

# BARDA Awards \$51.9 Million Contract to DNAe to Develop Semiconductor DNA Sequencing Platform for Rapid Diagnosis of Antimicrobial Resistant Infections and Influenza

- First next-generation sequencing platform to receive funding from BARDA
- Up to \$51.9 million, contract to support testing and FDA clearance of DNAe's sequencing platform for a series of applications
- Initial focus to address two of the most significant threats to global health, antimicrobial resistance and influenza

London, UK and Carlsbad, CA, USA – 30 September 2016 – DNA Electronics ('DNAe'), the inventors of semiconductor-based next-generation DNA sequencing (NGS) technology and developers of a revolutionary blood-to-result test for bloodstream infections, announces that the Biomedical Advanced Research and Development Authority (BARDA) a division of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) has awarded the Company a contract worth up to \$51.9 million to develop its sequencing platform for rapid diagnosis in two key applications; antimicrobial resistant infections and influenza.

Genomic information derived from DNA sequencing is transforming many areas of medicine. This is the first NGS platform supported by BARDA, with game-changing potential in the diagnosis and treatment of infectious diseases.

The Centers for Disease Control and Prevention (CDC) have estimated that more than 2 million people per year in the U.S. suffer antimicrobial resistant infections resulting in 23,000 deaths. The CDC also predicts that a flu pandemic could result in between 89,000 and 207,000 deaths in the U.S. and could cost the economy \$71.3-166.5 billion.

The contract for the project entitled PISCES (Pathogen Identification from Specimen, via Capture Extraction and Sequencing) will enable DNAe to complete the development and validation of its ground-breaking Genalysis® platform and support a series of applications to the U.S. Food and Drug Administration for marketing clearance.

The Genalysis® platform will combine the ability to sequence the DNA of the infectious organism, in a sealed microchip based system, direct from clinical specimen, with analysis that enables actionable identification of the disease agent within a few hours, a key requirement in the effective treatment of infectious diseases.

DNAe's first product will be a rapid blood-to-result diagnostic system to meet an unmet need in the treatment of serious bloodstream infections leading to sepsis. Sepsis is an area of very high unmet medical need, responsible for over 200,00 deaths per annum in the US, more than prostate cancer, breast cancer and AIDS combined<sup>1</sup>. In late stage development and testing, the new system is set for commercial launch in 2018.

In 2014, BARDA awarded a \$21.5 million, contract to DNAe's US operation (then called nanoMR, Inc.) to develop an automated sample preparation system that could reduce the time needed to test for bloodstream infections and biothreat agents such as anthrax from days to hours. DNAe acquired nanoMR in January 2015 to complete the workflow of its sample-to-result solution by combining nanoMR's novel Pathogen Capture System, which extracts and concentrates pathogens, such as bacteria or fungi directly from a raw blood sample, with its Genalysis® technology.

Sam Reed, President, U.S. Office, DNAe, based in Washington DC, and who is leading DNAe's sequencing program commented: "Our platform is truly revolutionary as it brings a powerful sequencing-based diagnostic capability into a rapid, user-friendly format. Importantly the platform can be operated by users who are not specially-trained in sequencing, enabling it to be used in a wide range of near-to-patient clinical environments where sequencing has not been possible before. Unlike existing sequencing devices, the platform operates 'push button' directly from raw clinical specimens such as blood or swabs, delivering a clinically-relevant report for the physician."

Bloodstream infections afflict over 1 million patients per year in the US alone, making it the single most expensive disease in terms of total healthcare expenditure<sup>2</sup>. DNAe's Genalysis® platform will revolutionize care by very rapidly identifying the causative pathogens and their antibiotic resistance profile from a wide range of potential causes. This has the potential to drive reduced mortality, reduced length of stay in critical care, reduced healthcare expenditure, and improved management of antibiotics. In influenza testing, the platform has the potential to ultimately identify the strain subtype and antiviral resistance markers, guiding antiviral usage in critical patients or for management of patients during a pandemic.

Dr Steve Allen, CEO DNAe Group Holdings said: "DNA sequencing-based tests that can rapidly provide accurate diagnostic information on infectious diseases will be a game-changer in terms of how clinicians treat infectious diseases in the future. It will enable the choice of treatment to be highly specific and tailored to the causative pathogens. Antimicrobial resistance and the threat of an influenza pandemic are two of the most critical threats to human life, and areas of huge unmet need. The support and cooperation of the U.S. Government will be instrumental in our mission to provide rapid diagnostics to support healthcare professionals, enabling a more effective public health response to these crises."

Semiconductor-based DNA sequencing was invented by DNAe's Founder, Executive Chairman, and Regius Professor at Imperial College London (Department of EEE), Professor Chris Toumazou and his group at Imperial. A highly acclaimed serial entrepreneur, this invention has earned him the UK Institution of Engineering and Technology (IET)'s highest honour, the Faraday Medal and the European Patent Office's prestigious Inventor of the Year Award for Research in 2014, and the Gabor Medal of the Royal Society in 2013. DNAe owns and applies his patented technology to create rapid diagnostics that address critical unmet needs in healthcare applications. The semiconductor sequencing technology is licensed to Thermo-Fisher for research use.

Professor Toumazou, DNAe said: "This collaboration demonstrates the suitability of DNAe's NGS-based platform to address a range of clinical needs, demonstrated by the applications in antimicrobial resistance and influenza testing, where there is a very high unmet need."

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## About DNAe - www.dnae.com

DNAe is commercialising its pioneering semiconductor DNA analysis technology for healthcare applications where rapid near-patient live diagnostics is needed to provide actionable information to clinicians, saving lives by enabling the right treatment at the right time.

In January 2015 DNAe acquired nanoMR, Inc. (now DNA Electronics Inc.), a developer of a novel system for rapid isolation of rare cells in the bloodstream. DNAe is developing a complete sample to result genomic analysis platform combining DNA Electronics Inc.'s Pathogen Capture System with its own Genalysis® semiconductor DNA analysis technology. Built into a compact device for use at the point of need, the system will diagnose accurately and rapidly what infection a patient has, providing the clinician with actionable information to help select the appropriate antibiotics to treat the disease.

DNAe's initial focus is on infectious disease diagnostics, where speed and DNA-specific information can make the difference between life and death. DNAe's first product, will be a diagnostic test for bloodstream infections for use in the management and prevention of sepsis.

A private company, with operations in London, UK, and Carlsbad, CA and Washington DC, USA, DNAe has strong financial backing from its investors, including major shareholder Genting Berhad, a Malaysian-based global investor with a growing portfolio of cutting–edge life sciences companies.

#### References

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