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BIOMEDICAL INC

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“The next generation of diagnostic medicine”

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“…breath analysis is the new frontier and the future of medical testing…"

Dr. Raed Dweik
Professor of Medicine,
Director, Breath Analysis Program,
The Cleveland Clinic.

Overview

- Breathtec Biomedical, Inc. (“Breathtec”) was formed to propel research in the area of breath analysis as a medical screening tool.
- Efforts target the development of commercially viable methods for the early screening of diseases such as lung & breast diseases, alzheimer’s, parkinson’s, diabetes, liver, heart and respiratory diseases.
- 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 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.

Recent News & Events

4/10/15: Corporate formation

1/1/16: Launch with Dr. Rick Yost Group and **University of Florida** patent agreement (FAIMS).

2/1/16: Initial Public Offering (Canada): CSE: BTH

2/8/16: Public Offering (Frankfurt): XFRA: 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: Public Offering (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 in Surrey, Canada at **Innovation Boulevard**.

Technology Partners

UF UNIVERSITY of FLORIDA

TECHNION Israel Institute of Technology

INNOVATION BOULEVARD

Fingerprints Identify You | "Breath Prints" Reveal Your Health

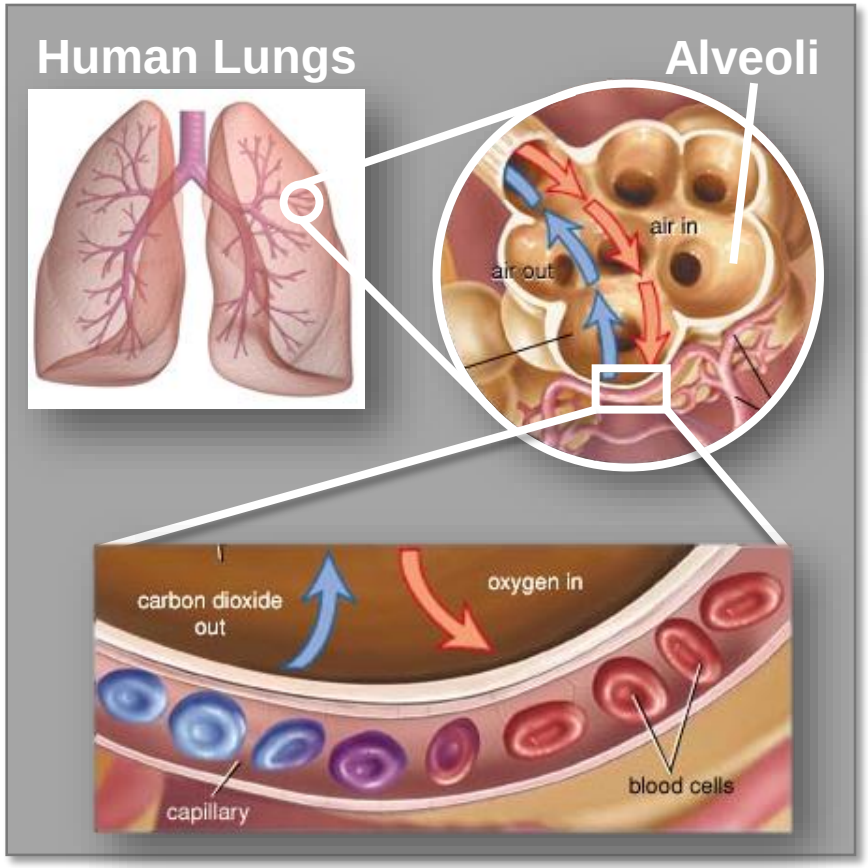
Breath Biomarkers Identify Disease

Molecules in your blood can be measured in your breath.

- There exists a blood-breath interface in the lungs known as *alveoli*.
- Molecules diffuse out of blood and into breath.

Breathtec aims to deliver a non-invasive, alternative screening solution for a wide variety of disease indications.

