



J. Dean Zikria, CEO

"Worldwide, the costs for asthma treatment are more than those for tuberculosis and AIDS combined. We have the catalyst to contain costs **and** offer superior diagnosis and prognosis."

#### MANAGEMENT TEAM

##### J. Dean Zikria

Chief Executive Officer

##### Solomon Ssenyange, PhD

Chairman, Co-Founder

##### Ryan Leard

CTO, Co-Founder

##### Brian Awabdy

VP, Engineering

#### SCIENTIFIC ADVISORS

##### Randall Brown, MD, MPH, AE-C

University of Michigan

##### Kenneth P. Moritsugu, MD

Former Acting Surgeon General of the United States

##### Eric Topol, MD

The Scripps Research Institute

#### FINANCING

##### Investors

Shanghai Fosun Pharmaceutical (China), NTK Spark Plug Co. (Japan), South Valley Angels, Iconical, Ohio Innovation Foundation, Carmen Innovation

##### Capital Raised

\$29 Million Total  
(Through Series C)

## Handheld Breath Analyzers May Revolutionize Asthma Management

Point-of-care and at-home devices are designed detect infinitesimal level of **fractional exhaled nitric oxide (FeNO) biomarker** in a patient's breath, measure the underlying level of inflammation and warn against a future asthmatic event.

#### ■ Asthma Diagnosis and Management: Significant Unmet Clinical Need.

Despite new medications, little progress has been made in developing new diagnostic and monitoring technologies for respiratory diseases such as asthma. Today's standard of care is characterized by products, technologies and procedures that have not changed significantly in years—such as spirometers. These technologies offer little insight for clinicians to make better clinical decisions for their patients in terms of initial diagnosis and continuous monitoring of asthmatic conditions. In terms of diagnosis of asthma, large numbers of asthmatics go untreated: 50% of children, and 33% of adults. (Source: CDC) Regarding monitoring, there are no solid-state devices to measure airway inflammation—through FeNO scores—on a continuous basis.

#### ■ Next-Gen Gold Standard for Asthma Diagnosis and Management.

Spirometrix's **FeNO (fractional exhaled nitric oxide)-measurement** breath analyzers are based on the world's most advanced, patent-protected, solid-state exhaled breath sensor. Combining advanced materials with proprietary algorithms, the Spirometrix sensor provides high sensitivity in its ability to detect concentration differences of less than 5 parts per billion down to 5 parts per billion by volume. In measuring parts per billion versus parts per million by volume, Spirometrix's breath analyzers are designed to help predict when an asthmatic will have his next acute event. The patient exhales at a slow rate for 10 seconds to generate results in less than one minute. The **Fenom PRO™ Point-of-Care Breath Analyzer** is designed to be used in the allergist/GP/immunologist/pulmonologist's office. The **Fenom Home™ At-Home Breath Analyzer** is designed as a consumer device used by the patient directly, and on a regular basis as required. These devices include an asthma digital ecosystem that are designed to put the NO scores in context and allow for better clinical decisions. This is well-aligned with the Company's goals of providing a unique and valuable tool for clinical decision support.

#### ■ Significant and Diverse Global Markets for the Spirometrix Platform.

Spirometrix's patented solid-state sensor platform technology is the gateway to a wide range of healthcare's largest global diseases and conditions, and systems to treat them. If a disease generates an exhaled biomarker, Spirometrix's sensors can measure it. The Company's first target market is respiratory illness, with five pipeline diseases overall: asthma, COPD, lung cancer, heart failure, and metabolic diseases. In each disease, millions of patients worldwide are treated annually.

## 10-Second Diagnostic and Prognostic Breath Analyzer for Asthma

Measurement of **FeNO** levels in breath is a biomarker that is strongly recommended by the **American Thoracic Society** and **European Respiratory Society**.

