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**LungLife AI, Inc.**  
(the "**Company**" or "**LungLife**")

### **Confirmation of Issue Price for Placing & Subscription**

**Fundraising of 9,659,091 Common Shares at 176 pence per share  
and  
Admission to trading on AIM**

LONDON, UK. AND THOUSAND OAKS, CALIFORNIA, US (2 July 2021). LungLife AI (AIM: LLAI), a developer of clinical diagnostic solutions for lung cancer enhanced by artificial intelligence, announces that it has raised approximately £17 million by way of a Placing and Subscription (the "**Fundraising**") at the Issue Price of 176 pence per share.

On Admission, LungLife will have 25,480,790 Common Shares in issue, all of which will be admitted to trading on AIM, and a free float of approximately 50.6 per cent. It is expected that Admission will become effective and that dealings will commence in the Common Shares on AIM at 8.00 a.m. on 8 July 2021 under the ticker LLAI. The Company's ISIN is USU5500L1045 and its SEDOL is BLPJ4G2.

The market capitalisation of the Company at the Issue Price will be approximately £44.85 million immediately following Admission.

Investec Bank plc is acting as Nominated Adviser, Sole Bookrunner and Sole Broker.

### **Key Highlights**

- LungLife is a developer of clinical diagnostic solutions for lung cancer enhanced by artificial intelligence. The Company's diagnostic solutions are designed to make a significant impact in the early detection of lung cancer.
- The Company's technology is a combination of the recovery of rare cells and blood-based biomarkers shown to be altered in lung cancer. The Company employs machine learning to improve biomarker detection, and

intends to build a deep, novel pool of lung cancer-related data for AI-enabled applications designed to improve its diagnostic solutions over time.

- The Company's core technologies are integrated in the LungLB® test, which is intended to be used as a tool to provide physicians with additional information to help in the decision-making process for people with indeterminate lung nodules that may be lung cancer following a CT scan. There are estimated to be over 1.5 million indeterminate lung nodules diagnosed each year in the United States. The LungLB® test may have additional utilities, the most significant of which is likely to be in monitoring individuals for recurrence following surgical removal of cancerous lung nodules.
- The Company has completed a 149 subject pilot study to evaluate the LungLB® test, which showed a well-balanced performance and a Positive Predictive Value of 89 per cent. The Company is now gearing up to proceed to a larger, multi-centre validation study to garner regulatory and reimbursement support and facilitate commercialisation.
- To support development of the LungLB® technology, the Company has entered into various agreements with the Icahn School of Medicine at Mount Sinai ("**Mount Sinai**"), which is an international leader in medical and scientific training and biomedical research and is part of the Mount Sinai Health System. Mount Sinai is committed to building a world-renowned lung cancer programme with expertise in screening, early detection and biomarker research and has recently established its Center of Excellence for Thoracic Oncology programme.

#### **Use of proceeds and reasons for Admission**

The Directors and Proposed Directors believe that raising money in a public market context provides a signal of quality to prospective partners and customers, raises the profile of the business and its diagnostic tests and provides a supportive platform on which to grow the business further through its clinical development and commercialisation plans, as well as supporting in-licensing of additional technologies or selective acquisitions as may be appropriate in the future.

The Directors and Proposed Directors anticipate that the net proceeds of the Fundraising will be sufficient to:

- complete the validation study and commence the utility study of the LungLB® test for indeterminate lung nodules, each of which are required in the context of seeking FDA authorisation and gathering support for reimbursement;
- commence the post-surgical monitoring validation study for the LungLB® test;
- obtain a code and commence pricing and coverage for Medicare reimbursement for the LungLB® test;
- further develop the Company's AI algorithms;
- fund the cash payments due under the Mount Sinai Licence Agreement and Mount Sinai SRA;
- cover general corporate overheads, including marketing and business development, other planned capital expenditure and for general working capital purposes; and
- pay Admission and Fundraising related fees and expenses.

**Paul Pagano, Chief Executive Officer of LungLife, said:** *"We are delighted with the support we have received in the completion of this fundraise as part of our admission to AIM. LungLife now has the capital to advance our AI-enabled LungLB® test for facilitating the early detection of lung cancer.*

*"Lung cancer accounts for nearly a quarter of all cancer-related deaths in the US and we hope that our LungLB® test will provide physicians with additional information needed to identify this disease earlier and reduce its impact. Our admission to AIM and the proceeds from the Fundraising will put the Company in a strong position to continue our work with distinguished partners as we gear up to proceed to a larger multi-centre pivotal validation study and secure regulatory authorisation and reimbursement support.*

*"We are pleased to continue our work alongside Mount Sinai and look forward to updating investors as the development of our LungLB® test progresses."*

#### **Admission Document**

The Admission Document will be published today and will be made available on the Company's website, at [www.lunglifeai.com](http://www.lunglifeai.com)

**For further information please contact:**

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## **Background to the Company**

### **Business overview**

#### **A significantly underserved medical need**

The Directors and Proposed Directors believe that the early detection of lung cancer is a significantly unmet medical need. According to the World Health Organisation, over 2.2 million new cases of lung cancer were diagnosed in 2020 and approximately 1.8 million deaths were recorded in 2020 globally. Nearly 80 per cent. of all lung cancers in the United States are diagnosed in later stages when survival rates are low because the options for curative treatment are then limited. This is in part due to the lack of effective early detection solutions and the fact that lung cancer largely develops asymptotically.

