Idaho Technology Provides FilmArray® Clinical Diagnostic Pipeline Update

**Developing Multiplex Diagnostic Tests for Rapid Detection of Gastrointestinal and Blood-Bourne Pathogens**

SALT LAKE CITY, UT, (August 2, 2012) - Idaho Technology, Inc., a privately held clinical diagnostics company dedicated to providing the world’s fastest, highest-quality instruments for pathogen identification and DNA analysis, today provided a development update on the Company’s pipeline of clinical diagnostic test candidates, which are based on the Company’s FilmArray system. Recently, the Company and its collaborators presented preliminary assessments of Idaho’s development-stage blood culture ID (BCID) and gastrointestinal (GI) panels at the 2012 American Society for Microbiology (ASM) General Meeting in San Francisco, California. These panels represent Idaho Technology’s most advanced clinical diagnostic test candidates, which pending successful clinical trials, will expand the current test menu for FilmArray, which includes the Company’s FDA-cleared, CE IVD marked respiratory panel, FilmArray RP.

Kirk Ririe, Chief Executive Officer of Idaho Technology, said, “We are pleased to report these encouraging findings, which demonstrate the broad applicability of our FilmArray rapid diagnostic platform. We recently initiated clinical trials for our BCID panel and expect to launch the clinical evaluation for our GI panel in the first quarter of next year. Pending regulatory clearance, we expect the BCID panel to be available commercially in the U.S. and Europe in the first half of 2013 and the GI panel to follow early in 2014.”

**Pipeline Update:**

*FilmArray BCID*

The Company’s BCID panel is designed to identify the numerous organisms that can cause sepsis, as well as detect the presence of selected antibiotic resistance genes. The FilmArray BCID panel is designed to detect about 90% of the pathogens isolated from positive aerobic blood cultures. Preliminary results when testing residual positive blood cultures at three external sites with a beta version of the FilmArray BCID panel showed good concordance between the FilmArray result and the gold standard of culture and biochemical identification. Rapid identification of a large range of pathogens in blood culture could improve the medical management of sepsis. The current version of FilmArray BCID tests simultaneously for eight Gram-positive and eleven Gram-negative bacteria, five yeast pathogens, and four antibiotic resistance genes. Given the promising results of the beta evaluations, clinical trials for the FilmArray BCID panel have been initiated with the goal of establishing the true product performance and to obtain FDA clearance and CE IVD marking for the FilmArray BCID panel.

*FilmArray GI*

The Company’s GI pathogen detection system aims to rapidly identify GI pathogens from minimally processed stool samples. The current development version of the panel simultaneously detects 25 different diarrheagenic pathogens including bacteria, viruses, and protozoa. In an early phase study, de-identified patient stool specimens submitted for standard-of-care testing were re-tested using FilmArray GI. In this initial evaluation, the FilmArray GI panel had good concordance with standard clinical testing. In addition, because the multiplex testing with FilmArray GI panel is able to detect several pathogens from a single patient sample, the number of pathogens identified as compared to the pathogens identified when the same samples were tested according to individual tests ordered by physicians was significantly higher. These results highlight the potential advantage of simultaneous multiplex pathogen detection using FilmArray GI, which is able to identify pathogens for which pathogen-specific testing was not requested or is not currently available.
In a second early phase study, the ability of FilmArray GI to detect *Clostridium difficile* infection (CDI), the leading cause of diarrhea with rising incidence and mortality, was examined. This study also demonstrated good concordance between the results of the FilmArray GI panel when compared to the result obtained from an FDA cleared molecular assay. As with the previous study, in addition to detecting *C. difficile*, the FilmArray GI panel was able to detect other pathogens known to cause diarrhea both in samples that tested positive for *C. difficile* and those that tested negative for *C. difficile*. These data suggest the use of a multiplex system like FilmArray GI may be beneficial in rapidly and accurately diagnosing diarrheal infections.

The FilmArray GI and BCID panels are currently not FDA cleared or CE IVD marked, are not for use in clinical *in vitro* diagnostic procedures, and are not currently commercially available.

Mr. Ririe concluded, “In addition to our clinical diagnostic pipeline, we continue to gain significant traction in the market with placements of our FilmArray RP only one year since its commercial launch. As a profitable clinical diagnostics company, we are committed to providing rapid, actionable results and unmatched user-friendliness to meet the needs of clinical laboratories and health care providers worldwide.”

**About FilmArray RP**

FilmArray RP is Idaho Technology’s first clinical diagnostic test designed to run on the Company’s novel FilmArray system, which represents a significant advancement in user-friendliness and multiplex infectious disease testing capability for hospital clinical labs. FilmArray RP rapidly detects nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections. Requiring only two minutes of hands-on time, FilmArray RP has about a 1-hour turnaround time, and simultaneously tests for the following panel of respiratory pathogens: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1 2009, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae*. FilmArray RP has received FDA-clearance for twenty targets and is available for use by hospital and clinical laboratory professionals in the United States. In addition, the European version of FilmArray RP is CE IVD marked for twenty-one targets. Idaho Technology is continuing to develop a broader test menu for its FilmArray system, including a blood culture ID panel, gastrointestinal panel, and a meningitis panel.

**About Idaho Technology, Inc.**

Idaho Technology, Inc. is a privately held clinical diagnostics company based in Salt Lake City, Utah. Founded in 1990, the Company currently holds over 70 patents related to polymerase chain reaction (PCR). The Company has used its extensive patent portfolio to successfully market nearly 200 products to the clinical, research and military markets. The Company manufactures and distributes its proprietary diagnostic respiratory panel, FilmArray RP, which operates on its user-friendly FilmArray system, to hospital-based clinical laboratories in the U.S. and E.U. The Company also collaborates with various U.S. governmental agencies including the Department of Health and Human Services and the Department of Defense. Among others, researchers, medical technicians, law enforcement officers, and soldiers in the field use company devices to detect or study disease-causing organisms. For further information, please visit [www.idahotech.com](http://www.idahotech.com).

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