



**breathtec**  
BIOMEDICAL INC

*The Next Generation of Diagnostic Medicine*

**Industry:** Biotechnology & Life Sciences

**Location:** W. Palm Beach, FL, USA

**Patent:** U.S. 8,237,118

**Founded:** October, 2015

**Website:** breathtecbiomedical.com

Breathtec Biomedical, Inc. ("Breathtec") was formed to propel innovative research in the area of breath analysis as a medical screening tool. Our efforts are aimed at leading the development of commercially viable methods for the early screening of diseases such as lung & breast diseases, alzheimer's, parkinson's, diabetes, liver/heart diseases and more.

The primary avenue of investigation is focused on innovation and advances in the field of mass spectrometry.

The principal opportunity arises from the potential of low-cost, non-intrusive early stage screening in general medical practice which could lead to notable advances in early detection of major life altering diseases.

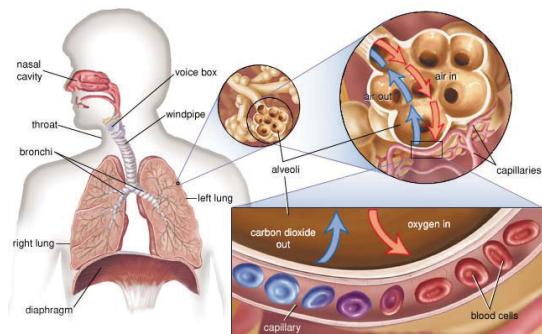
Regular screening using a simple breath test, could lead to significant advancement in remedial treatment protocols targeting major improvements in survivability and life quality.

### Breath Biomarkers Identify Disease

**Molecules in your blood can be measured in your breath.**

- A blood-breath interface in the lungs: alveoli
- Molecules diffuse out of blood and into breath

Breathtec aims to deliver a non-invasive, alternative screening solution for various health-related concerns including Respiratory Infections, Alzheimer's, Parkinson's, liver disease, kidney failure, diabetes, and asthma.



*"This is really a whole new field that has huge potential to revolutionize the way we do medical testing and monitoring. It has profound potential for global health. This is going to change medical diagnosis work."*

**Professor Perena Gouma**, Director,  
SBU Center for Nanomaterials and Sensor Development

### Technology Partners



### Potential screening applications

✓ Alzheimer's	✓ Respiratory Infections
✓ Parkinson's	✓ Sepsis
✓ Diabetes	✓ Traumatic Brain Injury
✓ Heart Disease	✓ Asthma
✓ Liver Disease	✓ And more...

### Recent Corporate News & Events

4/10/15: Company Formed  
1/1/16: Launch with Dr. Rick Yost team and Univ. Florida Patent agreement (FAIMS).  
2/1/16: Commences trading (Canada): CSE: BTI  
2/8/16: Commences trading (Frankfurt): XFR: BTI  
2/22/16: Appoints Industry Veteran Guy LaTorre, as Product Dev and Regulatory Consultant.  
4/4/16: Announces in-licensing & advanced technology acquisition opportunity.  
4/11/16: Enters NA-NOSE licensing agreement with Technion – Israel Institute of Technology.  
4/19/16: Appoints prestigious NA-NOSE developer, Prof. Hossam Haick to administer trials.  
5/19/16: Commences trading (USA): OTCQB: BTHCF  
5/24/16: Successful close of licensing agreement with Technion for development of NA-NOSE.  
6/28/16: Announces start of clinical trials to be held at Innovation Boulevard in Surrey, Canada.

## Yost Research Group - University of Florida

Led by Professor and Head of the Analytical Chemistry Division:

### Richard A. Yost Ph.D., Breathtec Scientific Advisor

- Key patent developed by Yost Research Group at the UFL
- Research focuses on analytical mass spectrometry: instrumentation, fundamentals, and applications
- Dr. Yost is recognized internationally as a leader in the field of analytical chemistry
- The group is a recognized world leader and pioneer in the development of FAIMS
- Recipient 1993 ASMS Award for the invention and patent (along with Prof. Chris Enke) of triple quadrupole mass spectrometer

Dr. Yost has supervised the research of over 100 graduate students, with funding totaling over \$40M from a wide range of sources (including NIH, NSF, NASA, DoD, DHS and USDA)

### Technology

#### Field Asymmetric Ion Mobility Spectrometry (FAIMS)

Compounds (Ions) are separated by mobility

- Function of the size, shape, charge
- Direct, real-time separation
- Continuous sample introduction

### An Ion filter

Only molecules of interest are allowed to be detected.

