Respirlyte Inc.

OPPORTUNITY

Respirlyte's lead innovation is a urine-based diagnostic to detect and monitor asthma. This assay is designed to help physicians distinguish asthma from other respiratory disorders, and provides them with an objective measure of severity of the disease. This technology is well-positioned to explore the use of metabolomic-based biomarkers in diagnosing and monitoring various asthma and non-asthma conditions (e.g. COPD) and has the potential to be a prognostic and companion diagnostic. The company is currently conducting studies to investigate metabolites that predict impending worsening of disease (prognostic), and is interested in developing a companion diagnostic to specific asthma and COPD therapies.

Currently, Respirlyte is seeking research partners to develop and commercialize its lead product, and industry partners to study responder versus non-responders to specific asthma and COPD therapies.

TECHNOLOGY

Metabolomics is the study of metabolite profiles in biofluids, which is capable of identifying unique biomarkers signatures associated with disease indications. Our hypothesis has been that different airway diseases will change the metabolism of a person in different ways that will be seen in the urine. Using metabolomics technology, a biomarker profile from the metabolome was identified and patented using nuclear magnetic resonance spectrometry (NMR). This biomarker profile is currently being validated on a mass spectrometry platform which has significant advantages with regard to accuracy, sensitivity and commercial potential. The urine-based NMR test could correctly diagnose blinded patient samples (healthy controls below the 0.5 line, stable asthma in outpatient clinic or unstable asthma in the ED above the 0.5 line) with greater than 90% accuracy. (Fig. 1) Using the same method Respirlyte has also developed a model which correctly classifies asthma and COPD patients.
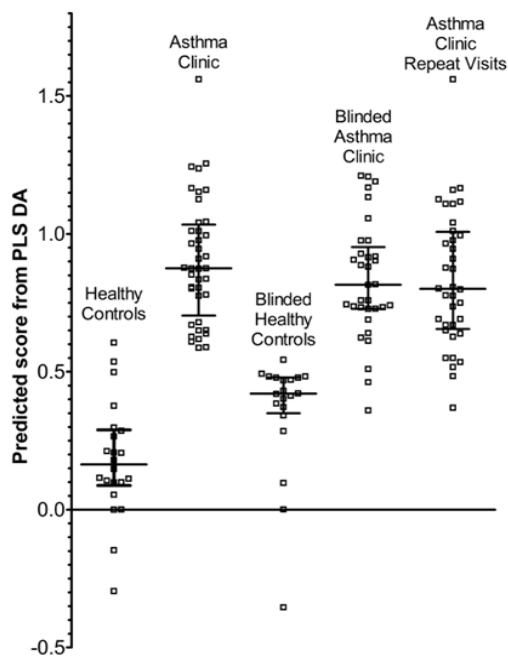

Figure 1.
Partial Least Squares Discrimination Analysis Comparison. Asthma and Control metabolomes correctly differentiate patient groups

DIFFERENTIATION

The competitive advantage of Respirlyte's test is in its ability to detect inflammation caused by asthma through a simple, noninvasive procedure that can be used objectively with patients of all ages. The competing *non*-invasive tests on the market today are either subjective in nature (medical history and physical exam), have a low accuracy (pulmonary function tests), or are age restrictive (spirometry and exhaled nitric oxide).

COMPANY

Dr. Darryl Adamko, President and CEO of Respirlyte, is a Pediatric Pulmonary specialist with strong bench research background after training in a Pediatric Pulmonary Fellowship at The John Hopkins University. Dr. Adamko's research focus has been within the field of asthma, in both understanding the mechanisms of virus induced asthma attacks and in the mechanisms underlying the development of asthma from infancy. In the last seven years, he has been the lead on team grants developing a novel way to diagnose and monitor patients with asthma using nuclear magnetic resonance analysis of urine

Respirlyte Inc. is a privately-held discovery stage company located in Saskatoon, Saskatchewan, Canada. The Company is focused on developing respiratory diagnostic assays through the use of metabolomic-based technologies. Having completed a proof-of-concept trial with 135 children, Respirlyte has identified a urine-based metabolite panel that can distinguish asthma from other respiratory conditions, and provide an objective measure of disease severity.

UNMET MEDICAL NEED

Asthma is one of the most common chronic illnesses, especially in children. There are over 235 million asthmatics worldwide, and 10% are in United States with an estimated annual cost of $18 billion. Childhood asthma is the number one chronic disease in infants and children, representing 25% of asthmatics in the U.S.

Compared to most chronic illnesses such as heart disease and diabetes, asthma is unique as it starts at a young age (before the age of five), which makes asthma more important in terms of years of life affected. Proper diagnosis with the right medications and management plan is critical in order to damage to growing lungs. Unfortunately, making the diagnosis of asthma and adjusting medications are more difficult than for other chronic diseases. The symptoms and objective measurements of lung function, often used to guide therapy, are largely based on the inflammation of the airways. Because measuring airway dysfunction and inflammation in a typical clinical setting is difficult, it is often not done. Instead doctors give trials of therapy. Current asthma diagnostic challenges:

• Standard non-invasive asthma diagnostics are insensitive or age-restricted (spirometry and exhaled eNO) or too labour intensive for a standard doctor's office (e.g. sputum analysis)

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