



For Akonni Biosystems

Kevin Banks, Ph.D.
(301) 698-0101
kbanks@akonni.com

For Press inquiries

Annette Summers
(925) 519-0608
Annette@genecom.biz

FOR IMMEDIATE RELEASE:

Akonni Pre-Clinical Results on Rapid, Low-cost Array Moves Company Closer to Commercialization for its Infectious Disease Test Portfolio

Data demonstrate that the TruDiagnosis® platform is ready for expanded, multi-site clinical trials

Frederick, MD. — January 8, 2013 — Akonni Biosystems announced results today from three pre-clinical studies that contribute to the body of clinical evidence that verifies the efficacy of Akonni's TruDiagnosis molecular diagnostics (MDx) platform. Akonni TruArray® Tests are designed to fulfill market needs for mid-multiplex molecular diagnostics (tens to hundreds of molecular markers) deployed in near point-of-care settings, at a similar cost to conventional culture tests and with the accuracy and speed of gold-standard low-multiplex approaches.

These studies, including those for methicillin-resistant *Staphylococcus aureus* (MRSA), multi-drug resistant *Mycobacterium tuberculosis* (MDR-TB), and influenza subtyping, were funded and developed over the past six years by carefully leveraging more than \$45M in private and public funding from the National Institutes of Health (NIH), Centers for Disease Control (CDC), National Science Foundation (NSF), and the Department of Defense (DOD).

"The development of highly extensible, mid-multiplex, low-cost diagnostics for use in near-point-of-care settings is critical for mitigating the uncontrolled spread of disease, especially in global health settings," says Kevin Banks, Ph.D., Vice President Strategic Development at Akonni Biosystems.

Well positioned to take advantage of a \$3.0B plus market

The aggregate market opportunity for infectious disease diagnostics exceeds \$3B in the United States alone, according to an October, 2012 report by Cowen & Company, LLC. Akonni's TruDiagnosis platform is positioned to exploit this and broader global health markets with its unique TruArray Tests, which are designed to significantly reduce the complexity and cost of traditional mid-multiplex microarray consumables, equipment, and workflows for laboratory technicians. Mid-level multiplexed molecular assays that can be deployed in the field or in lower-resource settings are particularly useful for infectious disease diagnostics, detecting drug resistance markers, and improving the health of at-risk populations.

"The studies described below demonstrate that we have minimized the technology risks of our platform, and it is time to expand these studies and begin the development and validation processes for regulatory approval," concluded Banks. "This year we expect to find funding partners so we can design and initiate these trials. Once we have gained CE-IVD and FDA clearances, we believe our lower cost MDx tests will facilitate better and more rapid treatment decisions in the clinic."

Streamlined chemistry simplifies workflow compared to other microarray platforms

Relative to the microarray products provided by Affymetrix (AFFX), Agilent (A), Combimatrix (CBMX), and by Luminex (LMNX), Akonni's TruArray tests significantly simplify microarray workflows by combining conventional target amplification, fragmentation and labeling processes into a single tube or microfluidic chamber. Preliminary studies also indicate that all amplification, labeling, hybridization, and wash steps can be combined into a single, self-contained amplification microarray consumable, resulting in an entirely closed-amplicon microarray-based test.

"These studies demonstrate the clinical viability of our TruDiagnosis platform and represents a significant advance over conventional mid-multiplexed molecular diagnostic platforms," explains Banks. Banks continues, "Multi-drug-resistant bacterial strains are evolving quickly, making today's gold-standard molecular diagnostic tests appear less effective because they fail to capture the diversity within the pathogenic population or have difficulty detecting certain types of genetic variants. For example, several PCR-based tests have difficulty detecting deletion variants such as the methicillin-resistant *Staphylococcus aureus* (MRSA) *mecA* dropout strains. Akonni's recent studies demonstrate that TruArrays can be used to detect known isolates, certain unknown isolates, and those for which traditional PCR alone is difficult to use."