A computed tomography ("CT") scan is the standard method for the early detection of lung cancer and multiple studies including The National Lung Screening Trial in the US showed a significant reduction in lung cancer-specific mortality with CT screening as these cancers were found at an earlier stage when they are more treatable. While the CT scan is highly sensitive (meaning that it is successful in detecting an indeterminate lung nodule), it suffers from low specificity (meaning that many of those indeterminate nodules will be benign or not harmful) and, accordingly, a high rate of false positives (where an indeterminate lung nodule is not lung cancer).

The methods available to physicians to diagnose cancer from an indeterminate nodule are inadequate and potentially result in harm to the patient and significant costs to the healthcare system. The Directors and Proposed Directors believe that the LungLB<sup>®</sup> test will provide significant benefit when added to the clinical care pathway by reducing the number of unnecessary invasive procedures and reducing delays in treatment that may otherwise afford cure.

#### **LungLB<sup>®</sup> test**

The Company expects to launch LungLB<sup>®</sup> in 2023. LungLB<sup>®</sup> is an AI-enhanced, blood-based test that uses circulating tumour cells ("CTC") to stratify cancerous and benign lung nodules identified by CT scan, which is intended to support the physician's decision to biopsy or to monitor non-invasively using additional imaging. The Company intends that the LungLB<sup>®</sup> test will undergo a multi-centre clinical validation study to support a submission for FDA authorisation, as well as a clinical utility study programme to measure the LungLB<sup>®</sup> test's short and long-term impacts on patient health and healthcare costs.

While the price has not yet been determined for the LungLB<sup>®</sup> test, the Directors and Proposed Directors believe that it will be less than one tenth of the cost of a lung biopsy (the average cost of which is \$14,587) and that is before taking into account the additional cost of care of dealing with any adverse event from a biopsy (the average cost of which is \$37,745).

#### **AI, machine learning**

The Company is in the process of developing the LungLB<sup>®</sup> test to utilise machine learning in order to more accurately identify and count CTCs with the aim of reducing operator hands-on time and increasing test performance. Achieving

optimal machine learning performance requires access to large and specific sets of data inputs. The Directors and the Proposed Directors believe that the quality and quantity of cells derived from the Company's pilot study will provide the necessary breadth of sufficiently detailed data to allow its machine learning algorithms to be developed, validated and improved in a timely and cost-effective manner.

The Company intends to deploy machine learning and deep learning and is working with Persistent Systems Limited ("**Persistent Systems**") to develop secure, cloud-based data integration software architecture, and secure, high-performance algorithms for its diagnostic tests.

### **Collaboration with Mount Sinai**

The Company has entered into various agreements with Mount Sinai, which is an international leader in medical and scientific training and biomedical research and is part of the Mount Sinai Health System, a large integrated healthcare provider in the US. The Mount Sinai Health System has approximately 6,600 associated physicians, eight hospitals, more than 300 community locations throughout the New York metropolitan area and receives approximately 4 million out-patient visits per year. Mount Sinai is committed to building a world-renowned lung cancer programme with expertise in screening, early detection and biomarker research and has recently established its Center of Excellence for Thoracic Oncology programme.

Further details of the agreements entered into between the Company and Mount Sinai are set out in the Admission Document.

It is expected that Mount Sinai will hold 9.7 per cent. of the share capital of the Company on Admission.

### **History of the Company**

The Company was incorporated on 30 December 2009 as Cynvenio Biosystems, Inc. and founded on technology licensed from the University of California, Santa Barbara.

From 2010 to 2014 the Company deployed the technology for CTC enrichment and detection for cancer diagnostics with input and funding from pharmaceutical companies and built the LiquidBiopsy® platform. The Company also built a CLIA-certified diagnostics laboratory and offered testing services to physicians with its first products focused on breast and prostate cancers using next generation DNA sequencing.

In 2015 and 2016, the Company evaluated technology from MD Anderson Cancer Center for the early detection of lung cancer, and on 29 June 2017 the Company signed an exclusive licence agreement for the technology, which is the basis of the LungLB® test. Since 2019, the Company made the strategic decision to focus on LungLB® test development and since then completed a 149 subject pilot study with subjects with indeterminate lung nodules, reduced reagent and labour costs, and filed multiple patent applications with a view to protecting additional aspects of the LungLB® test.

### **Directors and Proposed Directors**

#### Directors

#### **Paul Pagano, PhD (aged 37) – Chief Executive Officer**

Paul Pagano is the CEO of the Company and has over 16 years of experience in the sciences covering chemistry, engineering, and cancer biology. He was trained at UCLA in translational lung cancer research and has multiple publications spanning early disease pathogenesis and resistance to targeted lung therapy.

