

**Our purpose is simple.** To be a driving force in the early detection of lung cancer.



# Annual report and financial statements for the year ended 31 December 2021

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# Company information for the year ended 31 December 2021

Directors	Roy Davis (Non-Executive Chairman) Andrew Boteler (Senior Independent Non-Executive Director) James McCullough (Non-Executive Director) Sara Barrington (Non-Executive Director) Dr Paul Pagano (Chief Executive Officer) David Anderson (Chief Financial Officer)
Company Secretary	David Anderson
Registered Office	850 New Burton Road Suite 201, Dover Delaware 19904, USA
Nominated Adviser and Sole Broker	Investec Bank plc 30 Gresham Street London EC2V 7QP
Legal Adviser to the Company	Mayer Brown International LLP 201 Bishopsgate London EC2M 3AF
Auditors	Crowe U.K. LLP 55 Ludgate Hill London EC4M 7JW
Registrar	Link Market Services (Guernsey) Limited Mont Crevelt House Bulwer Avenue St Sampson Guernsey GY2 4HL
Depositary	Link Market Services Trustees Limited 10 <sup>th</sup> Floor, Central Square 29 Wellington Street Leeds LS1 4DL
Financial PR	Walbrook PR Limited 75 King William Street London, EC3N 7BE
Website	www.lunglifeai.com

# Chairman's statement for the year ended 31 December 2021

I am delighted to report on the first annual results for LungLife AI, Inc. since our admission to trading on AIM in July 2021. We have continued to deliver on the Company's objectives and remain committed to creating shareholder value as we proceed with the aim of being a driving force in the early detection of lung cancer through the completion of our LungLB<sup>®</sup> test multi-centre clinical validation study.

#### LungLB<sup>®</sup> test

According to the World Health Organization, over 2.2 million new cases of lung cancer were diagnosed in 2020 and approximately 1.8 million deaths from lung cancer were recorded in 2020 globally. Nearly 80% 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 asymptomatically.

LungLB<sup>®</sup> is a blood-based test that uses circulating tumour cells ("CTC") to stratify indeterminant lung nodules as either cancerous or benign following their identification by CT scan. Biopsy is currently part of the standard care pathway for lung nodules and the LungLB<sup>®</sup> test is designed to support the physician's decision to biopsy only when necessary, or to monitor non-invasively using additional imaging. There are estimated to be over 1.5 million indeterminant lung nodules identified each year in the United States<sup>1</sup> and LungLife's estimated 1 week turnaround from receipt of the blood sample to results can save a significant amount of stressful waiting time for the participant as well as unnecessary costly and often dangerous procedures. In 2021, we completed a 149 participant pilot study in subjects with indeterminate lung nodules which showed a well-balanced performance and a Positive Predictive Value of 89 per cent which we believe will support physician decision making.

#### Progress

We enrolled our first participant in February 2022 in our multi-centre clinical validation study. The multi-centre clinical study will be used to validate the LungLB<sup>®</sup> test performance, looking to repeat the high performance already observed in the pilot study completed earlier in the year. The study will enrol 425 participants across multiple US sites, including MD Anderson Cancer Center, Mount Sinai Hospital in New York City and multiple medical centres of the Veterans Affairs, which we recently announced, involving participants who present with indeterminate lung nodules that would otherwise be scheduled for needle biopsy. This first participant enrolment confirms that the Company is on track to enrol participants over the next 12 months, with study completion expected in Q1 2023.

In November 2021, our clinical laboratory in Thousand Oaks, California was awarded accreditation by the College of American Pathologists (CAP), a significant further independent validation of the quality of our laboratory procedures.

The successful granting of a CPT<sup>®</sup> code marks the first step on the path for commercial reimbursement. In October 2021 we applied to the American Medical Association for a CPT<sup>®</sup> Proprietary Laboratory Analyses (PLA) code and this was granted post year end and is scheduled to become effective on 1 April 2022.

Reimbursement in the US is comprised of three components: code, price, and coverage. CPT<sup>®</sup> codes offer health care professionals a uniform language for coding medical services and procedures, and the CPT<sup>®</sup> code allows clinical laboratories to more specifically identify their tests when billing Medicare and commercial insurers.

<sup>1</sup> 

Gould MK et al. Am J Respir Crit Care Med. 2015 PMID: 26214244.

#### Chairman's statement for the year ended 31 December 2021 *(continued)*

#### AIM IPO

In July 2021 we successfully raised gross proceeds of £17 million as part of the Company's admission to trading on AIM. Since then we have already fulfilled several of the aims that we set out to achieve including commencement of the clinical validation study and obtaining a CPT<sup>®</sup> code for Medicare reimbursement for the LungLB<sup>®</sup> test.

We anticipate that the net proceeds of the fundraise will be sufficient to complete the multi-centre validation study and commence the utility study of the LungLB<sup>®</sup> test for indeterminate lung nodules, commence the post-surgical monitoring validation study for the LungLB<sup>®</sup> test, and take the Company to early revenues in 2023.

We are hugely grateful to the support received from new shareholders who participated in our 2021 fundraise and prior shareholders who had supported the company to that point, and I would like to thank all of our shareholders for their continued support.

#### People

On admission to trading on AIM, David Anderson formally joined the Company as CFO after serving as a consultant since the beginning of 2020.

Paul and David have done a great job of bringing the Company to market and delivering on the aims set out at the Company's IPO. I would like to thank them for their excellent leadership during this dynamic time for the Company.

We also made senior hires in Clinical Trials, Quality, Research and Development and Project Management in the year and post year end bringing the team up to 13 full time, and 2 part time employees.

We also recently announced the appointment of Dr Drew Moghanaki to our Scientific Advisory Board.

On behalf of the Board, I would like to thank our employees, clinical partners, study participants, professional advisors, suppliers and shareholders for their support, and we look forward to providing further updates on progress throughout the current year.

#### Outlook

In addition to the continued enrolment of participants into our validation study, our focus this year is on reimbursement. The three constituent parts are code, price and coverage. We have received our code, the next stage is the pricing process and determining whether we fall under "cross-walk" or "gap fill". We have submitted our application for the New York Clinical Laboratory Evaluation Program ("CLEP") permit and will submit our Breakthrough Device application to the FDA when our advisors indicate the timing is right.

The next two years are incredibly exciting for LungLife and we look forward to updating shareholders on our progress during that time.

Roy Davis Chairman 25 March 2022

# Board of Directors for the year ended 31 December 2021

The Directors of the Company during the year were:

#### Roy Davis - Independent Non-Executive Chairman

Mr. Davis has extensive experience spanning medical devices, diagnostics, and the digital healthcare space. He is currently Chairman of Medica Company 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 Company 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 Company 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.

Andrew Boteler – Senior Independent Non-Executive Director, Chair of the Audit Committee and Remuneration Committee

Mr. Boteler is a UK qualified chartered accountant and currently Finance Director of Riverford Organic Farmers Limited and Non-Executive Director of Octopus AIM VCT plc. From 2009 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 year with high technology manufacturing companies. Mr. Boteler is experienced in M&A and fund raising, including management buy-out, trade sales and bank funding.

#### Sara Barrington - Non-Executive Director

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.

#### James McCullough – 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 life-sciences 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.

# Board of Directors for the year ended 31 December 2021 (continued)

#### Paul Pagano, PhD – Chief Executive Officer

Paul Pagano is the CEO of the Company and has over 17 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 seven 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.

#### David Anderson - Chief Financial Officer

David Anderson is a chartered accountant and member of the Institute of Chartered Accountants of England and Wales with over 26 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 Company 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 also the CFO and non-board member of Verici Dx Plc on a part-time basis.

#### Strategic report for the year ended 31 December 2021

#### Our Strategy and Business Model

LungLife, based in Thousand Oaks, California, US, is a developer of clinical diagnostic solutions for lung cancer, enhanced by artificial intelligence (**"AI"**). Lung cancer is one of the most lethal cancers, accounting for nearly a quarter of all cancer-related deaths in the US<sup>2</sup>, and its global incidence has increased by 37% from 2007-2017<sup>3</sup>. The Company's diagnostic solutions are designed to make significant improvements in the early detection of lung cancer.

LungLife's technology is a combination of the recovery of rare cells and blood-based biomarkers shown to be altered in lung cancer.

The Company's diagnostic, the LungLB® test, 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 (pulmonary) nodules following a CT scan that may be lung cancer, of which there are estimated to be over 1.5 million lung nodules diagnosed each year in the United States<sup>4</sup>. The LungLB® test may have other utilities, the most significant of which is likely to be in monitoring individuals for recurrence following surgical removal of the cancerous lung nodule. The Directors believe that the LungLB® test will provide significant benefit when added to the clinical care pathway by both reducing the number of unnecessary invasive procedures and by reducing delays in treatment from the "wait-and-see" pathway.

The Company has completed a pilot study to evaluate the LungLB® test and is now proceeding to a larger multicentre validation study, ahead of seeking FDA approval for the test. The study, which will enrol 425 participants, enrolled its first participant in February 2022, and is on-track to complete in Q1 2023. Through collaboration with major cancer medical centres, the Directors believe that the Company can effectively commercialise its tests, with the aim of having the commercialised test for sale in the United States in 2023.

#### **Company Overview**

#### A significantly underserved medical need

The Directors believe that the early detection of lung cancer is a significantly unmet medical need due to the fact that lung cancer largely develops asymptomatically. Low dose computed tomography (**"LDCT**") scan, a special form of computed tomography (**"CT**") scan, is the standard method for lung cancer screening. The National Lung Screening Trial, a research study sponsored by the National Cancer Institute in the US (**"NCI"**), showed a 20% reduction in lung cancer-specific mortality with LDCT screening<sup>5</sup>, as these cancers were found at an earlier stage when they are more treatable. A CT scan is also the method by which nodules are found incidentally, when the scan is performed for a reason other than lung cancer screening. While LDCT is highly sensitive (meaning that it is successful in detecting an indeterminate nodule), it suffers from low specificity (meaning that many of those indeterminate nodules will be benign) and, accordingly, a high rate of false positives (where an indeterminate lung nodule is not lung cancer).