The technology analyzes distinctive signatures in the breath which can be distinguished using our innovative technology.



Breath Analysis

Advantages

- 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, which can lead to damage from radiation exposure.
- Relatively inexpensive
- Rapid results
- Recent increase in breath-based tests approved by the US Food and Drug Administration (FDA)

Early Screening:

- **Higher Survival Rates**
- **Ease of Use – Faster Access**
- **Lower Cost**

Early identification can mean a better outcome. Many tests today are difficult, painful, expensive and may include lengthy delays.

Breath testing offers rapid screening & ongoing monitoring of:

- Diabetes
- Lung and breast diseases
- Alzheimer's & Parkinson's
- Heart & Liver diseases
- Stomach, respiratory illnesses *and much more…*

Technology Partner

Yost Research Group - UF | UNIVERSITY of FLORIDA

- Led by Professor and Head of the Analytical Chemistry Division: **Dr. Rick Yost.**
- Key patent developed by **Yost Research Group** at the UFL.
- Dr. Yost is recognized internationally as a leader in the field of analytical chemistry, particularly mass spectrometry.
- The group is a recognized world leader and pioneer in the development of FAIMS.
- 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).
- The research has led to over 160 publications and 16 patents to-date.
- Recipient of the 1993 ASMS Award for Distinguished Contribution to Mass Spectrometry for the invention and patent (along with Prof. Chris Enke) of the triple quadruple mass spectrometer.
- Over $30 Billion dollars worth of instruments have been sold based on these patents.

Technology Approach

Field Asymmetric Ion Mobility Spectrometry (FAIMS)

Ions are Separated by Mobility

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

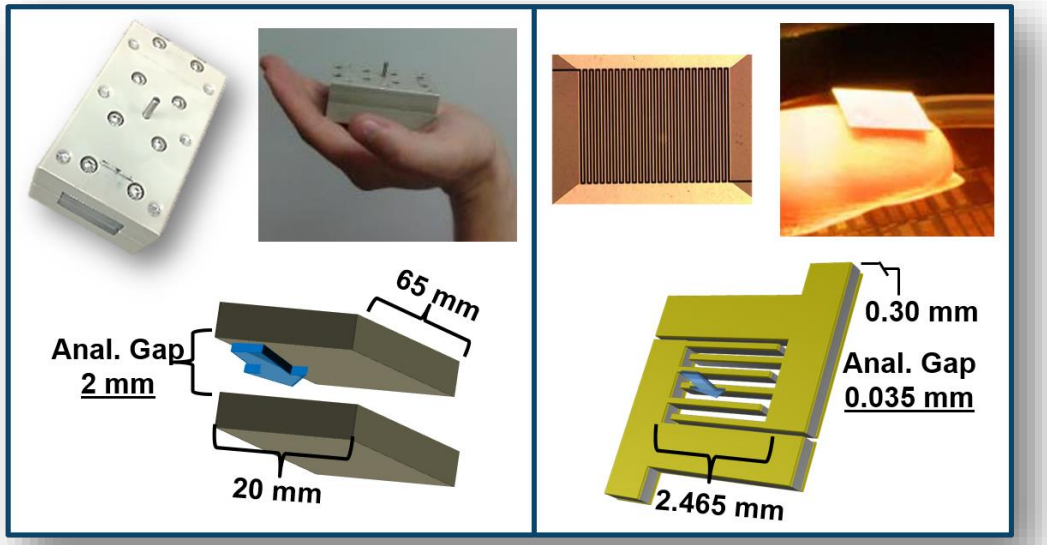
Like a coin sorter, ions are filtered via electric fields. Once filtered they can be identified.

An Ion filter: Only molecules of interest are allowed to be detected

- FAIMS is a mass spectrometry technique that exploits differences in ion mobility at very high electric fields, to separate ions in the millisecond timescale after liquid chromatography separation and prior to introduction to a mass spectrometer.
- **FAIMS** technology allows for miniaturization of breath testing devices and will enable development of non-invasive clinical diagnostic screening aids.
- Commercialization of FAIMS could revolutionize early detection of many deadly diseases.

