Monday, October 16, 2017 8:11 AM ET Exclusive Owlstone Medical CEO driven to make breath test for detecting disease a reality

By Etain Lavelle

Billy Boyle is a man on a mission: He wants to develop cancer diagnostics as advanced as the latest treatments.

In the 19 months since the company he founded has been focused on medical diagnostics, he has attracted the backing of Cancer Research UK and Britain's National Health Service to undertake large-scale clinical trials of a Breathalyzer-like approach to diagnosing disease. His aim? To spot cancer, infectious and inflammatory diseases early enough to save 100,000 lives and \$1.5 billion in healthcare costs by 2020.

"Breath has been around as an interesting curiosity for a long time," said Boyle, CEO of Owlstone Medical. "Without a shadow of a doubt there are thousands of chemicals on the breath which are reflective of an underlying biology and some of those will have utility in different medical applications."



Billy Boyle, CEO of Owlstone Medical

Source: Owlstone Medical

Boyle started working on his Field Asymmetric Ion Mobility Spectrometry, or FAIMS, technology in 2004. He has secured grants worth more than \$25 million from the U.S. military, in addition to \$28 million of external investment to use the technology in the detection of explosives and toxic gases. Having always believed that the approach could be used in medical diagnostics, Boyle was driven to explore his theory — and set up a spin-off to do so — following the loss of his wife due to the late diagnosis of colon cancer.

The experience crystallized his belief that it is not the lack of a new medicines that are to blame for high cancer mortality rates, but the failure to diagnose the disease in time. The earlier a cancer is diagnosed, the more likely its spread can be stalled.

The biggest lever

Big Pharma has been developing targeted medicines based on DNA profiles for some time, with notable examples like AstraZeneca PLC's Tagrisso.

A targeted therapy, Tagrisso received is breakthrough designation from the U.S. regulator on Oct. 9 for first-line treatment of non-small cell lung cancer in patients with a specific genetic profile: The cancer pill is effective in some 40% of the Asian population that express the EGFR-mutated version of the disease, compared with half that number in the U.S. and Europe. Boyle believes such targeted medicines could be more effective if the disease could be spotted before it has spread.

"What's the single biggest lever you could pull in the battle against cancer?" Boyle said. "Early detection is the place where you can make that decisive difference."

Searching for biomarkers that indicate disease has been a possibility with the introduction of DNA sequencing. While some companies are pursuing a blood-based approach known as the initiation biopsy, Owlstone measures volatile organic compounds within the breath that reflect metabolic processes taking place within a person's cells and tissues.

Having secured alliances with the Mayo Clinic and Imperial College London, in addition to setting up clinical trials with the NHS and the University of Warwick, Boyle is hoping to confirm that his breath diagnostic approach works — and is priced affordably.

"For us, it was about trying to tackle all the problems, not just making a sensor which is slightly more sensitive or specific, and really trying to overcome some of the skepticism which had developed around the field — which we had as well, to be honest with you — before we started looking at it," said Boyle.

Yet to be proven

Previous studies have shown only low levels of captured volatile organics in the breath, and Boyle is seeking to prove that the FAIMS technology is more sensitive.

"It's exciting and interesting and yet to be proven," David Grainger

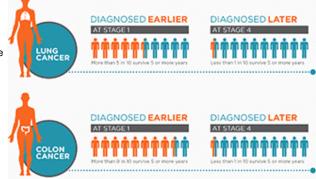
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of Medicxi Ventures, said in an interview with S&P Global Market Intelligence. "One imagines that modern analytical techniques coupled with machine learning ought to be able to do a pretty good job of diagnosing all kinds of things that way. I am sure somebody will at some point, whether it's these guys or someone else," said Grainger, who is not an investor in Owlstone.

Boyle would not be drawn on the timing of a possible IPO and said he has a long-standing cadre of investors. They include Aviva and entrepreneur Chris Toumazou, a professor of engineering at Imperial College London who invests in medical device companies.

"We obviously have sight on an eventual exit but we need to keep our eyes on the near term, driving the trials and development of the technology process," Boyle said.

The Cambridge, England-based group signed a collaboration agreement with AIM-listed 4D pharma PLC on March 7, to apply the biomarkers present in the breath to the development of



Early detection of select cancers

Source: Owlstone Medical

biotherapeutics, an experimental class of medicines based on the trillions of beneficial bacteria living on or in the human body. Boyle says he will be signing more collaborations in the months to come, although he declined to name any potential partners.