There are two general methods by which physicians try to diagnose lung cancer following a CT scan which finds indeterminate nodules. One is by way of biopsy of the indeterminate nodule. However, as a result of these false

<sup>&</sup>lt;sup>2</sup> Lim RJ *et al.* Cancer Epidemiol Biomarkers Prev. 2020 PMID: 32856614.

<sup>&</sup>lt;sup>3</sup> Fitzmaurice C *et al.* JAMA Oncol. 2019 PMCID: PMC6777271.

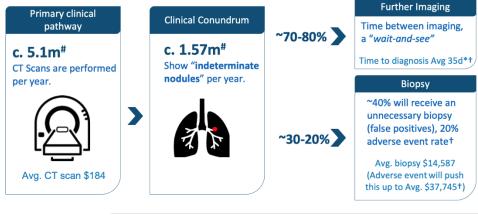
Gould MK *et al.* Am J Respir Crit Care Med. 2015 PMID: 26214244.

<sup>5</sup> Aberle DR et al. N Engl J Med. 2011 PMCID: PMC4356534.

#### Strategic report for the year ended 31 December 2021 (*continued*)

positives, it is estimated that more than 40% of biopsies of indeterminate lung nodules identified by LDCT scans are negative for lung cancer, and nearly 20% of biopsy participants are subject to adverse events such as collapsed lung, internal bleeding, and even death<sup>6</sup>. Follow-up on benign nodules is unnecessarily dangerous and expensive, as biopsy increases medical costs 28-fold, and adverse events from biopsies increase costs an additional four-fold<sup>7</sup>.

The other method, a less invasive "wait-and-see" approach, involves a follow-up CT scan in three to six months to look for patterns indicative of nodule growth; however, this results in significant anxiety for the participant in the meantime as it could result in a delay in treatment that may reduce the effectiveness of curative surgery. It has been estimated that over 5 million CT scans of the chest are performed each year and over 1.5 million indeterminate lung nodules are found each year in the United States alone<sup>3</sup>. Collectively this represents a significant medical need both in terms of participant well-being and impact on health economics.



+Lokhandwala et al (2016), Handy et al (2020) \*Jemal and Fedewa 2017 # Gould et al (2015) \*Average time to diagnosis incorporates both "wait-and-see" and biopsy pathways.

Figure 1: Clinical work-flow for participants found to have indeterminate lung nodules.

#### LungLB® test

The Company expects to launch LungLB® in 2023. LungLB® is a blood-based test 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® test will undergo a multi-centre clinical validation study to support a voluntary submission for FDA approval, as well as a multi-centre clinical utility study programme to measure the LungLB® test's short and long-term impacts on participant health via a reduction of unnecessary procedures, the minimisation of delays in treatment, and the positive impact on healthcare costs. The Company enrolled its first participant in its validation study in February 2022.

Cells within the lungs are exposed to a variety of harm every time a breath is taken: dust and dirt particles, fungal spores, bacteria, and viruses, all of which can cause inflammation and damage to the lungs. Lung tissue has evolved in such a way that a highly motile population of lung cells can migrate to an area of damaged lung tissue and repair it. Cancer is known to "hijack" many normal biological processes and use them to its advantage, and it is believed that pre-cancerous and cancerous lung cells acquire metastatic behaviour from natural motile processes in the lung. These cancer cell precursors are highly motile and are hypothesised to be the reason that lung cancer recurs often despite attempts to cure it via surgery when it is "localised" in early-stage disease. Indeed, circulating tumour cells ("CTCs") have been identified in individuals at-risk for lung cancer up to four years before cancerous nodules were found by CT scan. For this reason, the Directors believe CTCs represent an important biomarker for identifying lung cancer earlier and the reason the LungLB® test shows high performance, balanced sensitivity and specificity when compared to other tests.

<sup>6</sup> 

Lokhandwala T et al. Clin Lung Cancer. 2017 PMID: 27530054.

#### Strategic report for the year ended 31 December 2021 (continued)

The Directors further believe that the LungLB® 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 and participant anxiety from the "wait-and-see" pathway. Unnecessary procedures not only potentially harm participants but are also costly to the health care system. Given that blood tests are a prerequisite to ordering a lung biopsy, the LungLB® test fits easily within the standard care pathway. It is envisaged that physicians will be prompted to order the LungLB® test along with all other prerequisite tests when a lung biopsy is requested. While the test price has not yet been determined for the LungLB® test, the Directors believe that it will be considerably less than 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).

The LungLB® test is comprised of the following steps:

- starts with a blood draw, which is then shipped at ambient temperature (i.e. without the need for refrigeration) to the Company's laboratory in California, which is certified under the US Clinical Laboratory Improvement Amendments of 1988 ("CLIA");
- red blood cells and a subset of white blood cells are removed using antibodies and small magnets;
- remaining cells are then stained with proprietary FISH probes, which are specifically designed and targeted reagents for the LungLB® test, that are applied using well-established laboratory techniques. The FISH probes target regions of the DNA which are amplified when lung cancer is present;
- pictures of the cells stained with FISH probes are taken using a microscope, then sorted on a computer based on the number of FISH signals in each cell, as extra signals are associated with lung cancer, and reviewed by a laboratory technician; and
- following review, the test results are sent to the physician who requested the test, providing a dichotomous result as either "higher risk" or "lower risk" of lung cancer.

This process from receipt of the blood draw through to determining the result of the test takes approximately one week. The Company is building an AI algorithm to help more accurately sort pictures of cells prior to technician review, which the Directors believe will save technician time and effort.

#### **Clinical validation and studies**

Clinical trials for drugs have different phases (commonly referred to as Phase I, II, III, etc.) that achieve different things (for example, safety of the drug or whether or not the drug works). Similarly, different types of clinical studies for diagnostic tests are performed for different purposes. A pilot study is performed to understand if a diagnostic test shows a performance profile that is worth pursuing and to help with future study design. A validation study is larger than a pilot study and seeks to provide robust evidence of test performance and quality for regulatory bodies such as CLIA or the FDA. A utility study is performed to provide evidence that a test improves participant health and/or results in a reduction in healthcare costs and is used by insurance providers to inform reimbursement decisions.

#### **Pilot study**

The Company initiated a pilot study in 2018 that was comprised of subjects with indeterminate lung nodules, who were undergoing biopsy. The purpose of the pilot was to understand two main things: first, if the LungLB® test performed at a high enough level (in terms of sensitivity and specificity) to warrant further commitment; and second, based on that performance, to execute a power analysis in order to make a reasonable estimation of the number of subjects required for a validation study. Blood samples were received from three sites including Mount Sinai and The University of Texas MD Anderson Cancer Center ("MD Anderson Cancer Center"). The pilot study included 149 subjects; 111 with biopsy confirmed cancer and 38 with biopsy-confirmed benign nodules. Using receiver operator characteristics analysis, the sensitivity was determined to be 76.6% (85 of 111 malignant nodules correctly identified) and specificity 71.0% (27 of 38 benign nodules correctly identified), with a positive predictive value of 89%.

#### Strategic report for the year ended 31 December 2021 (*continued*)

#### Validation study

The results of the pilot study have led the Company to believe that the LungLB® test may improve the lives of people at risk for having lung cancer and reduce healthcare costs associated with the current clinical care pathway

Accordingly, the Company has now commenced a larger multi-centre validation study, ahead of voluntarily seeking FDA approval for the test. The study, which will enrol 425 participants across sites including MD Anderson Cancer Center, Mount Sinai Hospital and multiple medical centres of the Veterans Affairs, enroled its first participant in February 2022, and is on-track to complete in Q1 2023. It is intended that results from the multi-centre clinical validation study will support a voluntary submission for FDA approval.

#### Utility study

The Company plans to run a demographically broad and location diverse prospective clinical utility study with participation from a group of US academic medical centres. The clinical utility study is being designed to evaluate short and long-term impacts of the LungLB® test on healthcare costs and clinical outcomes. It is intended that results from the utility study will support test reimbursement from public and private insurers.

#### Commercialisation

The Company intends to continue building its collaborative, multi-centre study network to further develop, validate and commercialise the LungLB® test and its technology platform. It also intends to conduct both validation and utility studies under strict quality assurance procedures with the intention of filing for regulatory review with the FDA and agreeing suitable reimbursement rates. Based on its review of the competitive landscape in lung nodule management, the Directors believe that the LungLB® test will be the first blood-based test for nodule classification submitted to the FDA for regulatory review.

Whilst the LungLB® test can be clinically offered in the US as a Laboratory Developed Test ("LDT") under CLIA and related state laws, the Company intends to seek medical device marketing authorisation for the LungLB® test from the FDA, on a voluntary basis.

The Company has a licensing agreement with Chinese pharmaceutical company, Zhuhai Diagnostics Inc., which subsequently re-branded as SanMed Biotech Ltd ("SanMed"). Under the terms of SanMed's licence, which covers commercialisation of the LungLB® test in China, Hong Kong, Taiwan and Macau (the "SanMed Designated Region"), SanMed is obliged to pay royalties to the Company on LungLB® test sales in the SanMed Designated Region subject to SanMed commercialising the technology. The Company also sells FISH reagents to SanMed. In this year the Company received its first royalty income of US\$88,553.

Further, the Company has not ruled out pursuing a strategy to achieve appropriate regulatory review with European and other Asian agencies to expand the addressable market for its tests, either directly or through partnerships; however, the initial focus will be on the US market. The Directors believe that obtaining FDA approval would provide much greater support for the adoption of its diagnostic tests across clinical disciplines and assist in establishing private third-party and government-based reimbursement than would be the case with the LungLB® test as an LDT.