Technology Targets

- Miniaturization research is advanced.
- Target is a handheld device.
- An interim desktop device could commercialize the technology.
- Specific compounds make disease identification less complex and lower cost.
- Preliminary feasibility offers highly positive results.



FAIMS Receptors

- Breathtec holds an option to acquire key University of Florida **U.S. patent 8,237,118** entitled “Partial Ovoidal FAIMS Electrode.”

Commercial Goal

A Handheld Breath Analyzer

- Detection of diseases
- Real-time breath analysis

Non-invasive & Non-intrusive

- Collection anywhere, anytime
- Rapid results (minutes, not hours or days)
- Minimal handling/storage procedures
- Easy to use
- Relatively simple analysis

Proposed Design

Three Key Form Factors

✓ **Affordable**
- Miniaturized electronics & sensors
- Disposable consumables

✓ **Portable**
- Phase one: desktop
- Phase two: handheld

✓ **Adaptable**
- Internet connected
- Software updates
- Remote data capable

Disruptive Technology

"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

"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…**"

“and that means a lot of better health and welfare, for employers, for insurance, for physicians **... I think it's going to have a great impact, and very soon.”**

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

Technology Partner

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.

TECHNION
Israel Institute of Technology

LEAD PROPONENT

Prof. Hossam Haick, Principal 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 Licensed Technology

A Nanoscale Artificial Nose to Detect Specific Medical Conditions

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.

Breathtec has in-licensed with the Technion – Israel Institute of Technology, to further investigate and develop NA-NOSE disease detection capabilities for the breath detection of: Streptococcus; Methicillin resistant (MRSA); Staphylococcus; Enterococcus; Vancomycin resistant (VRE); Pneumococcus; Hemophilus influenza (HiB); Chickenpox; and the common cold.

NA-NOSE Device

The **NA-NOSE** technology detects the volatile biomarkers of diseases. The nanotechnology-based breath test was successfully applied in numerous research phase studies for a wide variety of diseases. In many diseases, NA-NOSE has shown an ability to distinguish between “healthy” and “disease” states as well as between the different stages of the disease (early vs. advanced).

Specifics of licensed technology:

- Novel, cross-sensitive nanowire-based sensors integrated in the ‘NA-NOSE’ device trained to detect target disease related mixtures of specific biomarkers;
- Novel algorithms to reduce the dimensionality of the ‘NA-NOSE’ information to safely distinguish between healthy and unhealthy individuals, as well as between different sub-types of disease (e.g. different biomarkers of conditions per licensing agreement);
- Provision of ‘NA-NOSE’ prototype devices, to be tested in clinical studies/environments for diagnosis and research;
- Methodology for identification of new biomarkers that are related to different stages of target conditions.

Na-Nose Prototype

NA-NOSE Development

Breathtec has partnered with Innovation Boulevard (City of Surrey, Canada) for Clinical Trial Facilities

Trial Phases:

- Outpatient pilot strep study for detection of throat streptococcus infection and normative data.
- Design build for outpatient point of care in accordance with regulations for FDA class II/III device.
- Batch production 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) [1]) 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).

[1] 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)

Management

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. where he was responsible for identifying and managing the Company's relationships with its key clients in the dental products field, including product development of in-office and at-home use products using the company's proprietary ingredient. 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. which developed and sold synthetic bone grafting products for use in dental, head, neck and orthopedic surgeries. His responsibilities also included product development, manufacturing and business development activities. Prior to USBiomaterials, Guy was the Laboratory Manager of the University of Florida Advanced Materials Research Center where he was 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.

Management

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 also 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.

Management

Richard A. Yost Ph.D., Scientific Advisor

Dr. Yost, Col. Allen R. & Margaret G. Crow Professor and 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 the University of Florida 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.

