# **LungLifeAl**

LungLife Al, Inc (AIM: LLAI)

# **Company Summary**

#### **Investment Profile**

- Addressing unmet need for lung cancer, the biggest cancer killer
- 2. Proprietary and patented diagnostic technology based on simple blood draw
- 3. Successful validation study confirms test's strong performance in area of greatest unmet need
- 4. Commercially ready with necessary regulatory approvals and reimbursement in place

#### **Share Information**

Ticker	LLAI
Share Price	17.0p
Shares in issue	30.66m
Market Cap	£5.21m

(Source: The London Stock Exchange, June 2024)

#### **Latest Company Presentation**



Click to watch presentation

#### Major Shareholders (as of June 2024)

Name	%
Simon Raab	13.5
Unicorn Asset Management	12.7
Lombard Odier	9.5
Icahn School of Medicine at Mt Sinai	8.0
Octopus Investments Ltd	6.4
Stifel Nicolaus & Co	5.8
Frederick W Gluck	5.7
SYNO Ventures Master Fund LP	4.5
Livzon Pharmaceutical Group Inc	4.4
Investec Wealth & Investment Ltd	3.9
Accord Data Holdings Limited	3.1

#### (Source: company website)

## **Company Overview**

LungLife AI, based in California, US, has developed a best-in-class solution for early detection of lung cancer, the deadliest cancer globally.

June 2024

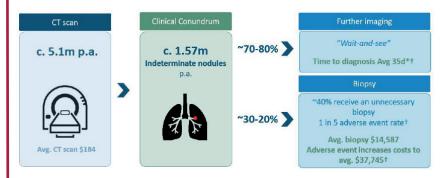
Using a simple blood draw, the Company's LungLB® test is designed to rapidly deliver key information to clinicians who are evaluating cancerous lung nodules found as a result of CT scans.

### LungLB®

Lung nodules are abnormal growths found by CT scan. They are often called "indeterminate" because at the time of discovery it is uncertain what they are - an infection, scar tissue, or cancer. Over 1.5M lung nodules are found every year in the United States, a number that will rise as additional screening is performed.

The current standard of care when such nodules are found is either biopsy or the "wait and see" pathway, asking the individual to return for another CT scan some months later. Neither is optimal – biopsies are dangerous, expensive, and often inconclusive, and "wait and see" for a cancerous nodule reduces potential for cure. There is currently no accurate means of detecting at this early stage whether such nodules are lung cancer.

#### Primary Clinical Pathway



LungLB®, based on a simple blood draw, works to prioritise cancerous nodule work-up and treatment to result in better outcomes for patients, by detecting whether or not an indeterminate nodule is likely to be cancerous or not, reducing the number of unnecessary biopsies and delays in treatment.

The Company concluded a pilot study in 2021 and in January 2024, concluded a larger, multi-site validation study. The data from the study successfully showed that LungLB® performed strongly in participants with smaller lung nodules (<15 mm), where where physicians consistently indicate the greatest unmet need and where cancer is at its most curable stage.

Further details on the study readout are available overleaf.



## Validation study data

In its multi-site validation study, LungLB® demonstrated:

- A strong positive predictive value (PPV) of 81% in patients with smaller nodules (<15mm). Current clinical standards of care generate a ~60% PPV.
- Outperformed the Mayo Risk Model nodule evaluation tool, a commonly used baseline comparator, with an area under the curve (AUC) of 72% for LungLB® vs 62% for Mayo.
- LungLB® also outperformed PET scan, another tool often employed nodule evaluation clinics, by ~21% (81% vs 67% PPV) in the small nodule group.

The validation study enrolled 425 patients across 17 hospital study sites. The strength of the results, particularly in the small nodules group, is enables publication and the execution of LungLife's commercial programme.

### Commercialisation plan

LungLB® was qualified as a Laboratory Developed Test (LDT) in 2019 following the successful receipt of CLIA certification for its clinical lab, meaning that the test can be commercialised immediately. LungLB® has also received approval from the New York State Department of Health ("NYSDOH"), which combined with CLIA gives regulatory authority to offer the test to >90% of the US population.

The initial launch of LungLB® will be through an Early Access Program as an LDT and with follow-on work to support utility studies through its network of clinical investigators and early adopters.













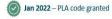


#### ▼ Reimbursement foundation in place













The Company is also seeking an appropriate strategic partner to help LungLB® reach its full commercial potential once it is ready for full launch.

#### **Publications**

To date, two key studies on LungLB® have been published in peer reviewed journals:

Pilot study demonstrating high test performance: <u>BMC Pulmonary Medicine</u>.

Health economics data projecting LungLB® to be cost effective in US healthcare system: <u>Journal of Medical Economics</u>.

### **Management Team**



CEO, Paul Pagano, has over 15 years of experience in the sciences covering chemistry, engineering, and cancer biology. Paul has held positions at Cynvenio Biosystems Inc where he developed and patented a microfluidic

platform for circulating tumor cell enrichment and analysis, and at Amgen Inc. in quality analytical laboratories. Paul was trained at UCLA in translational lung cancer research.

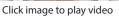


CFO, David Anderson, is a chartered accountant and member of the Institute of Chartered Accountants of England and Wales with over 25 years' experience of senior finance roles. He qualified with Stoy Hayward (now BDO

LLP) and from 1998 to 2009 before becoming an audit partner with Crowe Clark Whitehill (now Crowe UK LLP) from 2010 to 2012. Since then he has held senior finance roles with Strategic Minerals Plc, Hakkasan and C|T Group. He is currently consultant CFO of Verici Dx Plc. David received a BSc (Econ) from the London School of Economics.

## **About LungLife**







Scan for Linktree



8 July 2021 IPO raises £17m at a valuation of £45m

Jan 2022 AMA grants PLA reimbursement Feb 2022
First patients
enrolled in
multi-centre
validation study

Nov 2022 Medicare grants of \$2,030 per test for LungLB® Jan 2024
Positive data
readout of
multi-centre
validation study

2024 Clinical utility studies and Early Access Program to begin

2024 Reimbursement submission

For more information email: LungLifeAl@walbrookpr.com