#### **Revenue strategy**

The Company's revenue is expected to be derived from different sources including:

(a) standard private third-party and government medical insurance coverage and reimbursement for the LungLB® test, which is the Company's near-term focus in respect of revenue; and

(b) programme development and contract fees for Company-delivered services to support pharmaceutical companies with clinical trials in lung cancer. Prior to full-scale commercialisation, the Company intends to focus on getting its first revenues from early adopting institutions, potentially those identified through partnerships, including validation and utility sites.

#### Strategic report for the year ended 31 December 2021 (continued)

#### Company and Company History

The Company was incorporated and registered under the laws of the State of Delaware, US, on 30 December 2009 as a Delaware corporation with the name Cynvenio Biosystems, Inc. The Company changed its name to LungLife AI, Inc. on 1 May 2019.

The Company is domiciled in the State of Delaware, US, with its registered office at 850 New Burton Road, Suite 201, Dover, Delaware 19904. The principal place of business of the Company is 2545 W Hillcrest Drive, Suite 140, Thousand Oaks, California, CA 91320, USA.

The Company's principal activity is research and development of diagnostic products relating to lung cancer.

The principal legislation under which the Company operates is the Delaware Corporation Law.

The liability of the Company's Shareholders is limited.

The address of the Company's website, at which the information required by Rule 26 of the AIM Rules for Companies can be found, is <u>www.lunglifeai.com</u>.

The Company does not have any subsidiaries.

#### **Risks and uncertainties**

Set out below are the risks which the Directors believe could materially affect the Company's ability to achieve its financial and operating objectives and control or mitigating activities adopted to manage them. The risks are not listed in order of significance.

# Positive results from pilot trials and early clinical studies of the Company's LungLB® test are not necessarily predictive of the results of later clinical studies. If the Company cannot replicate the positive results from earlier tests or studies in its later-stage clinical studies, it may be unable to successfully develop, obtain regulatory approval for, and commercialise its diagnostic tests

Positive results from early-stage clinical studies may not necessarily be predictive of the results from later-stage clinical studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused, among other things, by pre-clinical findings made while clinical trials were underway or by "overfitting" the data when the studies are small and unreliably predict future observations. Moreover, pre-clinical and clinical data is often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain regulatory approval. The Company may face setbacks if the participant population in the pilot study does not reflect the participant population in large studies it carries out due to different participant demographics, such as age, smoking history, relative risk for lung cancer and comorbidities that may cause interference with biomarker analysis.

The LungLB® test needs to undergo a large-scale clinical validation to support a submission for FDA approval. Whilst the Company has employed statisticians and advisors to help shape the clinical validation study, there are no guarantees that the study will meet its pre-defined performance endpoints or that the FDA will require additional endpoints or follow-on studies which could result in extended study time and costs. If the Company fails to produce positive results in future clinical trials, the development timeline and regulatory approval and commercialisation prospects for its product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected.

#### Strategic report for the year ended 31 December 2021 (continued)

#### There is no guarantee that physicians will choose to adopt the LungLB® test

The LungLB® test is a test used to stratify cancerous and benign lung nodules and is intended to support a physician's decision to biopsy or to monitor non-invasively using additional imaging. However, there is no guarantee that physicians will choose to adopt the LungLB® test. The frequency of use of the LungLB® test in lung nodules identified during lung cancer screening, lung nodules found incidentally, and recurrence monitoring following lung cancer surgery will initially depend on the treating physician's preference and health status of the participant, which are outside the control of the Company. Low adoption of the LungL®® test by physicians would negatively impact the Company's commercial prospects and its financial results, and its ability to generate significant revenues could be delayed or adversely affected.

# The Company does not have collaborations in place with institutions for utility studies and there is no guarantee that the Company will be able to demonstrate clinical utility of the LungLB® test

Following the clinical validation study, the Company intends to run a clinical utility study to support applications for reimbursement, which is necessary for successful commercialisation of the LungLB® test and to provide further evidence to support marketing claims. In order for a test to be covered by Medicare, it must show the test is "reasonable and necessary" by providing evidence of clinical validity and utility. The results from a utility study aim to measure the LungLB® test's short and long-term impacts on participant health and the impact on healthcare costs and clinical utility is therefore a significant part of the application for reimbursement.

The Company intends to secure support from multiple US academic medical centres for its clinical utility study. However, the Company has not yet identified which institutions, in addition to Mount Sinai, will carry out the utility studies and has not yet entered into the relevant agreements with these institutions. There is a risk that the Company will not be able to secure these collaborations, which would impact the Company's ability to proceed to the utility study stage. Whilst the utility study is not a source of continuing revenue, it is a short-term revenue stream available before the Company is able to generate revenue from sales of the LungLB® test outside of the studies following the validation study and FDA approval.

Furthermore, there is a risk that the Company will not be able to demonstrate the clinical utility of the LungLB® test in early lung cancer detection in a real-world setting, by showing the benefits of the LungLB® test to participants, which would impact the Company's ability to secure reimbursement. If such reimbursement is not achieved, it will make commercialisation of the LungLB® test significantly more challenging and would impact the Company's ability to generate revenue.

# The Company operates in a competitive market and may face competition from competitors involved in lung cancer detection

The Company may face competition from competitors involved in lung cancer detection who may develop more advanced or alternative tests for the early detection of cancer to the LungLB® test. The future success of the Company depends, in part, on its ability to maintain a competitive position, including an ability to further progress through the necessary preclinical and clinical trials to support commercialisation, marketing authorisation where necessary, and coverage and reimbursement.

Demand for the LungLB® test could be adversely impacted by the development of alternative technologies and alternative medical practices specifically intended for the early detection of lung cancer and the role of Al diagnostics in this. Some of the Company's competitors may have access to greater research, development, marketing, financial and personnel resources which may provide commercial advantages to those competitors. New products may be more effective, cheaper or more effectively marketed than the Company's LungLB® test, meaning other companies may succeed in commercialising products earlier than the Company. As a result, there is the possibility that new technologies or products may be superior to, or render obsolete, the technologies and products that the Company is currently developing. A substantial increase in competition for any of these reasons could require the Company to, for example, increase its marketing or capital expenditure or require the Company to change its business model to remain competitive, which may have an adverse impact on the Company's business including its profitability and/or financial condition. While the Company will seek to develop its capabilities in order to remain competitive, there can

#### Strategic report for the year ended 31 December 2021 *(continued)*

be no assurance that research and development by others will not render the Company's products obsolete or uncompetitive. Any failure of the Company to ensure that its diagnostic tests remain up to date with the latest advances may have a material adverse impact on the Company's competitiveness and financial performance.

#### The Company is dependent upon its strategic collaboration with Mount Sinai

The Company is planning on collaborating with Mount Sinai to test and validate its LungLB® test as well as to collaborate on future products. Certain aspects of this collaboration have been formalised in the Mount Sinai CTA, the Mount Sinai Licence Agreement and the Mount Sinai SRA.

Whilst the Company is setting up or intends to set up collaborations for its validation and utility studies with multiple academic institutions, Mount Sinai is viewed as a key collaborator due to its expertise in lung cancer and the amount of useful participant data it holds. Furthermore, as set out in the Mount Sinai MOU, the Company intends to run a clinical utility study to support appropriate applications for reimbursement and believes that Mount Sinai intends to participate in it by enrolling participants with indeterminate lung nodules for evaluation of the LungLB® test in an IRB-approved clinical utility study, which is expected to begin in late 2022.

Whilst the Company has an on-going study with Mount Sinai under the Mount Sinai SRA and the Mount Sinai CTA, the Mount Sinai MOU is non-binding and there is a risk that the Company will not enter into an agreement to undertake a clinical utility study with Mount Sinai in relation to the LungLB® test.

If the agreement which is the subject of the Mount Sinai MOU is not entered into, or if any of the agreements with Mount Sinai that have been entered into are terminated at an early stage, or expire without renewal, this is likely to have a material adverse effect on the Company and its ability to achieve its commercial objectives in the anticipated timeframe, as it might lead to delays in testing and validating the LungLB® test (as a result of, for example, slower participant enrolment) and the future product development.

It is expected that, upon the exercise of the option under the Mount Sinai Licence Agreement, the Company will be granted access, on a de-identified basis, to certain Mount Sinai data related to lung cancer participants. Exercise of the option contained in the Mount Sinai Licence Agreement is conditional on (i) Admission; (ii) clearance by Mount Sinai's information security team; and (iii) IRB, data security and data use approvals. Mount Sinai is under an obligation to use commercially reasonable efforts to obtain such clearances and approvals (other than Admission); however there is no guarantee that Mount Sinai will obtain such clearances and approval. If such clearances and approvals are not obtained, the option would not become exercisable meaning that the Company would not be granted the access to the Licensed Information. Further, given that the Option Fee is non-refundable, neither the cash payment made to Mount Sinai would be repaid nor the Consideration Shares issued to Mount Sinai would be redeemed. This could have a material adverse impact on the Company and its future development programme.

The Company's product development will rely on computer-based interrogation of certain biological and health record data to provide insights that the Company anticipates will have clinical (and therefore commercial) value. The majority of this data is owned and controlled by Mount Sinai. Accordingly, if the Mount Sinai Licence Agreement and/or the Mount Sinai SRA are terminated for any reason, and the Company is unable to source suitable alternate data, the development of the Company's diagnostic test pipeline would likely be curtailed dramatically in the short term, unless and until the Company found a suitable alternative source of data of equivalent quality and quantity.

The rights to any IP developed as a result of the Mount Sinai Licence Agreement will be owned by the Company (provided that such IP does not contain any confidential information which is owned by Mount Sinai). However, there can be no guarantee that the use of Mount Sinai's de-identified participant data will result in the generation of intellectual property that is clinically or commercially valuable. If it does not create valuable intellectual property, it is likely that further product development would be required, including separate validation and utility studies.

These factors relate to a single counterparty collaboration and so any issues arising with that counter-party collaboration may affect multiple factors simultaneously.

