



Owlstone Developing Breath Biopsy Tests for Cancer, Asthma as Pharma Services Business Expands

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• *Premium*

NEW YORK (360Dx) – Backed by a fresh round of financing, Owlstone Medical is intensifying its efforts to bring tests for lung cancer, colorectal cancer, and asthma to market on its Breath Biopsy platform in coming years.

The privately held Cambridge, UK-based company [announced earlier this month](#) that it had raised an additional £11 million (\$15 million) to support the commercialization of its platform, which detects volatile organic compound markers in breath. Owlstone Medical has raised \$38.5 million since former parent firm Owlstone Inc. [spun it off](#) two years ago to focus solely on medical applications.



"Since the spinout we've made a great deal of progress building our Breath Biopsy platform ... with the reproducibility required for large-scale clinical trials," CEO Billy Boyle said.

Some of that progress includes gaining a CE mark for ReCIVA, Owlstone Medical's breath collection device, which its clients use to capture biomarkers present in breath using the firm's core field asymmetric ion mobility spectrometry (FAIMS) chip technology.

Boyle said that the CE-marked device is already in use at approximately 100 clinical sites.

The company has also rolled out a service for clients, including pharmaceutical companies, that wish to integrate Owlstone Medical's Breath Biopsy test into their own precision medicine programs, including as a companion diagnostic. It's a business opportunity that the firm believes will develop into a reliable revenue stream.

Boyle noted that the firm's Breath Biopsy Service has been attracting "high-profile pharmaceutical clients," since its launch last year. In November, it announced that [GSK would be using the platform](#) in a Phase II clinical trial for drug candidates in its respiratory disease pipeline.

The company's latest round of funding, therefore, is expected to buttress both its diagnostics pipeline as well as its services business. Yet Owlstone Medical's timeline for delivering tests to market remains dependent on a series of clinical trials taking place, Boyle noted. As such, "no hard dates" exist for when they might hit the market.

For its own tests, Owlstone Medical first relies on mass spectrometry to identify biomarkers of interest in breath, before programming its FAIMS chips to detect specific target compounds of interest.

The most advanced program is Owlstone Medical's test for lung cancer. The UK's National Health Service has funded the Lung Cancer Indicator Detection (LuCID) study to assess the ability of Owlstone Medical's approach for diagnosing lung cancer. Boyle said the trial, which began recruiting participants in October 2015, before Owlstone Medical was even established, aims to enroll up to 4,000 patients across 26 clinical sites in multiple countries before recruitment is slated to end in August 2019.

Patients suspected of having lung cancer will be invited to take part in the study by their general practitioner, supplying about 2.5 liters of breath during 10 minutes of breathing, and the samples will be assessed using Owlstone Medical's approach. The company aims to show via the LuCID trial that its test can identify lung cancer earlier than other methods, with the eventual goal of seeing the platform implemented for large-scale screening for the disease.

Boyle noted that Owlstone Medical last year presented interim data at the European Respiratory Society International Congress in Milan, based on results from the 1,518 patients it had recruited to date. Owlstone Medical will also provide an update on the trial at the International Association for the Study of Lung Cancer's World Conference on Lung Cancer, which will be held in Toronto in September.

"The LuCID Trial continues to progress ... with recruitment going well, and lung cancer will be the area to see the launch of the first Breath Biopsy test," Boyle said.

Meantime, Owlstone Medical is engaged in three other trials related to various indications. The company is working with investigators at Warwick University in the UK to study the use of the Breath Biopsy platform to detect early stage colorectal cancer in urine and breath. Ultimately, they hope to recruit up to 1,400 patients for the study, called InTERCEPT, which commenced in February 2017.

"Recruitment for this trial is going according to plan," said Boyle. The next step for the partners will be to perform an interim analysis of the data they have collected once they reach their first recruitment milestone later this year, he said.

Owlstone Medical is also engaged in STRATA, an asthma stratification study funded through a £148,722 Innovate UK grant. According to Boyle, the aim of STRATA is to use breath-based biomarkers to select the best treatments for asthma patients. Last summer, the company also commenced the PAN Cancer Trial with Cancer Research UK for the early detection of eight different cancers.

"This trial is the latest addition to our clinical pipeline, so we have been working with CRUK and have reached our first milestone to get everything in place to initiate the trial," said Boyle, adding that patient recruitment will begin soon.

Boyle said that it will take "a few years" to complete the trials involving the Breath Biopsy platform, and that progress will depend on the rate at which patients can be recruited that meet the specific needs of each trial. "We are meeting our recruitment milestones for the trials so far, so we are optimistic," he noted.

He said the results that Owlstone Medical has been "encouraged" by the results it has presented publicly so far. "They reflect what we would expect to see in the patient population and also reflect the patient's disease status in terms of the various respiratory diseases that are represented in the population," Boyle said. "This gives us confidence that the VOC biomarker signatures we are observing in the data are reflective of the underlying disease the patient is experiencing."

While Owlstone Medical's diagnostics remain in development, Boyle reiterated that the firm, less than two years out from its founding, is already commercial today via its services arm, as well as through sales of ReCIVA to various clinical partners.

And once its tests do hit the market, Boyle believes that Owlstone Medical is well positioned to compete with other technologies, such as "low-performance" electronic noses that rely on chemical sensors to detect chemicals using pattern recognition, or "extremely expensive" mass spectrometers, considered the standard platform for biomarker detection, that "are half the size of a room." The firm's long-term goal, said Boyle, is to deliver to the market a menu of tests with the best attributes of both that "could be set up en masse for high-throughput analysis."