#### Fenom PRO™ Point Of Care Breath Analyzer



The Fenom PRO™ includes the application of the most advanced solid-state sensor technology in the world for the detection of biomarkers such as FeNO in the breath of patients.

#### Published<sup>1</sup> Benefits of FeNO Testing

- Reaffirm asthma diagnosis
- Differentiate asthma from other conditions
- Predict response to inhaled corticosteroid therapy
- Guide and optimize inhaled corticosteroid therapy
- Predict asthma relapse and loss of control
- Rapidly identify noncompliance
- Predict the outcome of allergy avoidance regimens
- Encourage adherence to therapy.

<sup>1</sup> 2011: Allergy Asthma Proceedings

FeNO has been shown to be a reliable, quantifiable measure of inflammation in the airway. Fenom PRO™ is designed to enable the detection of minute levels of FeNO in a patient's breath, thereby facilitating real-time insights to allow for immediate action and ongoing analysis.

## New Standard of Care for Respiratory Diseases such as Asthma Is Now Possible with the Fenom PRO™ P-O-C Breath Analyzer

FeNO biomarker measurement is a unique prognostic result by which patient and physician can forecast, *for the first time*, the next acute event and prevent it through continuous therapy management.

- **SIGNIFICANT UNMET CLINICAL NEED** Asthma is a progressive, chronic inflammatory respiratory disease with no known cure. Worldwide, 235 million persons suffer from asthma, says the World Health Organization (WHO), resulting in more than 180,000 deaths annually. In spite of new drugs, very little progress has been made in developing new diagnostic and monitoring technologies for successfully treating respiratory diseases such as asthma. In fact, according to the American Lung Association (ALA), one in three asthma patients is not compliant with treatment regimens.
- **CLINICALLY ESTABLISHED BIOMARKER** Measurement of *FeNO* (fractionalized exhaled nitric oxide) levels in breath has been shown to be a reliable, quantifiable measure of inflammation in the airway and a biomarker for diagnosis of asthma that is strongly recommended by medical institutions such as American Thoracic Society.
- **STATE-OF-THE-ART SENSOR MICROT TECHNOLOGY** Spirometrix's initial product, Fenom PRO™ Point-of-Care Breath Analyzer, is based on application of the most advanced solid-state sensor microtechnology in the world for detection of biomarkers in the breath of patients. Spirometrix's sensor raises the bar through improvements in sensitivity, measuring as low as 10 parts per billion by volume, thus achieving the requisite sensitivity to accurately detect the FeNO biomarker.
- **THE SPIROMETRIX DIGITAL ECOSYSTEM™** An innovative digital patient network connects information captured through the Fenom PRO's biometric device into a cloud-based portal, providing actionable insights for patients, physicians, and payers (see illustrations below) for comprehensive long-term disease management. The Digital Ecosystem will: (1) make patients realize if they are at risk of an imminent asthma attack; (2) empower physicians to better track the efficacy of various therapy regimens; (3) enable continuous monitoring and care; (4) track patient adherence; (5) provide payers better assessment of high-risk populations to introduce care earlier; (6) populate a greater biometric data set on which to base clinical decisions.

What the experts are saying:



Randall Brown, MD, MPH, AE-C  
Dir., Asthma Programs, Ctr for Managing Chronic Disease, University of Michigan

*"With the current standard of costly asthma care, millions of asthmatics, both children and adults, go untreated."*



Kenneth P. Moritsugu, MD  
Former Acting US Surgeon General

*"I am certain that Issuance of guidelines from the American Thoracic Society will drive adoption of FeNO testing."*

Note: Fenom PRO™ Point-of-Care Breath Analyzer is for investigational use only.