#### Strategic report for the year ended 31 December 2021 *(continued)*

#### The Company is reliant on collaborations with various hospitals for its multi-site validation study

The Company is reliant on multiple collaborators for its validation study, in addition to the Company's relationship with Mount Sinai noted above.

The primary objective of the expanded multi-site validation study will be to evaluate the LungLB® test and the Company is reliant upon these sites enrolling participants and collecting blood samples for the validation study.

However, there is no guarantee that the Company will be able to secure the intended collaboration agreements and be able to develop biobanks with these institutions. In addition, even if the collaboration agreements are entered into, the Company will be reliant on these institutions being able to successfully enrol participants and collect the requisite blood samples. If the collaboration agreements are not entered into, or if these collaborations are terminated at an early stage, this is likely to have a material adverse effect on the Company's ability to validate the LungLB® tests, which would lead to a delay in carrying out the utility studies. If the collaboration agreements are delayed, this is likely to impact the accrual rate of study subjects and impact timelines including regulatory submissions and approvals.

#### The Company is reliant on support from CROs

The Company will rely on appointed CROs and clinical study sites to ensure that its clinical studies are conducted properly and within the required timescales. The appointed CRO may also assist the Company with on-boarding additional clinical sites for its validation and utility studies (although this would be at the Company's discretion). The Company intends to appoint an established CRO that will be able to offer the support required for its validation study. Whilst the Company is in advanced discussions with a possible CRO for its clinical validation studies in relation to its LungLB® test, there is no guarantee that the Company will be able to secure a partnership with this CRO (or another CRO) on acceptable terms.

In addition, whilst the Company will have an agreement in place with the appointed CRO, the Company will have limited control over the CRO's activities and costs. If the Company's CRO does not successfully carry out its contractual duties or obligations or fails to meet expected deadlines, or if the quality or accuracy of the clinical data it obtains is compromised due to its failure to adhere to clinical protocols or regulatory requirements, or for any other reason, the Company's clinical studies may be extended, delayed or terminated and the Company may be unable to obtain regulatory approval or successfully commercialise its product candidates. As a result, the Company's financial results and the commercial prospects for its product candidates may be harmed, its costs may increase, and its ability to generate significant revenues could be delayed or adversely affected.

#### There are risks associated with offering the LungLB® test as an LDT that are outside the Company's control

The LungLB® test already has status as an LDT through the Company's CLIA-certified laboratory and the Company may be able to generate revenue from offering the LungLB® test as an LDT. However, there are inherent risks associated with offering the LungLB® test as an LDT that are outside the Company's control, including test uptake, which would have an impact on the amount of revenue the Company could generate.

#### The Company's AI programme for analysing results from the LungLB® test may need to be developed further

The Company's AI programme is developed by a third party. The Company has worked with a third party to develop a machine learning algorithm that automatically analyses the cells and results from blood samples for the LungLB® test. The Company is voluntarily exploring the use of an AI programme built by

#### Strategic report for the year ended 31 December 2021 *(continued)*

a third party as it is able to considerably reduce the analysis time involved, resulting in more efficient review and analysis carried out by the Company's technicians.

# The Company is dependent on other third parties who provide certain resources and services to the Company as the Company has limited resources in the short-term

The Company relies in part on external resources to conduct the research, development, manufacture and clinical testing of its LungLB® test, including in relation to the Company's laboratory systems which rely on software developed by external manufacturers. The future development of the LungLB® test and other diagnostic tests will partly depend upon the performance of these third parties. The Company cannot guarantee that the relevant third parties will be able to carry out their obligations under the relevant arrangements.

In the future the Company may depend on external resources in marketing, sales and distribution of its diagnostic tests. The Company cannot guarantee that it will be able to assign competent partners to conduct these tasks or that these tasks can be completed on the basis of terms which are beneficial to the Company. Additionally, whilst the Directors are responsible for making decisions on behalf of the Company, the Directors will rely to a certain extent on the advice of external professional advisors. There is no guarantee that the Company will receive the correct advice from such advisers.

Disagreements between the Company and any third parties could lead to delays in the Company's research and development programme and/or commercialisation plans. If any third parties were to terminate their relationships with the Company, the Company would be required to obtain development and/or commercialisation services from other third parties or develop the relevant functions internally.

# The Company is reliant upon the expertise and continued service of a small number of key individuals of its management, board of directors and scientific advisors

The Company relies on the expertise and experience of a small number of key individuals of its management (in particular Paul Pagano and David Anderson), Directors and scientific advisors to continue to develop and manage the business of the Company. The retention of their services cannot be guaranteed. Accordingly, the departure of these key individuals could have a negative impact on the Company's operations, financial conditions, its ability to execute the Company's business strategy and future prospects. The Company generally includes non-disclosure provisions in employee and consultant contracts, however the laws of particular states in the US, particularly in California, may limit the enforceability or remedies for breach of such non-disclosure provisions. The Company does not include non-compete provisions that prohibit the individual from engaging in certain types of competition with the Company following the termination of the employment due to the laws of California in relation to non-compete provisions. There is therefore a risk that an employee could terminate his or her employment and compete with the Company if judicial remedies are limited.

#### Strategic report for the year ended 31 December 2021 *(continued)*

Going forwards, the Company will rely, in part, on the recruitment of appropriately qualified personnel, including personnel with a high level of scientific and technical expertise in the industry. The Company may be unable to find a sufficient number of appropriately highly trained individuals to satisfy its growth rate which could affects its ability to develop products as planned.

In addition, if the Company fails to succeed in pre-clinical or clinical studies, it may make it more challenging to recruit and retain appropriately qualified personnel. The Company's inability to recruit key personnel or the loss of the services of key personnel or consultants may impede the progress of the Company's research and development objectives as well as the commercialisation of its lead and other products.

# The Company is reliant on the FISH probes for the LungLB® test, which are manufactured and supplied by a limited number of third parties

The Company is reliant on a third-party manufacturer and supplier of the FISH probes used for the LungLB® test. The Company uses custom-designed FISH probes derived from bacterial artificial chromosome ("**BAC**") clones, for the LungLB® test, which are only available from a limited number of third parties. The Company cannot guarantee that the third party that currently manufactures and supplies these BAC clones will continue to produce the BAC clones and/or continue to supply the Company with the BAC clones.

If this third party was to stop supplying the Company with the BAC clones, the Company would be required to obtain the BAC clones from a limited number of other third parties who supply FISH probes. Whilst the Company could contract with other suppliers of FISH probes to build bespoke FISH probes for the Company, this could lead to a delay in the development, use and/or commercialisation of the LungLB® test and potential increased costs for the Company, and there can be no guarantee that the Company would be able to secure a contract for bespoke FISH probes on acceptable terms.

#### The Company may need to raise additional funding to take advantage of future opportunities

The Company may need to raise additional funding to take advantage of future opportunities. No assurance can be given that any such additional funding will be available or, if available, that it will be on terms that are favourable to the Company or shareholders. If the Company is unable to obtain additional funding as required, it may be required to reduce the scope of its operations or anticipated expansion.

# The Company is reliant upon proprietary IP, exclusive rights to use proprietary IP, and know-how to develop its diagnostic tests and to create and sustain a competitive advantage

The Company relies to a significant extent on patent protection for its inventions. Some of the Company's patent rights have not yet been granted and remain pending applications.

The Company has also entered into a patent and technology licence agreement with MD Anderson in relation to lung cancer FISH probes used in the LungLB® test. Some legacy licensed MD Anderson patents will expire in August 2021. MD Anderson has submitted an application for the patent relating to the lung cancer FISH probes used in the LungLB® test, which the Company will have an exclusive licence to use if the patent is successfully granted to MD Anderson. However, it is not clear what rights might ultimately be granted in respect of IP applications submitted by either the Company or MD Anderson. It is also possible that granted patents might be revoked or challenged in post-grant proceedings. If patent rights were not granted or revoked, this would likely have a material adverse effect on the Company and its ability to achieve its commercial objectives and profitability and may ultimately lead to the Company not being able to develop its LungLB® test or future diagnostic tests.

The Company does not currently own any registered trademarks outside of the United States. Whilst the Company has applied to register the trademarks "LungLife AI" and "LungLB" in the UK, this application is pending approval and may not be successfully registered. The Company therefore does not have trademark protection in any other country and the brand used by the Company may not be available in all the territories in which the Company might want to use the brand in the future. Further, there can be no assurance that the ownership, scope or validity of any

#### Strategic report for the year ended 31 December 2021 (continued)

patents or other IP registered in the Company's name from time-to-time will not be challenged by third parties, nor that the Company has or will have the resources to pursue any infringer of such IP from time to time due to the costs associated with challenging any such infringements.

In addition to the Company's patent portfolio, the Company relies on unpatented proprietary technology, processes and knowhow. Whilst the Company has non-disclosure agreements in place with key customers, suppliers, partners and employees who have access to this proprietary information and knowhow, such agreements may be breached and the Company may face enforcement proceedings, with potentially inadequate remedies.

Further, there can be no assurance that other companies or individuals have not developed or will not develop similar products, duplicate any of the Company's products or design around any patents or other IP held by the Company. Equally, there can be no assurance that other companies or individuals will not acquire substantial equivalent techniques or otherwise gain access to the Company's unpatented proprietary technology or disclose such technology or that the Company can ultimately protect meaningful rights to such unpatented proprietary technology.

#### The Company's strategy involves generating commercially valuable IP that can be protected

The Company intends to further build its IP portfolio. No assurance can be given that any future patent applications will result in granted patents, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company's patents will be held valid if challenged or that third parties will not claim rights in or ownership of the patents and other proprietary rights held by the Company.

#### The Company's use of certain biomarkers may be challenged

The Company uses blood-based biomarker analysis to test and develop its LungLB® test, including CTC biomarkers. The IP landscape for protection of biomarkers for disease identification and management has changed considerably in the US due to recent US Supreme Court rulings and is likely to continue to do so. While the Directors believe that the Company can build IP protection for its diagnostic tests, there can be no guarantee that this IP protection will completely withstand challenge by a competitor, nor can the scope of the Company's claims be assured to provide adequate barriers to competitive entry in and of themselves.

