PulmonIR 

Developing Medical Devices for Diagnosing & Monitoring Lung Conditions

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MEDIWALES INNOVATION AWARDS WINNER 2016

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Company History

- Early-stage medical device company developing products for the global respiratory diagnostics market
- Forecast to reach US$7.45 billion by 2021. Key disease segments include chronic obstructive pulmonary disease and lung cancer
- A spin-out from Swansea University established in February 2016 and based on the work of Professor Paul Lewis
- Received substantial venture capital investment from:

ipgroup

FINANCE WALES
CYLLID CYMRU

Swansea Innovations
Swansea University Innovation Fund

- £120,000 Welsh Government grant: Health Technology & Telehealth Fund
- Winner of the 2016 MediWales Start-up Award

Source: Respiratory Diagnostics Market by Product & Service - Global Forecast to 2021, marketsandmarkets.com, November 2016

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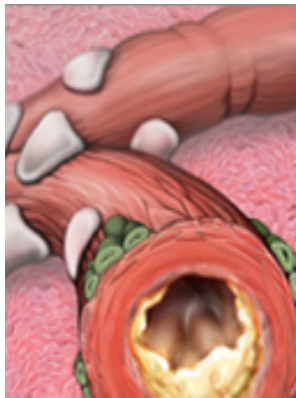
Diagnostic Platform

- Using well-established infrared spectroscopy techniques to analyse sputum produced by patients with respiratory diseases
- Changes in the conformation of molecules present in patient sputum can be detected and are characteristic of particular disease states
- Unique combinations of absorption at particular wavelengths have been identified and protected via patent applications
- These combinations can be identified using proprietary algorithms that deliver a diagnostic result
- Diagnostic applications identified in Chronic Obstructive Pulmonary Disease (COPD) and Lung Cancer
- Users will include patients, health visitors, general practitioners, respiratory clinics, care homes and pharmaceutical companies

COPD – Lead Application

- Collective name for a group of conditions including **emphysema** and **chronic bronchitis** that cause inflammation, making it harder to breathe
- Main cause is **smoking**, but long-term exposure to harmful fumes and dust in the environment also contributes
- No cure, but there is the potential to **manage** the condition to improve symptoms and reduce flare-ups (exacerbations)
- There are 1.2 million people living with COPD in the UK with a further 115,000 people being diagnosed each year
- Accounts for 140,000 hospital admissions and over 1 million bed days each year across the UK
- Nearly 30,000 people die from COPD each year

Source: The Battle for Breath - The Impact of Lung Disease in the UK, British Lung Foundation, 2016



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Lung Cancer

- Most lung cancers develop in the airways, but can also start in the lung tissue itself
- Over 85% of cases occur in current or former smokers, but it can also be caused by passive smoking and exposure to harmful fumes & dust
- 85,000 people living following diagnosis, but only 50% survive for more than 6 months due to late stage discovery
- Over 43,000 people diagnosed with lung cancer every year, with 35,000 people dying from the condition per annum
- Accounts for 45,000 hospital admissions and over 450,000 bed days per year

Source: The Battle for Breath - The Impact of Lung Disease in the UK, British Lung Foundation, 2016

COPD - Current Technology

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Spirometry

- Well-established method – BUT:
- Inaccurate
- Insensitive – 60% accuracy at best

Prototype for Clinical POC

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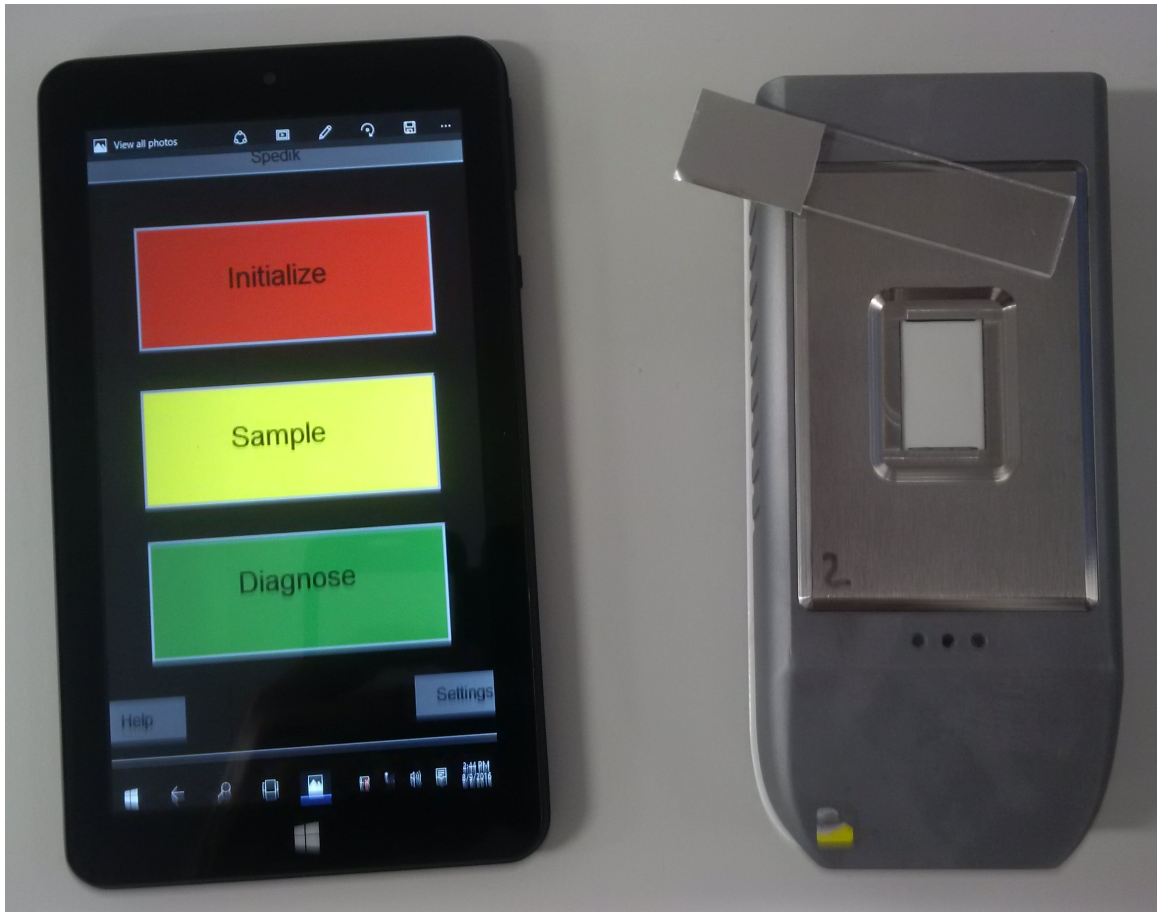