He serves as a member of the Florida Board of Governors (Regents) and as the Chair of the Advisory Council of Faculty Senates of Florida. He is past Chair of the UF Faculty Senate and served on the UF Board of Trustees. He served as Treasurer and Secretary of the American Society for Mass Spectrometry, and on the editorial boards of The Journal of the American Society for Mass Spectrometry and The International Journal of Mass Spectrometry.

Management

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.

Prof. Haick's ground-breaking research has led to the development of the NA-NOSE nanotechnology-based breath test technology for detecting biomarkers of disease. Certain disease conditions produce chemicals called volatile organic compounds (VOCs), which easily evaporate into the air and produce a discernible scent profile. The Na-NOSE chip detects the unique "signature" of VOCs in exhaled breath. 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.

Management

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

Dr. Costanzo enjoys a passion for science that has directed his career path firmly into the field of 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. During this period 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. Through his efforts, he acquired a vast knowledge of analytical techniques and methodologies and an immense desire for scientific progress.

Previously, Costanzo obtained his Bachelor of Science in chemistry at the State University of New York (Buffalo). During this period he 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. Upon graduation in 2010 he moved to the University of Florida for Ph.D. studies and as a result of his efforts has recently joined with Breathtec Biomedical to propel his own bioanalytical research through the development of revolutionary clinical devices utilizing his background in ion mobility, mass spectrometry, and exhaled breath analysis.

Management

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 is a practicing physician in British Columbia and owner of AIM medical imaging. He has pioneered advances in the field of whole body medical imaging and authored numerous publications and presented at international medical conferences on whole body imaging and cancer detection.

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.

Company Profile

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Addendum A

Disease Indications

Bio Medical Applications

- Lung & Breast Diseases
- Diabetes
- Alzheimer's & Parkinson’s
- Heart Disease
- Respiratory Diseases
- And more…

Anything in your body that is eventually in the blood can be measured in your breath.

It’s just a question of identification and measurement.

Lung/Breast Cancers

Only applicable to UFL FAIMS Technology

- 2011 study reported dogs have demonstrated ability to sniff out cancer in human breath.
- Numerous breath tests have been developed for specific cancers especially lung and breast cancers.
- Research shows breath testing is at least as accurate as breast X-rays routinely used in hospitals.
- Breath test results are available immediately after test administration
- Breath tests may reduce the need for uncomfortable mammograms and limit the radiation exposure during testing
- Early screening may reduce incidences of unnecessary procedures

Scope

- In North America, the lifetime probability of being diagnosed with an invasive cancer is higher for men (43%) than for women (38%). **Improving cancer survival rates requires earlier detection.**
  - Lung 2015 (USA) New patients: 240,390. Deaths: 162,460. Global mortality: 1.59 million (2012).
  - Breast 2015 (USA) New patients: 234,190. Deaths 40,730. Global mortality: 521,000 (2012).

Alzheimer’s & Parkinson’s

Alzheimer's (AD) & Parkinson's (PD):

- AD and PD: the most common neurodegenerative diseases.
- AD is a profound life changing condition and diagnosis is typically late stage
- A shift to earlier identification, could add decades before onset, and means an important step forward for the patient.
- Breath analysis of exhaled volatile organic compounds (VOCs) offers real promise.
- A growing number of studies clearly demonstrates the effectiveness of VOCs analysis in identifying pathologies, including neurodegenerative diseases, offering future potential as cost-effective, fast and reliable biomarkers for AD and PD.

Scope

- AD affects over 26 million people worldwide today
- PD currently prevails in 1.6% of the world population

Diabetes

- Characterised by elevated breath acetone levels. Researchers can use this biomarker as a possible screening tool.
- Current monitoring devices are mostly based on blood glucose analysis. The development of alternative devices that are non-invasive, inexpensive, and provide easy-to-use breath analysis could completely change the paradigm of self-monitoring diabetes.
- The test detects ‘ketones’ which accumulate in the body when insulin levels are low.
- People with diabetes frequently have heart disease and stroke which can lead to risk factors associated with cardiovascular and cerebrovascular disease, the leading cause of diabetes-related death.