Dr. Pagano has spent the last six years at the Company leading research & development teams in developing clinical diagnostics for lung cancer using liquid biopsy. During his time at the Company, he also developed and patented a microfluidic platform for CTC enrichment and analysis. Dr. Pagano previously worked at Amgen Inc. in quality analytical laboratories.

Dr. Pagano received a B.S. from UC Santa Barbara in microbiology and immunology, and earned a PhD in pharmacology from the David Geffen School of Medicine at UCLA.

**James McCullough (aged 53) – Independent Non-Executive Director**

James McCullough is the CEO of Renalytix AI plc and has experience building emerging technology companies in both the public and private sectors with specific expertise in the lifesciences industry.

Prior to his role at Renalytix AI plc, Mr. McCullough served as CEO of Exosome Diagnostics, Inc., a venture capital backed personalised medicine company developing non-invasive liquid biopsy diagnostics in cancer, which was acquired by Bio-Techne Corporation in 2018. He is a managing partner at Renwick Capital, LLC and also serves on the board of directors of Verici Dx Plc, Kantaro Biosciences, LLC and the GO2 Foundation for Lung Cancer. Mr. McCullough has served on the Board since 2019.

Mr. McCullough received his B.A. from Boston University and an M.B.A. from Columbia Business School.

Proposed Directors

**Roy Davis (aged 64) – Independent Non-Executive Chairman, Chair of the Nomination Committee**

Roy Davis will join the Board conditional upon Admission and it is proposed that Mr. Davis will be the Company's chairman. Mr. Davis has extensive experience spanning medical devices, diagnostics, and the digital healthcare space. He is currently Chairman of Medica Group PLC, the UK's leading teleradiology company, Edinburgh Molecular Imaging Limited, a cancer theragnostic imaging company, Foster & Freeman Limited, a leading forensic imaging manufacturer and RAIR Health Limited, an applied AI and health data company.

Prior to these roles, Mr. Davis served as the chief executive officer of Optos plc, a leading ophthalmology medical device business, from 2008 until June 2016 when he stepped down following the company's acquisition by Nikon Corporation.

Before joining Optos plc, he served from 2007 as chief executive officer of Gyrus Group plc, a leading medical device company, prior to its acquisition by the Olympus Corporation of Japan in 2008, having previously served as COO of Gyrus Group plc from 2003 and a Non-Executive Director since its initial public offering in 1997.

Prior to this, Mr. Davis was the CEO of NTERA Ltd, a nanotechnology company, and before that spent almost 10 years with Arthur D Little Limited, the global management consulting company, where he was Vice President and Global Head of its operations management business. Roy holds a mechanical engineering degree from the University of Southampton and an M.B.A. from the London Business School.

**David Anderson (aged 58) – Chief Financial Officer**

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 was an audit partner in their London office 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 Limited and CT Group International Ltd. Mr. Anderson has been serving the Company as CFO in a consultancy role since 2019 and will formally join the Board as CFO upon Admission. He is currently the CFO and non-board member of Verici Dx Plc on a part-time basis.

Mr. Anderson received a BSc (Econ) from the London School of Economics.

**Sara Barrington (aged 53) – Non-Executive Director**

Sara Barrington will join the Board conditional upon Admission. Ms. Barrington is CEO of Verici Dx Plc and CCO of Kantaro Biosciences, LLC. Ms. Barrington previously served as CEO of the Company from January 2019 to May 2020. She has held numerous senior roles including EVP of Business Operations with Bruin Biometrics, CFO of Exosome Diagnostics, Inc., and CFO at AusAm Biotechnologies. Prior to working in the US, she worked for British Telecom in London in business development and strategy.

Ms. Barrington received her B.A. from Lancaster University and she is qualified as a Chartered Accountant with the Institute of Chartered Accountants in England and Wales. She has also qualified with Chartered Institute of Marketing.

**Andrew Boteler (aged 54)** – *Senior Independent Non-Executive Director, Chair of the Audit Committee and Remuneration Committee*

Andrew Boteler will join the Board conditional upon Admission. Mr. Boteler is a UK qualified chartered accountant and currently Finance Director of Riverford Organic Farmers Limited and Non-Executive Director of Octopus VCT plc. From 2007 to 2019, Mr. Boteler was CFO of Gooch & Housego PLC and in addition was responsible for legal, investor relations and IT. He has had over 25 years working in the manufacturing sector, spending 19 of those years with high technology manufacturing companies. Mr. Boteler is experienced in M&A and fund raising, including management buy-out, trade sales and bank funding.

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The anticipated timetable for Admission may be influenced by a range of circumstances, including market conditions. There is no guarantee that Admission will occur. The price of shares and any income expected from them may go down as well as up and investors may not get back the full amount invested upon disposal of the shares. Past performance is no guide to future performance, and persons needing advice should consult an independent financial adviser. Neither the content of the Company's website nor any website accessible by hyperlinks on the Company's website is incorporated in, or forms part of, this announcement.

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