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FOR IMMEDIATE RELEASE:

Akonni Biosystems Awarded NIH Contract to Develop a Simple, Cost-Effective Device to Purify DNA from Sputum for Tuberculosis Testing

New device to provide solution for DNA extraction in remote settings

FREDERICK, MD – March 10, 2017 – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market [advanced MDx systems](#), today announced receipt of a \$300K contract from the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The award will enable Akonni to accelerate development of a low-cost, simple, field-based nucleic acid extraction device – a highly sought-after solution for a widely unmet need in the field of global health.

According to the World Health Organization (WHO), tuberculosis (TB) continues to cause significant mortality and morbidity throughout the world, recently surpassing HIV as the single largest killer of all infectious diseases. Standard diagnostic techniques for TB include sputum smear microscopy and microbiological culture confirmation. As a result, diagnosis of TB is both difficult and time-consuming, especially in smear-negative, HIV-infected and pediatric patients. Next-generation tests for TB show promise as faster, more sensitive alternatives to traditional methods. Sputum, which is the most common specimen type for diagnosing TB, is very challenging to process, particularly for molecular testing methods. Driven by the growing need for robust methods to isolate and purify DNA for molecular detection, the NIH is seeking a simple, cost-effective device to process sputum and stabilize the purified DNA for downstream processing, even in the harsh environmental conditions of TB endemic areas. Also, the purified DNA sample must be suitable for many different downstream detection technologies (i.e. sequencing, isothermal amplification, PCR, etc.) to uncouple the very difficult and costly step of sample processing from the development of the MDx test. This allows the sputum processing and molecular testing to be delinked, with processing done immediately at the point-of-care, or at a centralized facility.

Akonni's Rebecca Holmberg, PhD, Principal Investigator (PI) and Project Director on the contract stated, "we have been approached by several different parties, all looking for a similar solution – a simple, rapid, low-cost nucleic acid extraction device that can be used by untrained

personnel in the field in developing countries, and produce high-quality, purified nucleic acids that are compatible with several different downstream detection methods. We are excited to work on such an important and valuable solution.”

Michael Reinemann, MPH, Director of Business Development for Akonni, said, “this latest award will help accelerate a key corporate objective of bringing affordable, effective next-generation solutions to low-resource settings. The sample preparation contract complements Akonni’s proprietary TruArray[®] MDR-TB test, which simultaneously interrogates hundreds of genetic markers from a single patient sample, in order to identify common drug-resistant strains of TB. Our patented, innovative microfluidic design and manufacturing procedures enable us to produce the tests at a price point that is affordable for lower-cost settings where TB is prevalent.” Previously, Akonni was awarded an NIH grant to accelerate development of its fully-automated, sample-to-answer system for identifying a broader range of multi-drug-resistant strains of TB. In 2014, Akonni, in partnership with Harvard University, was awarded a [\\$29M NIH grant](#) to further develop its drug-resistant TB diagnostic. Early results from these grant-funded projects have demonstrated promising results, even in non-sputum based samples such as stool, using the Akonni nucleic acid extraction technology and diagnostic platform, thus accelerating the development of Akonni’s next-generation automated multiplexed MDR/XDR-TB diagnostic testing.

For more information visit: www.akonni.com.

About Akonni Biosystems

Akonni Biosystems was founded in 2003 and has been issued 17 US and 24 International patents primarily covering sample preparation, microfluidic devices, bioinstrumentation, and integrated systems. Product development has been supported by a series of government grants and contracts from NIH, CDC, DOE, DOD, NIJ, and NSF. The company significantly advanced the original technology by improving the system’s capabilities from sample preparation to test result. Commercial products in Akonni’s near-term pipeline include rapid sample preparation technologies for nucleic acid extraction and multiplex panel assays for detecting clinically relevant genotypes for pharmacogenomics, human chronic diseases, and genotypes for infectious diseases such as multidrug-resistant tuberculosis (MDR-TB), extensively drug-resistant tuberculosis (XDR-TB), upper respiratory infections, viral encephalitis, and hospital-acquired infections (MRSA).