# The Company is at a relatively early stage of operations in relation to lung cancer detection and extensive research and development is required, which subjects the Company to various requirements, and may ultimately be unsuccessful

The Company was incorporated on 30 December 2009, however, is still at a relatively early stage of operations in relation to lung cancer detection and the LungLB® test is still being developed. As a result, the Company must conduct extensive research and development, including clinical evaluations, to establish the safety and effectiveness (including the clinical and analytical validity and clinical utility) of its clinical testing and software products. Research may be governed by various regulatory requirements with regard to human subject protection and other issues which could delay such research or cause it to fail. The LungLB® test is not ready for commercial launch and there are risks in completing the processes required to enable this product to be launched on the market, which may lead to delays and/or it not being possible for the LungLB® test or possible future diagnostic tests to be commercialised. Further, research and development activities may ultimately fail to show the utility and validity of the Company's clinical testing and products and there can be no assurance at this stage that the LungLB® test will deliver the results expected.

#### The Company is subject to research and product development risk

The Company may not be able to develop new products or to identify specific market needs that can be addressed by tests or solutions developed by the Company. Product development will be a key ongoing activity in the Company. However, there can be no guarantee that further products will be developed, successfully launched, or accepted by the market. All new product development has an inherent level of risk and can be a lengthy process and suffer unforeseen delays, cost overruns and setbacks, such as difficultly recruiting participants into clinical

#### Strategic report for the year ended 31 December 2021 *(continued)*

trials. The nature of the diagnostics industry may mean new products may become obsolete as a result of competition or regulatory changes which could have a material adverse effect on the Company's business, results of operations and financial condition.

In addition, research and development may subject to various requirements, such as research subject protection for individuals participating in clinical evaluations of new products, IRB oversight, regulatory authorisations, and design control requirements. Failure to comply with requirements could result in penalties, delay, or prevent commercialisation of products.

#### The Company may not obtain FDA approval for the LungLB® test and/or any future diagnostic tests

The Company intends to apply for FDA regulatory approval for use of the LungLB® test in the US and there can be no guarantee that FDA approval will be granted to the Company. The FDA regulates, among other medical products, "medical devices" which include certain articles intended for use in the diagnosis, prevention, cure, mitigation, or treatment of disease or intended to effect the structure or function of the body. Whilst FDA pre-market approval is not currently required for the Company's LungLB® test to be marketed as an LDT, based on the classification of the device, the legislation may change to require FDA approval of the Company's LungLB® test. In general, devices that require FDA pre-market authorisation may not be commercially distributed or promoted prior to obtaining such authorisation, although they may be distributed and used for the purpose of developing the clinical data necessary to support FDA marketing authorisation, subject to certain limitations. Post-market changes to a cleared or approved device also may be subject to prior review, depending on the scope of the change and its potential impact on device safety and effectiveness.

The FDA also regulates a category of medical devices, called *in-vitro* diagnostic medical devices, or IVDs, that are used in the collection, preparation, and examination of specimens from the human body. The FDA historically has taken the position that tests developed in-house by a clinical laboratory and used to analyse participant specimens meet the definition of an IVD and fall within the agency's regulatory jurisdiction. At the same time, the FDA historically has for the most part exercised "enforcement discretion", i.e., has not required clinical laboratories performing LDTs to comply with IVD device requirements. In the past, the FDA has signalled intent to modify its enforcement discretion policy with regard to LDT regulation, and in 2014 proposed a regulatory framework for LDTs, which it abandoned before implementation in 2016. It is possible, however, that at any time, the FDA may take further steps with respect to asserting regulatory authority over specific LDTs, classes of LDTs, or LDTs generally. It is also possible that Congress will enact legislation directing the FDA to regulate LDTs. Either of these scenarios would drastically change the regulatory landscape for these tests.

Failure to comply with applicable pre- and post-market device requirements can result in a determination by the FDA that a device is "adulterated" or "misbranded" in violation of the US Federal Food, Drug, and Cosmetics Act. The statute provides for a number of penalties, including seizure, injunction, criminal, and civil monetary penalties, for the sale or distribution of adulterated or misbranded devices.

The Company may apply for Breakthrough Designation. If the Company is unsuccessful in obtaining Breakthrough Designation, it would not be eligible for faster review with the FDA. Both an application for Breakthrough Designation and FDA submission are independent, voluntary processes and would not prevent the Company from commercialising the technology. However, the Directors believe that FDA clearance would support test adoption.

However, there is no guarantee that the Company will receive Breakthrough Designation or that it will receive FDA clearance. If the Company cannot secure Breakthrough Designation and FDA clearance, the Company will be at risk for not receiving test reimbursement revenue while seeking coverage, and thus revenue would be delayed.

#### Strategic report for the year ended 31 December 2021 *(continued)*

# The Company may not obtain certain other regulatory approvals for its diagnostic products, including necessary laboratory licensing and approval for laboratories and tests

The Company is currently in the process of applying for NYS CLEP regulatory approval for its clinical laboratory and the LungLB® test for use in participants from NYS. NYS CLEP approval will be necessary to run a clinical utility study using subjects from Mount Sinai in NYS. While it is possible that the Company could partner with institutions in jurisdictions for which its current CLIA licence allows, the inability to work with Mount Sinai could result in delays in study completion.

The Company may also need to comply with regulations regarding safety, quality and efficacy standards in order to market its LungLB® test and future diagnostic tests. These regulations, including the time required for regulatory review, vary from country to country and can be lengthy, expensive and uncertain. While efforts will be made to ensure compliance with required standards, there is no guarantee that any products will be able to achieve the necessary regulatory approvals for commercialisation of that product in any of the targeted markets and any such regulatory approval may include significant restrictions on the uses for which the Company's products can be promoted and used. In addition, the Company may be required to incur significant costs in obtaining and/or maintaining applicable regulatory approvals.

Delays or failure in obtaining regulatory licensure or approval for facilities, LDTs, or products through any applicable agency or governmental authority would likely have a serious adverse effect on the value of the Company and would negatively impact its financial performance. Such delay or failure may ultimately result in the Company becoming unviable.

# The Company's failure to maintain compliance of its clinical laboratory operations with applicable laws could result in substantial civil or criminal penalties

The operation of a clinical laboratory by the Company will be in a highly regulated environment which, among other things, will require maintaining compliance with CLIA certification and state clinical laboratory licensing requirements. Failure to maintain compliance with these requirements may result in a range of enforcement actions, including certificate or licence suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties and criminal sanctions. Such failure may also result in significant adverse publicity. Any of these consequences could limit or entirely prevent continued operation of the Company and therefore impact its financial performance.

# The Company is subject to various health regulatory laws pertaining to fraud and abuse and related matters, and any failure to comply with such laws could result in substantial civil or criminal penalties

The Company's employees, independent contractors, consultants, and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for the Company and harm the Company's operations and reputation.

The Company is exposed to the risk that the Company's employees, independent contractors, consultants, and collaborators may engage in fraud or other misconduct to comply with manufacturing standards the Company has established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-US regulatory authorities, to report financial information or data accurately or to disclose unauthorised activities to the Company. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to the Company's reputation. It is not always possible to identify and deter misconduct, and the precautions the Company will take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Company from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws, standards or regulations. If any such actions are instituted against the Company, or the Company's key employees, independent contractors, consultants, or collaborators, and the Company is not successful in defending ourselves or asserting the Company's rights, those actions could have a significant impact on the Company's business and results of operations, including the imposition of significant

#### Strategic report for the year ended 31 December 2021 *(continued)*

criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, additional reporting requirements and oversight if the Company becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the Company may be required to curtail or restructure the Company's operations.

# The Company will be reliant on multiple information technology systems, which may be affected by unanticipated damage, disruption or shutdown

Once developed, the Company will be reliant on multiple information technology systems, which will be integral to the provision of the LungLB® test and other future diagnostic tests. Any damage, disruption or shutdown due to problems with upgrading or replacing software, power outages, hardware issues, viruses, cyber-attacks, telecommunication or connectivity failures, human error or other unanticipated events that effect the Company's information technology systems may have a significant impact the Company's ability to provide its diagnostic tests, on a short or longer-term basis. Although the Company plans to have appropriate safeguards and backup systems in place, including those provided by its suppliers, there can be no guarantee that such safeguards and systems will adequately cover all risks of damage, disruption or shutdown or whether the Company's insurance policies would cover any adverse effects of such events on the Company's business operations and overall financial position.

# The Company's failure to prevent a data breach would result in serious reputational damage to the Company and may result in civil or criminal lawsuits and associated penalties

The Company takes its responsibility to maintain participant confidentiality and protect participant data extremely seriously. By its nature, the de-identified data that is being processed is highly sensitive and includes genetic and demographic information, the processing of which is subject to the most onerous obligations of applicable data protection legislation. If, due to a technical oversight or malicious action by an employee or third party, the privacy, security or integrity of the data were compromised, the Company would be obliged to report such breach once it became aware under applicable laws and regulations such as HIPAA or other state specific laws.

Depending on the nature and extent of the breach, the Company may become subject to a regulator investigation, which would divert time and financial resources from the day-to-day operation of the business and may result in civil or criminal lawsuits and financial penalties as well as adverse publicity. If third parties and/or customers of the Company become aware of such breaches, they may opt to cancel existing contracts or not enter new contracts with the Company, reducing revenue. The Company may also be required to personally inform the participants whose data was released or accessed as a result of a data breach, which may increase the severity of the reputational damage and may lead to participants revoking their consent for the data to be used by the Company. To mitigate the risk of a data breach or related issue, the Company will employ technical security measures to protect data and work closely with its data providers to ensure that each party understands its obligations to protect data.

