



FOR IMMEDIATE RELEASE:

Xhale Awarded National Institute of Drug Abuse (NIDA) Grant for Further Development of Innovative Breath-Based SMART[®] Adherence Tool.

GAINESVILLE, FL – August 22, 2012

Xhale, Inc. announced today it has been awarded a \$1.7 million Small Business Innovation Research (SBIR) Phase II grant by the NIH National Institute of Mental Health (NIMH) to continue the development of SMART[®] (Self Monitoring and Reporting Therapeutics), a breath-based medication adherence system for HIV/AIDS therapies.

In 2007, NIH / NIMH awarded Xhale an SBIR Phase I grant to test the technical merit of SMART[®]. SBIR Phase II grants enable SBIR Phase I grantees to further develop their technology and prepare it for commercialization. Xhale will use the Phase II grant to develop and test additional functionality, accuracy and system usability. The result will be a commercial version of the system which will have multiple benefits to patients, doctors, researchers and pharmaceutical companies.

As with the Phase I SBIR, Dr. Richard Melker, CTO of Xhale, will be the principal investigator for the project. “Medication adherence has tremendous impact on patient health,” said Dr. Melker. “This is particularly true with HIV/AIDS patients where just a 10% change in adherence is associated with doubling of viral load and a 21% increase in the risk of developing full blown AIDS. NIH was particularly interested since non-adherence to antibiotic or antiviral regimens also pose a serious threat to public health through the emergence of resistant organisms.”

“Building on our Phase I achievements, we will design and deploy a handheld, breath-based medication adherence device,” reports Dr. Donn Dennis, project Co-investigator and CSO for Xhale. “The system will first remind the patient to take their medication. After ingesting their medication, the patient will blow into the device which will detect and document that the appropriate medication was taken at the proper time. This technology should improve adherence rates, especially in high-risk populations, and provide pharmaceutical companies and the FDA with a higher quality data set for evaluating drug safety and efficacy in clinical trials.”

The New England Healthcare Institute (NEHI) in its August 2009 report noted that poor medication adherence costs the U.S. as much as \$290 billion annually (13% of total health care expenditures), and affects virtually every aspect of the health care system. Besides an estimated \$47 billion each year for drug-related hospitalizations, not taking medications as prescribed has been associated with as many as 40% of admissions to nursing homes and with an additional \$2,000 a year per patient in medical costs for visits to physicians' offices.

This is the third time in two years that Xhale has been awarded an SBIR grant. Previous awards were SBIR Phase I awards from the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism.



There is a great need for a method to improve drug compliance which provides simple monitoring of medication dosing which is non-invasive, intuitive, and sanitary. Non-compliance of patients to drug regimens prescribed by their physicians results in excessive healthcare costs estimated to be around \$100 billion per year through lost work days, increased cost of medical care, higher compliance rates, as well as drug wastage. Non-compliance refers to the failure to take the prescribed dosage at the prescribed time which results in under medication or overmedication. Non-compliance of patients with communicable diseases costs the public health authorities millions of dollars annually and increases the likelihood of drug-resistance, with potential for widespread dissemination of drug-resistant pathogens resulting in epidemics.

This method determines whether a patient has taken a medication, by providing a patient a medication comprising a combination of a least one active therapeutic agent and an odorous compound or olfactory marker, which is then detectable in gaseous exhaled breath. The patient then blows into an electronic SMART™ device which analyzes the patient's exhaled breath for detection, or absence, of the odorous compound or olfactory marker to determine compliance. Presence of the markers indicates the patient has taken the medication at the prescribed time and in the prescribed dosage. The system is also expected to be an important tool for use in pharmaceutical clinical trials as part of drug development.

Xhale, Inc. is a medical technology innovator, developing products that transform healthcare and save lives. The company is a world leader in the use of sensors that analyze vapor and exhaled breath and is focused on novel patient-centric monitoring solutions. Its current product lines include SMART®, the world's only definitive medication adherence monitoring system, and Assurance™, a replacement for conventional finger-based pulse oximetry which will monitor multiple patient parameters from a single-point-of-contact sensor, more comfortably and conveniently than finger-based pulse oximetry with fewer false alarms.

For more information, please visit www.xhale.com or contact the company at IR@Xhale.com or 352-371-8488.