

Your Breath: Your Health™

Non-Invasive Deep Lung Sampling

Dr. Sterghios A. Moschos FIBMS FRSC
CSO and founder

A spin-out from Northumbria University

Exhaled Breath as a Patient Sample



- Rich in biomarkers
- Health and 40+ Diseases:
 - Cancers
 - Respiratory
 - Liver & metabolic
- Limited use in the clinic
 - Reproducibility
 - Contamination
 - Sample loss
 - Safety

PBM-HALE™ Solves Key Problems:

- Separates and Collects 2 major fractions of breath, simultaneously
 1. Oral and Upper Airway Large Droplets
 2. Fine Aerosols from the Deep Lungs
- In 2 separate vials
 - Distinct sample capture mechanisms
 - No cross-contamination
 - No sample loss
- Highly reproducibly
 - $R^2 = 0.9992$ for deep lung sample
- Deep Lung samples: No intubation or sedation necessary

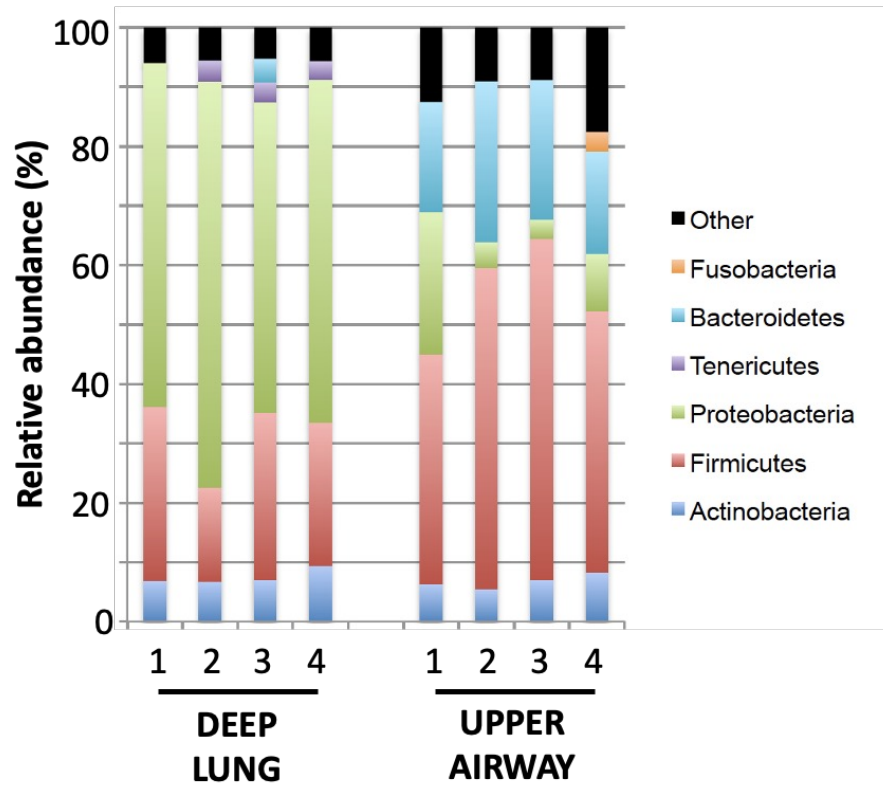


PBM-HALE™

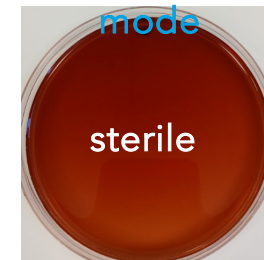
GRANTED PATENTS: WO2017153755A1 & WO2019053423A1

PBM-HALE™ offers access to all pathogen & biomarker classes

Microbiomics



Collection
mode



2 min sampling

Closest samples: lung surgery
(60% proteobacteria)

(Sze MA et al. Am. J. Resp. Crit. Care Med. 2012)

PBM-HALE™ offers access to all pathogen & biomarker classes

- Viruses, bacteria, fungi
- Protein (0.83 µg/ml)
- RNA (6.03 µg/ml)
- DNA (0.50 µg/ml)
- Short-to-long chain fatty acids (C₆-C₂₄)
- Glycans, medications, drugs of abuse

To Open New Opportunities:

➤ 0-5 year old wheeze

- 1/3 of all children <3yo¹
- “No way to test right now”



➤ Elderly lung infections

- 1:25 of all UK hospital admissions⁴
- >120,500 cases among 65yo+ per annum^{5,6}

“Antibiotics and hope for the best”



1. Martinez FD NEJM 1995; 2. Brand PL ERJ 2014; 3. USA, EU, Canada, Japan; China: anticipated higher due to pollution; 4. [BLF, 2016](#); 5. ONS 2019; 6. [LGA 2017](#).