“Current testing for diabetes requires a blood test which can be traumatic for children.”

Scope

- 382 million patients globally. By 2035, 592 million (1 in 10).
- Type 2 diabetes mellitus increased by 30.5% between 2001 and 2009 in children and adolescents. Nearly 50% of all childhood diabetes.

Liver Diseases

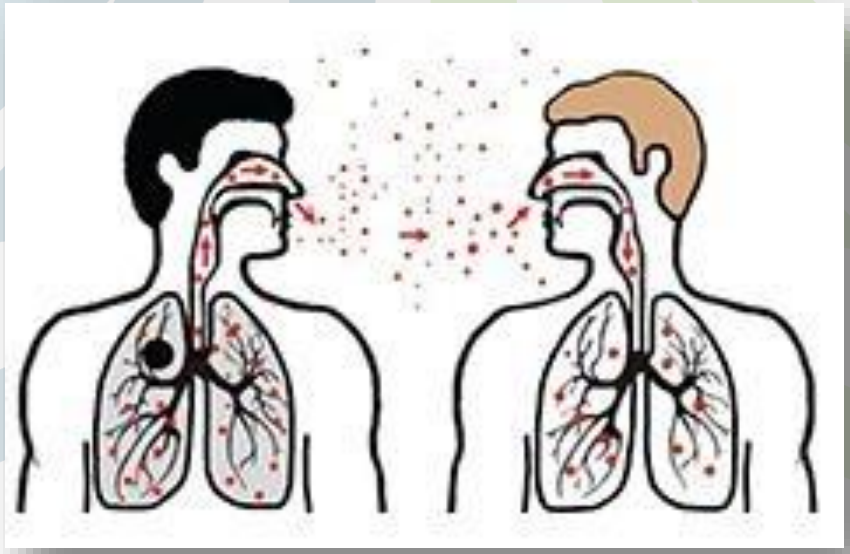
- Breath testing for liver diseases provides a safe, non-invasive method of assessing liver function by continuously measuring the by-product of 13C-methacetin metabolism in the breath of test subjects.
- The test also provides relatively accurate measure of fibrosis and inflammation levels.
- Breath testing avoids traumatic liver biopsy and extensive blood tests.
- In 2013, 29 million in EU and over 30 million in the USA have liver disease (1 in 10 Americans).

"The new test could be used to assess prognosis from the earliest stages of liver disease to cirrhosis, to help doctors determine whether a cirrhotic patient has enough liver function to undergo a surgical procedure, to prioritize patients for liver transplantation, and perhaps to decide when patients need to start therapy for chronic viral hepatitis…"

Gadi Lalazar, M.D.,
Hebrew University-
Hadassah Medical Center,
Jerusalem

Tuberculosis *

- Tuberculosis* (TB) is responsible for more deaths worldwide than any other infectious agent apart from HIV/AIDS (2012).
- There are around 8.6 million new cases, and 1.3 million deaths from TB every year.
- Diagnosis is still mostly performed by trained technicians examining sputum samples under a microscope (WHO tuberculosis factsheet).
- A simple breath test could be instrumental in early detection.*



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* Only applicable to UFL FAIMS Technology

Heart Disease

- An experimental breath test, designed to quickly identify patients suffering from heart failure has demonstrated promise in early trials.
- Study teams have so far been able to correctly diagnose heart failure among newly hospitalized patients with a **100 percent accuracy.**
- The breath test correctly identified all the patients with heart failure, clearly distinguishing them from those cardiac cases where heart failure was not an issue.

Scope

- The leading cause of death for both men and women.
- Every 60 seconds someone dies from a heart disease-related event, about 610,000 Americans (2009). Every 7 minutes in Canada at over 69,500 (2011).
- US and Canadian economic losses exceed $121 billion every year in physician services, hospital costs, lost wages and decreased productivity

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