- Once filtered they can be identified
- It's like a coin sorter, but ions are filtered via electric field

### Commercial Goal

Develop a handheld breath analyzer

- Detection of diseases
- Real-time breath analysis

### Three Key Form Factors

#### ✓ Affordable

- Miniaturized electronics
- Disposable consumables

#### ✓ Portable

- Phase one: desktop
- Phase two: handheld

#### ✓ Adaptable

- Internet connected
- Software updates
- Remote data capable



Proposed Design

*"We expect to have a prototype of the FAIMS device developed in Q3-Q4 of 2016 and will work alongside our partner to advance the technology towards the clinic. We are pleased with the progress our team has made thus far and are encouraged by the early data we are seeing."*

Dr. Michael Costanzo, CEO of Breathtec

## Technion – Israel Institute of Technology

Established in 1912, the Technion is the oldest university in Israel and is among the most selective. Technion's 565 faculty members currently include three Nobel Laureates. The Technion has an impressive record in technology transfer. As of 2011, 424 patents were granted to Technion innovations, with 845 patents pending. Partners include incubators, entrepreneurs, private investors, VCs and angel groups. It has strategic partnerships with Microsoft, IBM, Intel, Philips, Johnson & Johnson, Coca Cola, among others.

### Prof. Hossam Haick, Lead Researcher & Breathtec Consultant

- The F.M.W. Academic Chair
- Head, Laboratory for Nanomaterial-Based Devices (LNBD)
- Director, SNIFFPHOHE: Horizon 2020 ICT Program
- Director, VOLGACORE: EuroNanoMed II Program
- Director, LCAOS: FP7 Health Program
- Department of Chemical Engineering and Russell Berrie Nanotechnology Institute, Technion – Israel Institute of Technology, Haifa, Israel

### Na-Nose Technology In-licensed from Technion

#### Nanoscale Artificial Nose to Detect Specific Medical Conditions

Breathtec licensed for detection indications of Streptococcus; Methicillin resistant (MRSA); Staphylococcus; Enterococcus; Vancomycin resistant (VRE); Pneumococcus; Hemophilus influenza (HiB); Chickenpox; and the Common Cold.

### Overview

Respiratory infections are a leading cause of mortality and morbidity worldwide. These disease conditions lead to considerable healthcare costs, and routine tests may not allow rapid accurate identification of viruses or bacteria. Over-treatments and inappropriate over-use of antibiotics are an ongoing and costly issue. Available tests and methods have limited ability or availability, leading to delays in diagnosis and/or discrimination between various types of the respiratory infection.

### NA-NOSE Technology

Breathtec benefits from:

- Proto-types of novel, cross-sensitive nanowire-based sensors integrated in the 'NA-NOSE', trained to detect target disease related mixtures of biomarkers;
- Novel algorithms that manage 'NA-NOSE' information to safely distinguish between healthy and unhealthy individuals, as well as between different sub-types of disease;
- NA-NOSE' prototype devices, to be tested in clinical studies/environments for diagnosis and research;
- Methods for identification of new biomarkers that are related to different stages of target conditions.



Na-Nose Prototype

The NA-NOSE breath test has been successfully applied in numerous research phase studies for a wide variety of diseases.

## Breathtec Begins Na-Nose Clinical Trials

NA-NOSE trials scheduled for implementation at Innovation Boulevard – Surrey, Canada.



**Innovation Boulevard** is a partnership of health, business, higher education, and government creating new health technologies to improve peoples' lives.

