



Xhale Awarded NIH / NIMH SBIR (Small Business Innovation Research) Phase II Grant for a Breath-Based Medication Adherence System

Press Release

August 27, 2009

Gainesville, FL - Xhale, Inc. 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 blow AIDS. NIHM 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.

This release is also available on the Wall Street Journal's Market Watch website [here](#).

About Xhale

Xhale's breath-based technologies have the potential to broadly improve the quality of health care via innovations in personalized medicine. These technologies have applications in the medical, home, law enforcement and industrial diagnostic markets. For more information, please visit www.xhale.com.