Preliminary Clinical Studies

- High cost - £5,000 per spectrometer
- Prove diagnostic capability
- Demonstrate exacerbation prediction

SPEDIC Trial

Spectroscopic Technology to Predict Exacerbations and Diagnose COPD

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Longitudinal Study

- COPD Exacerbation detection
- Raw sputum
- 50 patients
- 5 sputum samples per week
- 12 months

Prince Charles Hospital, Merthyr Tydfil

Prifysgol Abertawe
Swansea University

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Cwm Taf
University Health Board

Case-Control Study

- COPD diagnostic study
- Raw sputum & urine
- Collection @ time of diagnosis
- 100 newly diagnosed cases
- v
- 100 non-COPD smokers

SPEDIC Trial

Spectroscopic Technology to Predict Exacerbations and Diagnose COPD

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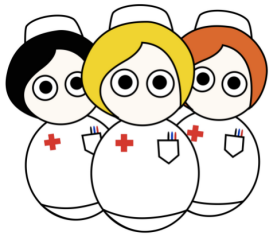
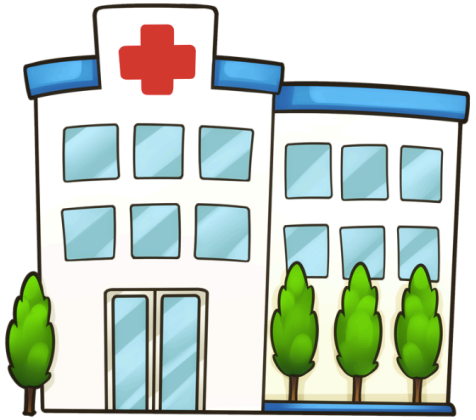
Patients recruited in respiratory clinics



1 x Research Nurse
3 x Healthcare Assistants

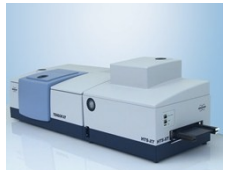
5 sputum samples / patient / week



Prince Charles Hospital

FTIR analysis Swansea University

FTIR analysis



Future Plans

- Focus on **product development** work and on planning and commencing **regulatory clinical trials**
- Currently shortlisted for a new **Innovate UK Investment Accelerator** award that will support product design and demonstrate that a suitable price point can be achieved
- In parallel, plans for the next round of clinical trials are being developed that will focus on securing **CE marking**, **US FDA** and **Chinese FDA** approvals
- **Adoption** and **Sales** into the **global** respiratory diagnostics market
- Aim to create **high quality jobs** in Wales that service both national and **export** markets, delivering **significant returns** for our investors, and enabling **significant healthcare cost savings**

Next: Product Development

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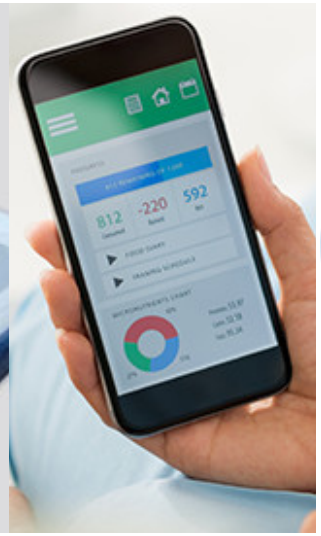

Design for regulatory clinical trials

- Can price point be reached?
- Conduct further clinical trials to obtain necessary data
- Secure CE marking, US FDA and Chinese FDA approvals

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Thank you for your attention

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