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**FOR IMMEDIATE RELEASE:**

## **Akonni Biosystems Strengthens Leadership Team with Multiple Key Appointments**

### **New hires round out commercialization staff**

**FREDERICK, MD – January 25, 2017** – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market integrated MDx systems, announced today the appointments of key members to its leadership team. Michael Murphy, M.Sc. joined as Vice President, Regulatory Affairs; Sandra Foster, Ph.D. as Director of Quality Assurance and Michael Reinemann, MPH as Director of Business Development. The new additions to Akonni's leadership team fill critical gaps needed to ensure Akonni's successful commercialization of its robust product lines. These experienced individuals further strengthen Akonni's leadership team as the company prepares for its first FDA submission for a pharmacogenomic test on the Akonni TruDiagnosis® system.

Michael Murphy is an industry pioneer and thought-leader in the field of Pharmacogenomics, with more than 33 years of scientific and business experience. He is a serial entrepreneur in the personalized medicine space and in 1997 was founder of Intek Labs, the first international Pharmacogenomics company. Following the acquisition of Intek Labs by PPD, Inc., Mr. Murphy was the co-founder, President and CEO of Gentriss Corporation. Gentriss was acquired by Cancer Genetics Inc. in 2015 while Mr. Murphy served on the Board of Directors at Gentriss. In 2007, Gentriss spun off its diagnostic group and Mr. Murphy served as the President and CEO of ParagonDx, one of the first companies to win FDA clearance of a Rapid Genotyping Kit for patients taking the anticoagulant, Warfarin. He has also held Executive Vice President management positions with PPGx and Clingenix. Prior to joining Akonni, Mr. Murphy served for 7 years as President of Conatus Consulting, a regulatory consulting practice based in Raleigh, NC. Mr. Murphy is a frequent lecturer and author on Pharmacogenomic topics, and currently sits on the editorial review board of the journal, *Pharmacogenomics*. He has been responsible for over 15 successful 510(k) submissions, FDA audits and inspections. He brings the expertise in FDA regulations and Quality Management Systems for medical devices that Akonni needs to advance its commercialization and registration efforts.

Sandra Foster brings a unique blend of scientific knowledge and quality experience. She began her scientific career as a Medical Technologist (MT, ASCP), working in hospital laboratories. From the clinical lab she transitioned to research before going to graduate school. She earned a Ph.D. in Immunology from the University of Texas Southwestern Medical Center, followed by a post-doctoral fellowship at Duke University. Dr. Foster spent 12 years in clinical-phase biotechnology companies in roles of increasing responsibility from pre-clinical research and product design and development, to directing the manufacture of clinical trial materials and leading Quality Assurance and Regulatory Compliance. She designed ISO 14644-compliant clean room facilities for the manufacture of cellular therapy products for clinical trials, and implemented quality systems to support those activities. She designed, wrote and implemented process validations, operator qualifications, aseptic process simulations, comparability protocols, and authored multiple CMC sections for INDs. Immediately prior to joining Akonni, Dr. Foster owned her own consulting company, Triangle GxP Solutions, LLC as well as worked collaboratively with Mr. Murphy at Conatus. Client projects included translating R&D protocols into cGMP compliant SOPs, implementing quality systems, conducting client staff training, BLA, and pre-approval inspection (PAI) readiness. In her role as Director of Quality Assurance for Akonni, she leads design control efforts for product development, manages Device History Files, and prepares Akonni's first audit for ISO 13485 Certification and FDA submission.

Michael Reinemann has an exceptional track record of developing and implementing strategic, data-driven marketing and sales initiatives for diagnostic products resulting in strong double-digit growth and increased market share. Mr. Reinemann brings a diverse background, with experience in both technical and business roles. While earning his Master's in Public Health at Columbia University in New York and working at the Mailman School of Public Health's Center for Infection and Immunity, Mr. Reinemann worked on pioneering research projects in immunotherapy and pathogen discovery, and implemented cutting-edge technologies for highly multiplexed analysis and next-generation sequencing. Prior to joining Akonni in June of 2016, Mr. Reinemann served in various Commercial Operations roles at Qiagen. During his time at Qiagen, Mr. Reinemann led marketing and sales efforts that accelerated the growth of what has become the company's single biggest revenue-contributing product. As Regional Marketing Manager of North America, Mr. Reinemann's achievements included year-over-year growth of 55%, and the introduction of innovative co-marketing initiatives with strategic accounts, resulting in customer-specific growth of 75%. As Senior Global Product Manager, Mr. Reinemann managed a \$150M product line with an annual growth rate of 25%, leading cross-functional project teams on commercial efforts as well as product development and product launches. His international business experience positions Akonni for success as the company navigates late-stage product development, registration, and commercialization of its technologies.

"We are very excited to announce these essential additions to Akonni's leadership team," said Charles Daitch, Ph.D., President and CEO of Akonni Biosystems. "Each of these talented individuals bring valuable experience, demonstrated core competencies and dynamic industry insights from successful

careers in clinical diagnostics. Our ability to hire people of this caliber speaks to the competitiveness of our product lines and their readiness to move expeditiously through the regulatory process. We are confident that we have the expertise needed to achieve our first FDA clearance and successful commercial launch of our TruDiagnosis platform.”

Akonni is aggressively pursuing regulatory clearance of two product platforms – the TruDx®2000 platform and the TruTip® Automated Workstation. TruDx2000 is Akonni’s modular version of the TruDiagnosis® system, consisting of TruArray® three-dimensional (3D) gel-drop microarray diagnostic test devices and the TruDx Imager, complete with custom software for data analysis and reporting; the TruDx2000 can be bundled with or without the TruTip sample prep workstation depending on the needs of each clinical lab. The TruArray microfluidic device incorporates new, proprietary on-chip PCR technology, resulting in a much more user-friendly workflow, multiplexed detection, and a closed-amplicon system that virtually eliminates the risk of PCR contamination. The proprietary 3D gel-drop microarray nano-test-tubes can be tailored to detect genetic, protein or metabolite markers, providing the potential for access to a much broader range of diagnostic information from a single platform. The TruTip Automated Workstation is a small, affordable, fully-automated benchtop instrument. TruTip is a revolutionary technology that simplifies sample preparation by combining the complex protocols of DNA or RNA purification into just a few easy steps. The TruTip Automated Workstation is Akonni’s new nucleic acid purification instrument, which, in addition to blood and saliva, can homogenize and purify difficult samples such as sputum, stool and tissue.

For more information visit: [www.akonni.com](http://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).