# The outbreak of epidemics or pandemics, such as COVID-19, may disrupt and/or otherwise negatively impact the operations of the Company, third party suppliers and/or its customers, and may result in the Company's core business being put on hold as viral testing is not a core business of the Company

The Company's core business could be materially and adversely affected by the outbreak of a widespread health pandemic, such as COVID-19 or similar. The occurrence of a prolonged epidemic or pandemic or other adverse health developments in the US or elsewhere in the world could materially disrupt the Company's business and operations, including temporary suspension or delay of clinical trials and testing, closure of laboratories, or delays to regulatory submissions and approvals. The Company's operations could also be disrupted if its employees, customers and suppliers contract such a virus. The Company's revenue and profitability could be adversely affected as a result and the measures the Company can take to mitigate such a risk are limited given the nature of epidemic or pandemic outbreaks and inherent uncertainty.

#### Strategic report for the year ended 31 December 2021 *(continued)*

# Unexpected closures of the Company's laboratory in California, or unforeseen damage to the Company's laboratory equipment, may occur which could result in disruptions to the Company's operations

The Company is reliant on the performance and availability of its CLIA-certified laboratory and laboratory equipment. The Company may not be able to access its laboratory as a result of events beyond the control of the Company, such as extreme weather conditions, flood, fire, theft or terrorist action. An unexpected closure of the

Company's laboratory in California, or unforeseen damage to the Company's equipment which it relies on to use, test, evaluate and develop the LungLB® test, could result in disruptions to the Company's operations, including delays to the development of the LungLB® test, and could lead to increased costs for the Company associated with the closure of the laboratory and/or damage to the equipment

#### Financial Performance

The financial performance of the Company in the year to 31 December 2021 reflects the IPO which took place on 8 July 2021 and involved the conversion of Convertible Loan Notes and existing shares prior to the Admission of the new common shares onto AIM.

#### Statement of Comprehensive Income

The loss for the year of \$7,444,188 is after charging a portion of the expenses incurred on the share issue of \$1,101,370, disclosed as exceptional, with the balance of expenses of the share issue of \$1,000,354 charged directly to reserves. The loss excluding this exceptional item was \$6,342,818.

The Company generated revenues of \$195,566 comprising royalty income from its sub licensee in China of \$88,553 and consumable sales of fluorescent in situ hybridisation (FISH) probes of \$107,013 to the same sub-licensee. The royalty income represents the first such income under the sub licence calculated at 6% of underlying sales. In turn the Company pays a 6% royalty on this income to MD Anderson Cancer Center.

The largest cost incurred in the year was employee expenses (\$1,760,012) followed by research and development costs (\$1,343,132), being those external costs incurred in the development of our LungLB® test and AI algorithm.

Other operating income relates to payment received under the US Government Paycheck Protection Program, akin to the UK furlough scheme. This represented a one time loan that was subsequently forgiven in full. Finance expense of \$309,327 related to interest charged on the Convertible Loan Notes, which formed part of the balance on the Notes subsequently converted into new common shares at the time of the IPO. The balance of \$107,601 reflects the charge for lease liabilities, being leases for certain tangible assets and the leasehold premises occupied by the Company.

#### Statement of Financial Position

Cash at the end of the year was \$14,628,351, reflecting the net proceeds of the AIM admission of \$21,342,405, payment of \$1,800,000 to the Icahn School of Medicine of Mount Sinai ("Mount Sinai") under the terms of the License Agreement with Mount Sinai, and working capital for the year. The payment of \$1,800,000 together with the 1,656,888 consideration shares issued to Mount Sinai at issue price of 176p constitutes the intangible asset of \$5,818,359. The option fee gives the Company access in the future to the de-identified participant records held by Mount Sinai to assist in the development of future products. As this asset is therefore not currently being utilised no amortisation has been charged to date.

Extension to the lease on the Company's premises and financing of a further microscope gave rise to movement on right of use assets and lease liabilities.

#### Strategic report for the year ended 31 December 2021 (continued)

#### Financial Performance (continued)

#### Statement of Cash Flows

The net outflow from operating activities was \$7,538,876, funded in part by the gross proceeds from the AIM admission of \$23,444,129 and in the period before the AIM admission \$1,612,421 of new Convertible Loan Notes. These Notes were converted in full as part of the Company's reorganisation prior to the AIM admission. The net inflow of cash in the year was \$14,500,723 contributing to the closing cash balance of \$14,628,351.

#### Stakeholder engagement

Although not required the Directors consider that, in line with best practice, they conduct their duties and, act in a way they consider, in good faith, would be most likely to promote the success of the Company for the benefit of its members as a whole, and in doing so have regard to a range of matters when making decisions for the long term. Key decisions and matters that are of strategic importance to the Company are appropriately informed by the following factors Identified in section 172(1)(a) to (f) of the Companies Act 2006 which requires each Director to act in the way he or she considers would be most likely to promote the success of the company for the benefit of its members as a whole, with regard to the following matters:

- (a) the likely consequences of any decision in the long term
- (b) the interests of the Company's employees
- (c) the need to foster the Company's business relationships with suppliers, customers and others.
- (d) the impact of the Company's operations on the community and the environment
- (e) the desirability of the Company maintaining a reputation for high standards of business conduct; and
- (f) the need to act fairly between members of the Company.

The Company's activities and progress regarding these matters since our IPO on 8 July 2021 have been described above in the other sections of the Strategic Report, and in the Directors' Report and Corporate Governance Statements below.

This report was approved by the Board of Directors on 25 March 2022 and signed on its behalf by:

Paul Pagano Director

#### Directors' report for the year ended 31 December 2021

The Directors present their report on the affairs of LungLife AI, Inc. (the "Company") and its subsidiary, referred to as the Company, together with the audited Financial Statements and Independent Auditors' Report for the year ended 31 December 2021.

#### **Principal activities**

The main activity of the Company is a developer of clinical diagnostic solutions for lung cancer.

#### **Results and dividends**

During the year ended 31 December 2021 the Company recorded a loss after tax of US\$7,444,188 (2020 – loss US\$4,839,023) and a net cash outflow from operating activities of US\$7,538,698 (2020 – US\$2,874,025)

The Directors do not recommend the payment of a dividend.

#### Going concern

The Company is in the development phase of its business and has not generated any revenues beyond the sale of consumables and royalty income. At 31 December 2021 the Company has available cash resources of \$14,628,351.

In considering the appropriateness of this basis of preparation, the Directors have reviewed the Company and Company working capital forecasts for a minimum of 12 months from the date of the approval of this financial information. Based on their consideration the Directors have reasonable expectation that the Company has adequate resources to continue for the foreseeable future and that carrying values of intangible assets are supported. Thus, the adoption of the going concern basis of accounting in preparing this financial information is considered appropriate.

#### **Political donations**

The Company made no political donations in the year.

#### Future developments

The Company's future developments are outlined in the Strategic Report on pages 6 to 21.

#### Financial risk management

Financial risk management policies and objectives for capital management are outlined in the principal risks and uncertainties section of the Strategic Report on pages 10 to 20 and in note 5 to the financial statements.

#### **Directors' indemnities**

The Company has made qualifying third-party indemnity provisions for the benefit of its Directors, which were made during the year and remain in force at the date of this report.

#### Events after the reporting year

There have been no events since 31 December 2021 that require disclosure in these financial statements.

#### Directors' report for the year ended 31 December 2021 *(continued)*

#### Directors

The Directors of the company throughout the year and to the date of this report were:

Simon Raab (resigned 1 July 2021) Frederick Gluck (resigned 1 July 2021) Justin Xiang (resigned 1 July 2021) Jenny Liu (resigned 1 July 2021) Dennis Stubblefield (resigned 3 May 2021) Jeffrey Kob (resigned 3 May 2021) Roy Davis (appointed 8 July 2021) Andrew Boteler (appointed 8 July 2021) James McCullough Sara Barrington (appointed 8 July 2021) Dr Paul Pagano David Anderson (appointed 8 July 2021)

#### **Directors' shareholdings**

The holdings in the share capital of the Company of those Directors serving at 31 December 2021 and as at the date of signing of these financial statement, all of which are beneficial, were as follows:

	On 31 December 2021 Ordinary Shares of £0.001 each
Roy Davis	14,204
Andrew Boteler	5,681
James McCullough	-
Sara Barrington	-
Dr Paul Pagano	-
David Anderson	-

All of the shares were acquired during the year.

#### Substantial shareholdings

As of 28 February 2022, the following interests in 3% or more of the issued Ordinary Share capital had been notified to the Company:

		Percentage of issued
Shareholder	Number of shares	share capital
Simon Rabb	4,148,293	16.3%
Icahn School of Medicine at Mount Sinai	2,469,842	9.7%
Octopus Investments Limited	1,968,750	7.7%
Unicorn Asset Management	1,750,000	6.9%
Syno Ventures Master Fund L.P.	1,673,668	6.6%
Investec Wealth & Investment Limited	1,608,993	6.3%
Frederick W Gluck	1,530,596	6.0%
Livzon Pharmaceutical Company, Inc.	1,347,653	5.3%
Lombard Odier	1,268,363	4.9%
Killik & Co	1,119,972	4.4%
Accord Data Holdings Limited	954,048	3.7%

#### Directors' report for the year ended 31 December 2021 *(continued)*

#### Corporate Social Responsibility

The Board recognises its employment, environmental and health and safety responsibilities. It devotes appropriate resources towards monitoring and improving compliance with existing standards. The Executive Directors are responsible for these areas at Board level, ensuring that the Company's policies are upheld and providing the necessary resources.

The Company is committed to identifying and minimising any effect on the environment caused by its operations and the Board recognises that the Company has a duty to be a good corporate citizen and to respect and comply with the laws, regulations, and where appropriate the customs and culture of the territories in which it operates.

#### Employees

The Company is committed to achieving equal opportunities and to complying with relevant anti-discrimination legislation. It is established Company policy to offer employees and job applicants the opportunity to benefit from fair employment, without regard to their sex, sexual orientation, marital status, race, religion or belief, age or disability. Employees are encouraged to train and develop their careers.