### Introducing a New Standard of Care: the Fenom™ System

Fenom™: A POC Device Centric Asthma Monitoring Ecosystem



Keeps Stakeholders Informed on Status of the Factors Causing Airway Inflammation Thereby Leading to Improved Outcomes & Quality of Life

### Right Information to Right Stakeholder at Right Time



- More Complete Data Set with a Longitudinal Patient Record
- Better Therapy Decisions (i.e. Decision Support)
- **Better Outcomes...**

Spirometrix physician product delivers a holistic system for assessing asthma status of a patient, such as the patient physiological vitals and their environment using real-time data. The doctor and patient will make decision based on "real-time" information.

## Like his father, Spirometrix CEO Dean Zikria has melded science with medicine and invention with business.

With a recent Series C cash infusion of \$17.4 million, Spirometrix is poised to dramatically change the way that potentially deadly respiratory diseases such as asthma may be predicted and thwarted.

**Dean Zikria combined science with business at a young age, when at 19 he started his first company in the surgical device/education space.** He used the money that was gifted to him when he graduated from high school and started Advanced Surgical Technologies, Inc. This company developed and marketed various surgical training devices/boards that allowed surgeons to practice and hone their technical skills, such as knot-tying and anastomosis.

**Since then,** he's conducted medical research at Columbia University's College of Physicians & Surgeons; been awarded patents for both devices and therapeutics; worked as a management consultant; and been an executive at some of the largest and most impressive healthcare companies: McKesson, Pfizer, and Johnson & Johnson.

**In his youth,** Dean worked closely with his father, Dr. Bashir A. Zikria, Professor Emeritus of Surgery at Columbia University College of Physicians and Surgeons, where he taught for more than 25 years. Dr. Zikria's groundbreaking clinical research defined "What is Cigarette Smoke Poisoning." Along the way, he was awarded 10 U.S. patents for his inventions. He shares two of these patents—"Capillary membrane stabilization and reduction of tissue injury through use of biodegradable macromolecules with antioxidants and/or other chemicals" (US 6,207,654); and "Compositions based on polysaccharides and protein C and methods of using the same for preventing and treating sepsis and other conditions" (US 7,041,655)—with Dean.

**Dean strongly shares** his father's interest in science and medicine, invention and business: He majored in biology as an undergraduate at Rutgers University and went directly on to earn an MBA from the Rutgers University School of Management. Dean is the co-inventor along with his father on two seminal drug patents noted above as well as sole inventor on another patent; and now has Spirometrix poised to completely change how asthmatics are diagnosed and managed for their disease.



J. Dean Zikria  
Chief Executive Officer

■ Prior to joining Spirometrix in 2014, Mr. Zikria was an executive with **Johnson & Johnson** for 4 years, most recently as Head of Global Marketing for Animas, the insulin pump business of J&J's Medical Devices & Diagnostics – Diabetes Care Franchise. ■ Previously, Mr. Zikria was an executive for nearly 7 years with **Pfizer**, most recently as the Head of Strategy & Innovation for Pfizer's North America, Specialty Pharmaceuticals unit. ■ In 2004, Mr. Zikria founded **The Afghan Child Foundation**, a nonprofit charitable organization which he is still very active; his charity provides vaccines and other medicines and medical equipment for the benefit of children in Afghanistan. ■ Mr. Zikria earned a Master's in Business Administration (MBA) degree from Rutgers University School of Graduate Management; and a Bachelor of Science (BS) degree in Biology from Rutgers University, where he played varsity football as a defensive back. Mr. Zikria is a serial inventor, holding several patents, including US 6,207,654, US 7,041,655.

## Self-made entrepreneur Dr. Solomon Ssenyange was forced to leave one of the poorest nations in the world.

Uganda is bordered to the east by Kenya, to the north by South Sudan, to the west by the Democratic Republic of the Congo, to the southwest by Rwanda, and to the south by Tanzania. Solomon Ssenyange was born in Uganda...