### Breathtec's plan for development activities required for pre, launch, and post commercialization activities;

- Outpatient pilot strep study for detection of throat streptococcus infection and normative data.
- Design/build for device suitable for outpatient point of care use in accordance with regulations for FDA class II/III device.
- Batch production of devices in compliance with ISO13485 standard for FDA and Medical Device Directive 93/42/EEC.
- Start pilot inpatient trial for hospital based infections for MRSA, lower respiratory tract infections (HiB, Pneumococcus, staphylococcus enterococcus and zoster). Tandem outpatient pilot viral study for zoster, and common cold.
- Wider scale Phase 1 strep study trials as required by FDA for premarket approval (assuming no predicate device for 510(k)\* to demonstrate device is safe and effective for intended use of strep throat infection.
- Regulatory clearance of the strep device in USA then EU for strep throat.
- Manufacture point of care device for strep throat.
- Regulatory clearance of the inpatient device in USA then EU for MRSA and lower respiratory infections.
- Regulatory clearance of the outpatient viral device in USA and EU for zoster and common cold.
- Manufacture of point of care device for inpatient and viral device.
- Post-market surveillance strep, inpatient and viral study tracking (likely required).

*\*NB this device may be labelled by FDA as a class III device if there is no predicate at the time of application and this would require a petition to lower class or 'de novo' 510(k)*

*"Our agreement with the Technion grants us the opportunity to collaboratively leverage their extraordinary expertise in the research phase, years of effort, and millions of Euro's already invested in the NA-NOSE project in order to move forward with a plan for commercialization of a new application in the area of disease detection thru breath. This is a game changing and disruptive technology that offers great promise, and we look forward to bringing the NA-NOSE Technology to North America and to rapidly advance it through clinical trials and regulatory approval."*

**Kal Malhi**, Breathtec President

## Effectiveness

### Benefits

- Non-invasive & Non-intrusive.
- Unlike blood or urine tests, a breath test can be conducted almost anywhere, anytime
- Can be performed repeatedly without adverse effects, (unlike X-rays)
- Relatively inexpensive
- Rapid results
- Advances in breath-based tests approved by the FDA

### Results

- Higher Survival Rates
- Ease of Use–Faster Access
- Lower Health Costs

The effectiveness of the 'NA-NOSE' in detecting volatile biomarkers specifically and selectively provides a launch pad for identifying or monitoring other indications of target conditions. The NA-NOSE technology would be suitable for use outside of specialist settings and could significantly reduce budgetary burdens at many regional and national healthcare organizations.

## Corporate Leadership

### **Guy LaTorre**, Chief Executive Officer

Mr. LaTorre brings over 25 years of experience in the development and commercialization of medical devices and consumer products in a startup company environment. Guy was a co-founder and Vice President of Business Development at Novamin Technology Inc. In that role, he formed and managed product development partnerships between NTI and the leading marketers of professional dental products, including Dentsply Corp, 3M Corp, Sultan Healthcare, Sunstar and others until the company was sold to GlaxoSmithKline (GSK) in 2010 for USD \$135 million. Previously, Guy was the Director of Scientific Affairs at USBiomaterials Corp. Prior to that, he was the Laboratory Manager of the University of Florida Advanced Materials Research Center and responsible for the managed transfer of licensed university technologies to private startup companies. Guy has been author or co-author of over fifty scientific publications and holds seven US patents with associated filings worldwide.

### **Kal Malhi**, President and Director

Mr. Malhi is a Canadian entrepreneur and businessman. He is a retired member of the Royal Canadian Mounted Police and President of BullRun Group, a private investment company specializing in early stage business development. His interest in issues of individual rights aligned with public safety through law enforcement initiatives shaped his vision in the founding of Cannabix Breathalyzer, Inc where Mr. Malhi was instrumental in growing the company from a startup to a publicly traded company with a valuation in excess of \$30 million dollars. This successful enterprise broadened his interest in breath analysis and the extraordinary opportunities in the sector. His extensive network of contacts and personal relationships has enabled him to assemble a growing team aimed at unearthing the potential for commercial breath analysis applications as a new and potentially high growth sector.