The Company has continued its policy of informing all employees of matters of concern to them as employees, both in their immediate work situation and in the wider context of the Company's well-being. Communication with employees is affected through the Board, the Company's management briefings structure, formal and informal meetings and through the Company's information systems.

#### **Directors Responsibilities**

The Directors are responsible for preparing the Strategic Report, the Directors' Report and the Financial Statements in accordance with applicable law and regulations.

The directors have elected to prepare the financial statements in accordance with UK adopted International Accounting Standards ('UK IFRS').

The directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Company and the Company and of the profit or loss of the Company for that year. In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently
- make judgements and accounting estimates that are reasonable and prudent
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements; and
- prepare 'the financial statements on the going concern basis unless 'it is inappropriate to presume that the company and Company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company. They are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

#### Directors' report for the year ended 31 December 2021 *(continued)*

#### **Directors Responsibilities** (continued)

The maintenance and integrity of the LungLife AI, Inc. website is the responsibility of the directors. Legislation in the United Kingdom governing the preparation and dissemination of the accounts and the other information included in annual reports may differ from legislation in other jurisdictions.

#### Auditors

Each of the persons who are directors at the time when this Directors' report is approved has confirmed that:

- so far as that Director is aware, there is no relevant audit information of which the Company and the Company's auditor is unaware; and
- that Director has taken all the steps that ought to have been taken as a Director in order to be aware of any
  relevant audit information and to establish that the Company and the Company's auditor is aware of that
  information.

Crowe U.K. LLP has expressed its willingness to continue in office and a resolution to reappoint the firm as Auditor and authorising the Directors to set their remuneration will be proposed at the forthcoming Annual General Meeting

This report was approved by the Board of Directors on 25 March 2022 and signed on its behalf by:

David Anderson Company Secretary

# Corporate governance statement for the year ended 31 December 2021

#### Dear Shareholder

I am pleased to present the Corporate Governance Statement of the Board of Directors of LungLife, AI Inc for the financial year ended 31 December 2021. The Company has adopted the Quoted Companies Alliance Corporate Governance Code ('QCA Code'). The QCA Code is a widely recognised benchmark for corporate governance of smaller quoted companies to which the UK Corporate Governance Code is not considered applicable, due to company size.

The Board considers that LungLife, AI complies with the QCA Code so far as is practicable, having regard to the Company's current stage of evolution. A statement detailing both how the Company complies with the QCA Code, and explanation of its areas of non-compliance, is outlined below.

#### **QCA Principles**

#### 1. Establish a strategy and business model which promotes long-term value for shareholders

LungLife AI is a diagnostic company focused on the early detection of lung cancer from a simple blood draw enhanced by artificial intelligence. 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% 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 screening strategies and the fact that early lung cancer largely develops asymptomatically.

To achieve our objective, we are initially focussed on two areas: assisting the clinician when a CT scan results in the identification of indeterminant nodules which may or may not be indications of lung cancer; and providing on-going monitoring for participants' post-surgery following the removal of the lung cancer. In both cases our diagnostic test in based on the same simple blood draw.

The Company's revenues since IPO have derived from the sale of consumables to China under the terms of a joint venture agreement.

Prior to full-scale commercialisation, the Company intends to focus on getting its first revenues from early adopting institutions, potentially those identified through partnerships, including validation and utility sites.

The Company has implemented remuneration policies that reinforce this strategy, by rewarding Executive Directors and senior management in a manner that ensures that they are properly incentivised and motivated to perform in the best interests of shareholders.

The key challenges in executing the company's strategy are set out in the principal risks and uncertainties section on pages 10 to 20.

#### 2. Seek to understand and meet shareholder needs and expectations

The Board is committed to maintaining good communication and having constructive dialogue with shareholders through our Interim and Annual Reports along with Regulatory News Service announcements. We also use the Company's website for both financial and general news relevant to shareholders. Throughout the Company's first year as a publicly listed entity, the Chairman is available to meet with the largest shareholders during the year without management present. The CEO intends to meet shareholders and other investors/potential investors at regular intervals during the year and host broker and analyst meetings from time to time.

The Board keeps in mind the proportions of direct, nominee and institutional shareholders, and distributes communications accordingly. The CEO has committed to meet with major shareholders regularly within the results cycle, including after the announcement of interim and final results, and the Executive team are responsible for ensuring that their expectations are understood by the wider Board. Board members attend the AGM, which will

# Corporate governance statement for the year ended 31 December 2021 *(continued)*

also provide an opportunity to meet, listen and engage with shareholders, and shareholders are encouraged to attend and ask questions.

The Company's Nominated Adviser and Broker, Investec, has been briefed regularly since IPO.

The Board intends to review other shareholder engagement strategies in 2022, with a view to ensuring that shareholder queries are addressed as efficiently as possible.

# 3. Take into account wider stakeholder and social responsibilities and their implications for long-term success

The Board recognises that the long-term success of the Company is reliant upon the efforts of employees of the Company and its contractors, suppliers, regulators and other stakeholders. The Board will implement an appropriate range of processes and systems that will guarantee close oversight and contact with its key resources and relationships.

LungLife seeks to be a socially responsible Company which has a positive impact on the community in which it operates. The Company employs a diverse workforce, with different nationalities. No discrimination is tolerated, and the Company is keen to ensure all employees have the opportunity to develop their capabilities. The Board will consider additional workforce engagement activities as the Company evolves.

Everyone within the Company is a valued member of the team and our aim is to help every individual achieve their full potential. We offer equal opportunities regardless of race, gender, gender identity or assignment, age, disability, religion and sexual orientation.

The Company will engage in a collaborative way with all stakeholders. We see that a collaborative approach, particularly with our scientific and clinical partners is key to be able to achieve our overall objective of achieving a significant rise in the early detection of lung cancer. The Company has no significant environmental or community impact but will continue to monitor and take action if this changes in the future.

# 4. Embed effective risk management, considering both opportunities and threats, throughout the organisation

The Board recognises the need for an effective and well-defined risk management process and the status of the key risks will be shared regularly with the Board, and the Board will thoroughly review the Company's risk register on an annual basis. The Board has established the Audit Committee, whose role is to assist the Board in fulfilling its oversight responsibilities by reviewing and monitoring, inter alia, the Company's system of internal controls and risk management.

Internal financial control systems were reviewed, designed and strengthened in the lead up to admission to meet the particular needs of the Company, its growth strategy, its publicly traded status and the risks to which it is exposed.

The review process involves the identification of risks, both standard industry-related risks and risks against related opportunities, assessment to determine the relative likelihood of them impacting the business and the potential severity of the impact, and determination of what needs to be done to manage them effectively. Risk management is integral to the ability of the Company to deliver on its strategic objectives.

The system of internal control is structured around an assessment of the various risks to the business and is designed to address those risks that the Board considers to be material. It acts to safeguard assets against unauthorised use or disposition and to maintain proper accounting records which produce reliable financial and management information. The Board has established appropriate reporting and control mechanisms to ensure the effectiveness of its control systems. These continue to evolve as the Company develops and expands.

# Corporate governance statement for the year ended 31 December 2021 *(continued)*

An internal audit function is not yet considered necessary as day-to-day control is sufficiently exercised by the Company's Executive Directors. However, the Board will continue to monitor the need for an internal audit function as the Company grows and evolves

#### 5. Maintain the board as a well-functioning, balanced team led by the Chair

The Board comprises of the CEO, Paul Pagano, the CFO, David Anderson, and 4 Non-Executives, Roy Davis, Andrew Boteler, James McCullough and Sara Barrington. Andrew Boteler is the Company's Senior Independent Director (**SID**), and Roy Davis is the Company's Chairman. Biographical details of the Directors can be found on pages 4 and 5. All the Non-Executive Directors are expected to dedicate at least 1 day a month to the Company, rising to 1 - 2 days if they also chair a committee, and the Chair is expected to dedicate 2 - 3 days per month. In practice many Non-Executives spend more than the minimum number of days on Company business.

The Board is pleased that the Chairman and all Directors can devote the time required to their respective tasks.

The Board intends to meet formally a minimum of 6 times in the year and a calendar of meetings and principal matters to be discussed is agreed at the beginning of each year. In order to be efficient, the Directors will meet formally and informally both in person and by telephone. Board and Committee document authors are made aware of proposed monthly deadlines through the calendar of meetings assembled at the beginning of the year. Board papers are collated by the relevant personnel (Chair, CFO, Committee Chairs), compiled into a Board/Committee Pack, and circulated before meetings, allowing time for full consideration and necessary clarifications before the meetings.

The Board has delegated specific responsibilities to the Audit, Remuneration, and Nomination Committees to support the Board and improve effectiveness, further details of which are provided under Principle 9. The Committees have the necessary skills and knowledge to discharge their duties effectively.

Member	Board (2 meetings held)	Audit Committee (No meetings held)	Remuneration Committee (1 meeting held)
Roy Davis	2/2	Nil	1/1
Paul Pagano	2/2	N/A	N/A
David Anderson	2/2	N/A	N/A
Andrew Boteler	2/2	Nil	1/1
James McCullough	2/2	Nil	1/1
Sara Barrington	2/2	Nil	N/A

#### Meeting attendance during 2021

# 6. Ensure that between them the Directors have the necessary up-to-date experience, skills and capabilities

The Directors have both a breadth and depth of skills and experience to fulfil their roles. The Company believes that the current balance of skills in the Board as a whole reflects a very broad range of commercial and professional skills across geographies and industries and each of the Directors has experience in public markets. The Non-Executive Directors will meet without the presence of the Executive Directors during the year, and also maintain ongoing communications with Executives between formal Board meetings.

# Corporate governance statement for the year ended 31 December 2021 *(continued)*

Biographical details of the Directors can be found on pages 4 and 5.

The Company has employed the services of ONE Advisory Limited to provide assistance to David Anderson, the Chief Financial Officer and Company Secretary. ONE Advisory are responsible for ensuring that the Company is compliant with relevant legislation, as well as helping the Chairman maintain excellent standards of corporate governance.