...His father, a physics teacher, was murdered when Solomon was 5 years old, during the time of despot Idi Amin Dada, human rights abuses, political repression, ethnic persecution, nepotism, corruption, and gross economic mismanagement. Solomon's mother fled to a refugee camp in another developing country, Kenya, with Solomon and his two brothers and a sister in tow. It would be nine years before the family would be able to leave Africa, when a church in Winnipeg, Manitoba, Canada, agreed to sponsor them. Solomon was 14 by then.

**Solomon remained in Canada** for 14 years, completing high school (at the top of his class); earning a bachelor's degree with distinction in chemistry from the University of Manitoba; earning a doctorate in analytical chemistry from the University of Alberta; and completing his post-doctoral studies at The Ohio State University.

**With his formal education completed**, Dr. Ssenyange, at 30, took his first professional position, at a company in the San Francisco Bay Area. But after six years there as a senior plating/process engineer, "I felt like a lab rat," he says. "I had bigger dreams than that." By pure happenstance, he was reading an article ("Beyond the Breathalyzer: Seeking Telltale Signs of Disease") in *The New York Times* on July 2, 2011, which explained that "scientists are building sophisticated electronic and chemical sniffers that examine the puffs of exhaled air for telltale signs of...asthma..." when "The proverbial light bulb went off in my head," he recalls. "I could use my knowledge of analytical chemistry, battery engineering and process development engineering to not only diagnose asthma via a nitric oxide biomarker in exhaled breath, but also predict a future ashmatic event."

**Dr. Ssenyange immediately quit his day job** and started looking for money to fund his start-up, Spirometrix. After 8 months of rejections, however, he was down to his final \$2000, and was ready to give up.

(cont'd on back)



Solomon Ssenyange, Ph.D.  
Chairman

■ Dr. Ssenyange is a co-founder of the company and was the CEO from the company inception until March 2014. He is an expert in solid-state electrochemical sensors with an emphasis in the fabrication of nitric oxide (NO), carbon monoxide (CO) and carbon dioxide (CO<sub>2</sub>) sensors. He is an inventor on patents for breath analysis of various biomarkers present in disease states. ■ Dr. Ssenyange received his training in analytical chemistry in the lab of Professor Mark McDermott at the University of Alberta and conducted cardiovascular research at the St. Boniface Cardiovascular Research Center in Winnipeg, Canada. He completed his postdoctoral studies on carbon based molecular electronics at The Ohio State University. Previous industrial experience includes development of plating solutions and planarization modules used in the MEMS-based probe cards required in semiconductor test and manufacturing. ■ He holds a B.S. in Chemistry from the University of Manitoba and a Ph.D. in Analytical Chemistry from the University of Alberta, Canada.

**When a friend** at his former place of employ learned that Dr. Ssenyenge was about to pull the plug on his dream of starting a company that could have an enormous positive impact on the diagnosis and prognosis of asthma, the friend, miraculously, was able to get Dr. Ssenyenge an appointment to see the founder of Skype™, Janus Friis, at his offices in London.

**”At the 33-minute point of my meeting with Mr. Friis,”** Dr. Ssenyenge recalls with clarity, “he asked me, ‘How much money do you need?’ “I walked away with a financial commitment from him on June 2, 2012.”

**Today, Dr. Solomon’s older brother and younger sister** also live in the United States, while his younger brother and mother still reside in Canada.

**In November 2014,** Dr. Ssenyenge’s company announced a nearly \$9 million Series B cash infusion to fast-forward development of a new standard of care for respiratory diseases such as asthma, made possible with the Spirometrix Fenom™ System: a unique device designed so that an asthma patient and a physician can forecast, for the first time, the next acute event and prevent it through continuous therapy management.

**In June 2016,** Spirometrix announced a \$17.4 million Series C financing that will drive commercialization of the company’s initial product, Fenom PRO™ Point-of-Care Breath Analyzer, a portable breath analyzer that measures nitric oxide in exhaled breath, a biomarker that foreshadows airway obstruction

**“I am living proof** that America is indeed the land of opportunity,” insists Dr. Ssenyenge.

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