Customers: Paediatric asthma clinicians



"PBM-HALE™ could solve asthma diagnosis in pre-schoolers."

Dr Louise Fleming
Clinical Senior Lecturer
National Heart & Lung Institute

Imperial College
London



NHS
Royal Brompton
& Harefield
NHS Foundation Trust

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“Antibiotics and beta-lactams for the best”



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“Antibiotic resistance for the best”



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**PBM-HALE™ retrieves deep lung samples
without intubation or surgery**

Customers: Respiratory Clinicians



*"PBM-HALE is fit for purpose,
as is"*

*"I need this for critically ill elderly
patients."*

Wonnie Ryu MD
Pulmonary Critical Care Clinician
Assistant Professor at Yale



Customers: Large Pharma

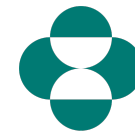


*"The future is in breath
diagnostics"*

"You need clinical validation data"

"Keep in touch"

Dr Terry Fetterhoff
Head, US Chief Technology Officer
Roche Diagnostics



MERCK

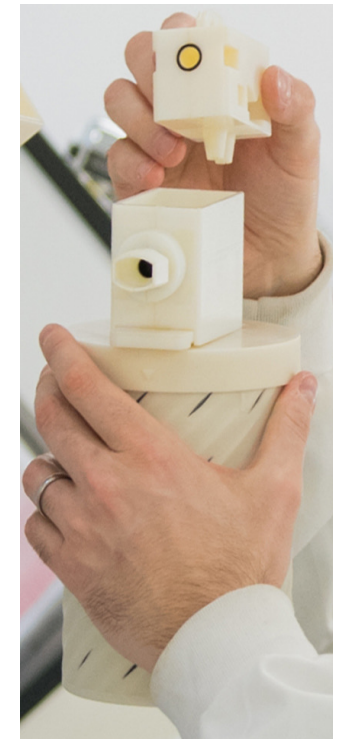


Our achievements:

- **Produced >40 PBM-HALE™ devices in house**
 - CAD / Modelling / 3D printing
 - Re-usable product

- **Demonstrated internally**
 - Operation physics
 - Sampling reproducibility
 - Breadth of biomarkers that can be measured

- **Obtained clinician and end user feedback**
 - Safety
 - Ease of use
 - Compliance
 - Regulatory classification¹



PBM-HALE™

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Competition in Exhaled Breath Sampling



FEATURE	PBM-HALE™	Eco Screen	Rtube	Exhalation Technology	Breath Biopsy	eNose	Turbo DECCS	PExA	BioScreen II	NIOSH Bioaerosol	SKC biosampler ¹
Saliva-free	✓	No	No	No	No	No	No	✓	No	No	No
No contamination	✓	No	No	No	No	No	No	No	No	No	No
No sample loss	✓	No	No	No	No	No	No	No	No	No	No
Reproducible	✓	No	No	✓	No	✓	No	No	No	✓	No
Upper vs lower lung	✓	No	No	✓	✓	No	No	✓	No	No	No
Operator safety	✓	No	No	No	No	No	No	No	No	✓	No
All biomarker types	✓	No	No	No	No	No	✓	No	✓	No	No
Cold chain free	Soon	No	No	No	Yes	N/A	No	No	No	Yes	No
Real time data	Soon	No	No	Yes	No	Yes	No	No	No	No	No
Country	GB	DE	USA	GB	GB	NL	ITA	SE	CN	USA	USA

1. Industry standard

All existing products suffer from one or more of the following limitations:

- Poor sample reproducibility
- Contamination (saliva / ambient)
- Sample loss
- Safety
- Upper and deep lung separation
- and, importantly, inability to analyse all classes of biomarkers.

The Team

➤ **Founder and CSO**
FIBMS

Dr Sterghios A. Moschos FRSC

19 years in industry and academia: biomarker discovery for respiratory disease; design & development of *in vitro* diagnostics & devices.



