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FOR IMMEDIATE RELEASE:

Akonni Biosystems Awarded NIH Grant to Support Commercialization of a Low-Cost, Simple, Rapid Point-Of-Care Test for Tuberculosis and its Resistance to First-Line Drugs

Funding will help accelerate commercialization of its MDR-TB test on a fully-integrated, sample-to-answer system, the TruDx[®]3000

FREDERICK, MD – November 14, 2017 – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market <u>advanced MDx systems</u>, today announced receipt of a \$300K Commercial Readiness Pilot (CRP) grant from the National Institutes of Health (NIH). Unlike other kinds of NIH research grants, CRP grants are intended to facilitate the transition of previously-funded Phase II projects to the commercialization stage, including activities related to clinical trials and regulatory submissions. This grant in particular will help Akonni accelerate the commercialization of its proprietary <u>TruArray®</u> MDR-TB test on its <u>TruDx®3000</u> sample-to-answer diagnostic platform.

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. Of all diseases, TB represents one of, if not the greatest, health disparities between socioeconomic classes. Further compounding this health disparity is the prevalence of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) cases. Each year there are approximately 500,000 new cases of MDR-TB, 10% of which have XDR-TB. Current diagnostic methodologies, available primarily to affluent healthcare communities, utilize microbial cultures, which require sophisticated laboratories and weeks before a result can be determined. In addition, difficulties for lower socioeconomic persons to commute and/or follow up with their physicians can result in a lack of appropriate treatment, potentially leading to further drug resistance.

In order to effectively address this global epidemic, a low-cost, simple, and rapid point-of-care (POC) test that accurately detects TB and its resistance to first-line drugs is needed. Currently available TB diagnostics lack the sensitivity, specificity, multiplexing capacity, and/or

affordability needed to achieve this goal. As such, Akonni is committed to commercializing a POC MDR-TB diagnostic that offers the sensitivity of culture methods, specificity of nucleic acid methods, and a broad coverage of clinically relevant mutations, at a fraction of the cost of existing molecular methods. "Funding from this grant will help accelerate critical elements of our commercialization plan for the MDR-TB test on the TruDx3000, including ISO 13485 certification and subsequent regulatory approvals," said Christopher Cooney, Principal Investigator on this project and Director of Engineering for Akonni.

For more information visit: <u>www.akonni.com</u>.

About Akonni Biosystems

Akonni Biosystems was founded in 2003 and has been issued 21 US and 36 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).