | Date |
|--|---------------|---|---------------|-------------------|
| Fully-functional prototype using commercial off-the-shelf components | Med | Demonstrated operation with mobile device | 5 | July 2017 |
| First iteration IC bench tested | Med | Bench test results quantify adherence to specifications | 5 | July 2017 |
| Second iteration IC bench tested (Option 1) | Med | Bench test results meet specification | 5 | April 2018 |
| Fully-functional product based on IC (Option 2) | Med | Demonstrated operation with mobile device in field test | 6 | September 2019 |

HOW

Projected Business Model: Vivonics will produce (through a contract manufacturer) and market MICROS as disposable wearable sensors, and will provide companion analysis / display software for Android mobile devices. Vivonics intends to seek Food & Drug Administration (FDA) approval of MICROS as a medical device in order to expand the technology applications past personal fitness monitors. As a medical device, MICROS has the potential to assist in casualty care monitoring.

Company Objectives: Vivonics plans to use MICROS as a platform upon which to build advanced human physiology data analysis software. Vivonics is seeking technology transition opportunities with DOD program offices interested in physiological monitoring, as well as connecting with strategic partners and investors for scale-up support and market entry assistance.

Potential Commercial Applications: Initial commercial application of the MICROS sensor system will be for consumer sales for personal fitness monitoring. Additional applications may include wearable medical device technologies to record EEG, ECG, and EDR during daily activities. However, with the superior data collection capabilities of MICROS and advanced fitness monitoring software, Vivonics expects to define a new high-end category of personal monitoring systems for the fitness or medical market.

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