Contact:
Michael Reinemann, Director of Business Development
301-698-0101
mreinemann@akonni.com

FOR IMMEDIATE RELEASE:

Akonni Biosystems Awarded Phase II NIH Contract to Advance its Device to Purify DNA from Sputum for Tuberculosis Testing

Simple, Cost-Effective Device Shown Effective in Phase I

FREDERICK, MD – Febuary 5, 2019 – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market advanced MDx systems, today announced receipt of a $3 million, three-year Phase II Small Business Innovation Research (SBIR) contract from the National Institute of Allergy and Infetious Diseases (NIAID) at the National Institutes of Health (NIH). Akonni received the Phase I contract in August 2016. During phase I, Akonni successfully completed each milestone set forth by the NIH, resulting in a simple device that can process high-volume sputum samples for sensitive *Mycobacterium tuberculosis* detection at smear-negative, culture-positive levels. Akonni is collaborating with Dr. Nicole Parrish, an Associate Professor of Pathology/Director of Mycobacteriology at the Johns Hopkins University School of Medicine with over 25 years of experience in Tuberculosis (TB) diagnostics, and MRIGlobal, who will be testing the systems.

"Our approach was to reduce the complexity of the instrument by limiting the automation, streamlining the workflow, and simplifying the user interface," said Dr. Rebecca Holmberg, Director of Application Development for Akonni. "The simple design lowers the demand on power consumption of the device so that it can run on battery power, and be controlled by a mobile phone application, which further simplifies the ease of use."

Phase II product development will focus on meeting the requirements of a low resource setting, including industrial design elements such as dust-protection, battery power, and user interface. It will also include a plan to transfer the device to commercial production under good manufacturing practices (GMP) that is compliant with the requirements of ISO 13485. The system will be validated using a real-time PCR detection test for TB to determine analytical and clinical sensitivity of the method as compared to a standard laboratory method. Following its completion, the system will be validated and ready for deployment in the intended use setting.

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.