➤ **Chairman of the Board**

Huw A. Edwards

30+ years global experience in emerging diagnostic technologies; CEO and Chairman experience in life-science companies.



➤ **CEO**

Pete Hotten

25+ years business management experience; with CEO, Board and non-executive roles; skilled IP strategist & commercial negotiator.



➤ **Chief Operating Officer**

Jonathan Brookes

15 years in the medical device industry; specialist in regulatory and quality management; Board level experience in operational leadership.



Investment

A 1.5-year, £750k runway:

Year 1

- Complete manufacturing design elements
- Devices to clinical test sites

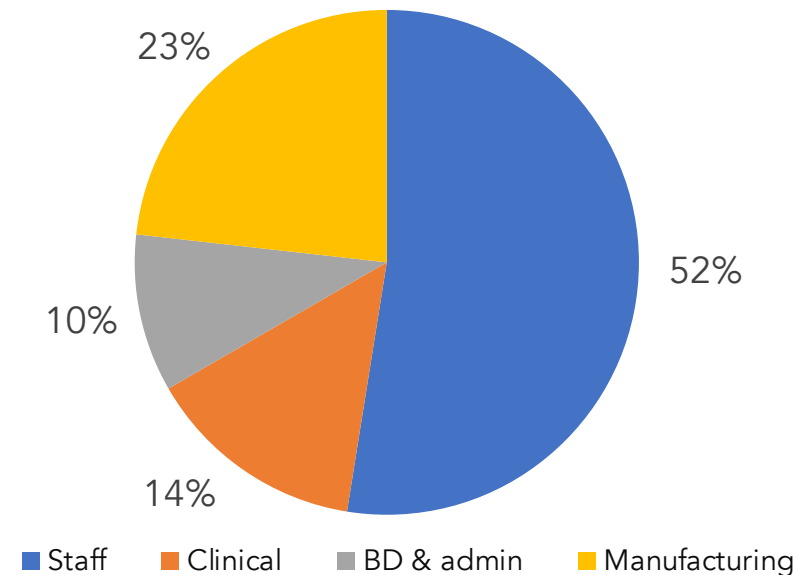
Year 2+

- Deliver regulatory approval (class I/A)
- Ramp up manufacturing & start sales
- Develop key out-licensing partnerships
- Develop further products

Subsequent funding will be needed:

- Grant, loan and equity capital mix.
- Break even forecast: Year 4

Use of funds



Your Breath: Your Health™

An Enabling Platform

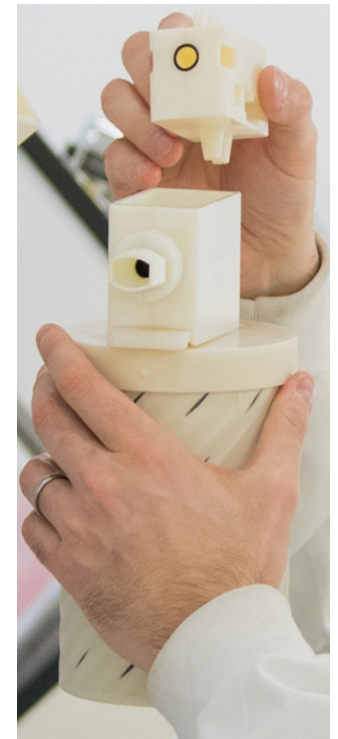
- High value
- Clinical stage
- Disruptive potential

The Business

- Multiple market segments beyond health
- Highly experienced core team with global reach

Your Opportunity

- £0.75m first round to market entry
- Sales within year 2



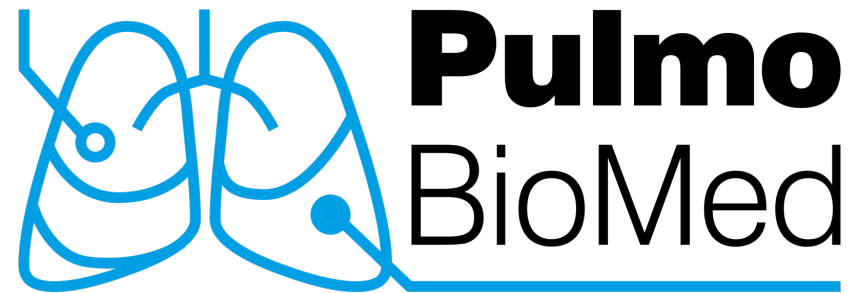
PBM-HALE™



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