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FOR IMMEDIATE RELEASE:

Akonni Biosystems Awarded NIH Grant to Support the Advancement of its Point-of-Care Diagnostic Platform

Funding will help accelerate commercialization of the TruDx® 3000, Akonni's fully-integrated, sample-to-answer diagnostic system

FREDERICK, MD – August 21, 2018 – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market <u>advanced MDx systems</u>, today announced receipt of a \$3 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH). Last year Akonni received a <u>2017 North American New Product Innovation Award</u> from Frost and Sullivan, which highlighted the potential of its unique, cost-effective diagnostic platform, <u>TruDiagnosis</u>[®]. This grant in particular will help Akonni accelerate the commercialization of its proprietary <u>TruArray</u>[®] test for Tuberculosis and simultaneous drug susceptibility testing (DST) on its <u>TruDx</u>[®] 3000 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. Akonni's recent strategic partnership with one of the leading molecular diagnostic companies in China, Righton Inc., will use their established sales distribution network to address the estimated 1 million new cases of tuberculosis each year in China.

"A low cost, point-of-care solution for guiding the treatment of drug resistant TB is desperately needed in low- and middle-income countries where few options for rapid diagnosis exist. A robust, portable device that can not only detect, but also characterize specific drug resistance profiles directly from a patient sample has the potential to transform drug resistant TB treatment globally, and is critical for achieving the World Health Organization's goal of a world free of TB," said Timothy Rodwell, MD, PhD, MPH, Associate Professor in the Division of Global Public Health, Department of Medicine at University of California, San Diego. The Akonni TB test on the TruDx 3000 includes an automated method of extracting DNA from sputum and a proprietary Lab-on-a-FilmTM diagnostic consumable, which consists of hundreds of molecular sensors printed on a conventional plastic film. This film replaces costly microarray glass, and the simple, yet elegant microfluidic design eliminates the need for expensive, complex pumps, valves or special coatings. The promise of this assembly strategy is that manufacturing throughput can increase from one part per minute using standard robotics to one part per second using the newspaper printing production method commonly known as "reel-to-reel manufacturing."

"We are grateful to the National Institutes of Health for giving us the opportunity to address this challenging clinical need," said Christopher Cooney, PhD, Principal Investigator on this project and Director of Engineering for Akonni.

For more information visit: www.akonni.com.

About Akonni Biosystems

Akonni Biosystems was founded in 2003 and has been issued 21 US and 37 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). Based on its recent analysis of microarray-based applications in the molecular diagnostics (MDx) market, Frost & Sullivan recognized Akonni Biosystems with the prestigious 2017 North American New Product Innovation Award.