Methicillin-resistant *Staphylococcus aureus* program

In collaboration with researchers from Johns Hopkins University, Akonni conducted a retrospective study on 87 clinical isolates and 246 nasal swab samples acquired from a non-random, high-risk patient population. Of the 87 isolates, the TruArray test accurately classified 86 (98.8%) and correctly identified 14 *mecA* dropout specimens that were falsely positive in the BD GeneOhm MRSA or BD GeneOhm StaphSR tests. The overall prevalence of MRSA in the clinical sample set was 16.7%. The TruArray test resulted in 80.5% sensitivity and 96.6% specificity, comparable to or better than Cepheid Xpert MRSA or BD GeneOhm tests when applied to similar, high-prevalence patient populations containing a significant number of *mecA* dropouts. This study was published in 2012 in the *Journal of Microbiological Methods*.

MDR-TB program

In collaboration with researchers from Johns Hopkins University, Akonni conducted a study with 185 *Mycobacterium tuberculosis* isolates representing a world-wide distribution of rifampin, isoniazid, streptomycin and ethambutol resistance genotypes. The simplified TruArray Test containing 96 unique probes for 39 drug-resistant mutations in 5 genes enabled a single technician to run up to 24 samples in under 6 hrs using an industry standard thermal cycler and a field-portable, low cost microarray imager. Of 196 mutations in the culture set that were also represented on the microarray, the TruArray test correctly detected 193 (98.4% success rate). This study is scheduled to be submitted for publication in the first quarter of 2013.

Influenza subtyping program

In collaboration with the United States Centers for Disease Control (CDC), New York Department of Health's Wadsworth Center, and Little Company of Mary Hospital (Chicago), Akonni developed a simplified TruArray Test for influenza detection, sub-typing, and neuramidase resistance detection from nasopharyngeal swabs (in viral transport medium). Limits of detection in clinical nasopharyngeal swab samples were approximately 100 RNA gene copies per test, regardless of influenza subtype. The most sensitive probes were those targeting seasonal and pandemic influenza A H275Y variants. Using a CDC surveillance and reporting guideline, definitive identification was provided for 164 of 178 samples (92%) and 328 of 342 hybridizations (95.9%). No false positives were detected. This study is scheduled to be submitted for publication in the first quarter of 2013.

Additional programs underway

Akonni is also developing a **Warfarin pharmacogenetic test** that discriminates three single nucleotide polymorphisms (SNPs) within the CYP2C9 and VKORC1 genes. Unique to Akonni's test for Warfarin, the amplification and hybridization workflow makes use of the ultra-rapid DNA extraction capabilities of Akonni's TruTip® sample preparation device, making it possible to use less invasive saliva samples. The assay can be completed in less than four hours from sample lysis to result for up to 24 samples at a time by a single technician. This study is scheduled to be submitted for publication in the first quarter of 2013.

Akonni's **environmental testing** group has developed and verified an amplification microarray for monitoring microbial community dynamics in groundwater. Analytical limits of detection were between 2 and 200 cell equivalents of purified DNA. Amplification microarray data were well correlated with 16S-targeted qPCR results and accurately detected expected changes in groundwater microbial community structure over time and in response to groundwater perturbations and treatments. The technology has been tested and deployed under various field conditions. The amplification microarray study is in press with *Applied and Environmental Microbiology* and builds upon a successful field trailer deployment of the TruDiagnosis platform described in a 2010 *Environmental Science and Technology* publication.

About Akonni Biosystems

Akonni develops highly innovative products and technologies designed to significantly increase productivity in the life science tools/sample preparation market and to dramatically lower the cost of testing in the molecular diagnostics (MDx) market. Akonni Biosystems was founded in 2003 and has more than 48 patents issued or pending. Supported by a series of government grants and contracts from NIH, CDC, DOE, DOD, NIJ, and NSF, the company has built on its founding technology by improving capabilities from sample preparation to final result. Akonni products and near-term pipeline projects include rapid sample preparation methodologies for nucleic acid extraction and mid-multiplex panel assays for detecting multi-drug-resistant tuberculosis (MDR-TB), upper respiratory infections, viral encephalitis, and healthcare-associated infections (MRSA).

Akonni products are currently for research use only. Not for use in diagnostic procedures.

For more information, please visit www.akonni.com.

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