## Richard A. Yost Ph.D., Scientific Advisor

Dr. Yost, Head of Analytical Chemistry at the University of Florida received his B.S. degree in Chemistry from the University of Arizona in 1974. In 1975 he pursued an NSF graduate fellowship at Michigan State University focusing on electronics and computerized instrumentation. He received his Ph.D. in 1979 and assumed the position of Assistant Professor at UF and went on to become head of the Analytical Chemistry Division. Dr. Yost's research has involved over 100 graduate students funded by over \$40 million in research grants, and has published over 160 papers and 16 patents. Over \$30 billion worth of instruments have been sold based on these patents.

## Prof. Hossam Haick, Consultant

Dr. Haick is a full Professor in Chemical Engineering and Nanotechnology at the Technion Israel Institute of Technology and an expert in the field of nanotechnology and non-invasive disease diagnosis. Dr. Haick is the recipient of the prestigious Marie Curie Excellence Award, ERC Award, and the FP-7 and Horizon 2020 consortium Awards. He is also the recipient of more than 56 international honors and prizes for his achievements. Prof. Haick has published over 170 articles and serves on the editorial board of several peer-reviewed journals, and is a senior scientific advisory member of several national and international companies and institutes. As a consultant to Breathtec, Prof. Haick will guide the company's development of the NA-NOSE disease detection system and design the clinical trials to be undertaken by the company.

## Michael T. Costanzo, Ph.D., Chief Technology Officer

Dr. Costanzo enjoys a passion for analytical chemistry. Over the past five years he has investigated a variety of advanced experimental methodologies and instrumentation with the Yost Research Group at the University of Florida. He utilized UV spectroscopy to help in standardizing procedures for manufacturing respiratory medications, employed novel ion mobility spectrometric techniques and devices to analyze exhaled breath, and performed multiple metabolomics studies of melanoma. He has acquired a vast knowledge of analytical techniques and methodologies. He obtained his Bachelor of Science in chemistry at the State University of New York (Buffalo). Conducted research under Dr. Troy Wood utilizing mass spectrometry to examine products of enzymatic protein digestion in the interest of studying metabolic markers of autism in children. Moved to the University of Florida (2010) for Ph.D. studies and has recently joined with Breathtec Biomedical to propel his bioanalytical research utilizing his background in ion mobility, mass spectrometry, and exhaled breath analysis.

## Raj Attariwala, MD, PhD. Lead Engineer

Dr. Attariwala is a dual board certified Radiologist and Nuclear Medicine physician certified in both Canada and the United States. He received his formal medical training at University of British Columbia with periods of specialized medical training at Memorial Sloan Kettering Cancer Centre (New York), UCLA and USC. He holds a doctorate in Biomedical Engineering from Northwestern University (Evanston, IL). Dr. Attariwala has extensively investigated breath testing applications and efficacy in a related role at Cannabix Technologies Inc. where he developed a breath testing system for drug impairment.

## Contact

**BREATHTEC BIOMEDICAL, Inc.**  
525 Okeechobee Blvd, Suite 1600  
West Palm Beach, Florida, 33401

### General Inquiries:

Telephone: +1 (604) 343-4551  
Email: info@breathtecbiomedical.com

### Media Inquiries:

Kal Malhi  
Telephone: +1(604) 805-4602  
Email: media@breathtecbiomedical.com

### Investor Relations:

CORE Capital Partners Inc.  
Telephone: +1 (604) 805-4602  
Email: investors@breathtecbiomedical.com

For more information:

[www.breathtecbiomedical.com](http://www.breathtecbiomedical.com)



*"Every individual has a breath print that differentiates them from other people, depending on what's going on in their body, and that print can tell us a lot about a person, what they've been exposed to and what disease they have. That's what makes the new field of breath testing so promising, because it is non-intrusive, so there is no risk involved, and you can do it anywhere, in a clinic, in a hospital, anywhere."*

Dr. Raed Dweik, Respiratory Institute at Cleveland Clinic

### Disclaimer

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