If required, the Directors are entitled to take independent legal advice and if the Board is informed in advance, the cost of the advice will be reimbursed by the Company. The Board shall review annually the appropriateness and opportunity for continuing professional development whether formal or informal.

In addition to their general Board responsibilities, Non-Executive Directors are encouraged to be involved in specific workshops or meetings, in line with their individual areas of expertise.

# 7. Evaluate board performance based on clear and relevant objectives, seeking continuous improvement

As the Board was established on admission, no evaluation exercise has been undertaken at this point. The Board will look to implement an evaluation exercise in the next financial year, and in the meantime, the Chairman will be responsible for gathering any feedback and identifying any improvements that are required or desirable.

The Nominations Committee, comprised of the Chairman and three Non-Executive Directors, intends to review the structure, size and composition required of the Board compared to its current position, make any recommendations to the Board, consider succession planning, and oversee the process to fill Board vacancies. The Nominations Committee was formed to keep key positions outside the Board and other personnel considered critical to the business under review. Findings from the Company's annual evaluation exercise and one-on-one reviews will be utilised in the Nominations Committee's succession planning discussions.

In addition, the Remuneration Committee were created on admission to review the performance of the Executive Directors and make recommendations to the Board on matters relating to their terms of employment and remuneration, including short-term bonus and long-term incentives (with targets consistent with the corporate strategy). The findings from annual evaluations and the achievement of financial and non-financial targets/goals discussed thereat will be considered by the Remuneration Committee in relation to recommendations to be made in respect of adjustments to executive remuneration.

#### 8. Promote a corporate culture that is based on ethical values and behaviours

The Board recognises that its decisions regarding strategy and risk will impact the corporate culture of the Company as a whole and that this will impact the performance of the Company. The Board is very aware that the tone and culture set by the Board will greatly impact all aspects of the Company as a whole and the way that employees behave. The corporate governance arrangements that the Board has adopted are designed to ensure that the Company delivers long term value to its shareholders, and that shareholders have the opportunity to express their views and expectations for the Company in a manner that encourages open dialogue with the Board.

A large part LungLife's activities are centred upon what needs to be an open and respectful dialogue with employees, clinicians, and other stakeholders. Therefore, the importance of sound ethical values and behaviours is crucial to the ability of the Company to successfully achieve its corporate objectives. The Board places great importance on this aspect of corporate life and seeks to ensure that this flows through all that the Company does. The Directors consider that at present, the Company has an open culture facilitating comprehensive dialogue and feedback and enabling positive and constructive challenge. This has brought us valuable insights and perspectives which we are using to guide a framework of actions that will facilitate the change process.

# Corporate governance statement for the year ended 31 December 2021 *(continued)*

The Company operates a whistleblowing policy to facilitate the reporting by employees of suspected misconduct, illegal acts or failure to act within the Company. The aim of this policy is to encourage employees and others who have serious concerns about any aspect of the Company's work to come forward and voice those concerns.

#### 9. Maintain governance structures and processes that are fit for purpose and support good decisionmaking by the board

The Board will examine our corporate governance arrangements on a regular basis and expects them to develop over time as the Company grows. Upon admission, the Board delegated tasks to Committees and persons as it saw fit, with the Chairman being accountable for the Board's effectiveness and the Executive Directors being accountable for the Company's business management and proactive engagement with shareholders. The Chairman is responsible for the leadership of the Board and ensuring its effectiveness in all aspects of its role. The Chairman is also responsible for the Company's Corporate Governance framework. He is also responsible for creating the right Board dynamic and ensuring that all important matters, in particular strategic decisions, receive adequate time and attention at Board meetings. The Executive Directors are responsible for the day-to-day running of the business and developing corporate strategy; while the Non-Executive Directors are tasked with constructively challenging the decisions of executive management and satisfying themselves that the systems of business risk management and internal financial controls are robust.

The role of the SID is to serve as a sounding board for the Chairman and act as an intermediary for other Directors. The SID is also available to shareholders if they have reason for concern that contact through the normal channels of the Executive Directors has failed. The SID is responsible for holding annual meetings with Non-Executives, without the Chairman present, to appraise the Chairman's performance.

The Board has adopted appropriate delegations of authority which sets out matters which are reserved to the Board. A schedule of specific matters reserved for the Board can be found on the Company's website, with matters including:

- Strategy and management
- Approval of major capital expenditure
- Financial reporting, risk management and internal controls
- Contracts, including potential acquisitions
- Corporate governance
- Approval of annual budgets
- Approval of annual reports
- Dividend recommendations and policy

The Chairman will continue to review the appropriateness of the Board's structures and processes on an ad hoc basis until such time that a formal Board evaluation process can be undertaken and will continue to include this as part of his roles and responsibilities as the Company evolves (see Principle 7). Governance structures are anticipated to change in tandem with the Company's goals, strategy, and business model.

# 10. Communicate how the company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders

The Board is committed to maintaining effective communication and having constructive dialogue with its shareholders. The Company aspires to have close ongoing relationships with its private shareholders, institutional shareholders, and analysts and for them to have the opportunity to discuss issues and provide feedback at meetings with the Company. The Board maintains that, if there is a resolution passed at an AGM with 20% votes against, the Company will seek to understand the reason for the result and, where appropriate, take suitable action.

The Board delegates authority to three Committees to assist in meeting its business objectives whilst ensuring a sound system of internal control and risk management. The Committees meet independently of Board meetings.

# Corporate governance statement for the year ended 31 December 2021 *(continued)*

The LungLife website is kept up to date and includes details on significant governance materials, developments, press and corporate news and presentations. Shareholders can sign up for investor notifications to guarantee that they get all news releases, financial reports, and other relevant shareholder announcements straight from the Company as soon as they are available.

#### **Board Committees**

The Board has assigned tasks and obligations to an Audit Committee, a Remuneration Committee, and a Nominations Committee.

#### Audit Committee

The Audit Committee has four members, Andrew Boteler (Chair) and Non-Executives Roy Davis, James McCullough and Sara Barrington. The CEO, CFO and external auditors attend meetings by invitation. The Audit Committee is responsible for assisting the Board in fulfilling its financial and risk responsibilities. The Audit Committee oversees the financial reporting, risk management and internal control procedures. The Audit Committee advises the Board on the appointment and removal of the external auditor and discusses the nature, scope, and results of the audit with the auditors. The Audit Committee reviews the extent of non-audit services provided by the auditors and reviews with them their independence and objectivity.

#### **Remuneration Committee**

The Remuneration Committee has three members, Andrew Boteler (Chair) and Non-Executives Roy Davis and James McCullough. Other members of the Board may attend the Committee's meetings at the request of the Committee Chairman. The remit of the Committee is primarily to determine and agree with the Board the framework or broad policy for the remuneration of the Company's Executive Directors and the Senior Management of the Company. The Remuneration Committee reviews the performance of the Executive Directors and makes recommendations to the Board on matters relating to their terms of employment and remuneration, including short term bonus and long-term incentives. The Remuneration Committee also considers the granting of long-term incentives and share options pursuant to the Company's option schemes.

#### **Nominations Committee**

The Nominations Committee has four members, Roy Davis (Chair), James McCullough, Sara Barrington and Andrew Boteler. The Nominations Committee regularly reviews the structure, size and composition required of the Board compared to its current position, makes recommendations to the Board, considers succession planning, and nominates candidates to fill Board vacancies. The Nominations Committee also keeps key positions outside the main board and other personnel considered critical to the business under review. The Nominations Committee meets at least twice per year, and otherwise as necessary to consider proposals for Board appointments and other matters.

The Chairman and the Board will continue to monitor and evolve the Company's corporate governance structures and processes, in order that these evolve over time, in line with the Company's growth and development.

Roy Davis Chairman 25 March 2022 David Anderson Company Secretary 25 March 2022

# Report of the remuneration committee for the year ended 31 December 2021

#### Statement of compliance

This report does not constitute a Directors' Remuneration Report in accordance with the Directors' Remuneration Regulations 2007 which do not apply to the Company as it is not fully listed. This report sets out the Company policy on Directors' remuneration, including emoluments, benefits and other share-based awards made to each Director.

#### Policy on Executive Directors' remuneration

Remuneration packages are designed to motivate and retain the Executive Director to ensure the continued development of the Company and to reward them for enhancing value to shareholders. The main elements of the remuneration package for the Executive Director are basic salary, performance-related bonuses, benefits and share based incentives.

#### Directors' remuneration

The remuneration of the Directors for the year ended 31 December 2021 is shown below:

emoluments	423,548	4,840	18,822	175,684	622,894
Total fees and					
	80,878	-	-	-	80,878
2021)					
James McCullough (year to 31 December	15,812	-	-	-	15,812
8 July to 31 December 2021)					
8 July to 31 December 2021) Sara Barrington (period	15,812	-	-	-	15,812
Andrew Boteler (period	21,672	-	-	-	21,672
Roy Davis (period 8 July to 31 December 2021)	27,582	-	-	-	27,582
Non-Executive Directors					
	342,670	4,840	18,822	175,684	542,016
David Anderson (period 8 July to 31 December 2021)	113,132	4,840	-	68,184	186,156
Dr Paul Pagano (year to 31 December 2021)	229,538	-	18,822	107,500	355,860
Executive Directors	Base Salary and fees US\$	Pension US\$	Benefits US\$	Bonus US\$	31 December 2021 US\$
					Year to

# Report of the remuneration committee for the year ended 31 December 2021 *(continued)*

#### Share option plans

The Company has three option plans: the 2010 Stock Option Incentive Plan, the 2020 Stock Incentive Plan and the 2021 Omnibus Long-Term Incentive Plan, (together "the Share Option Plans"). The options held by Directors as of 31 December 2021 under these Share Options Plans were as follows:

Option holder	Option price per ordinary share	Number of Ordinary Shares under option	Exercise period
Poul Pogono	£1.76	760 707	8 July 2021 8 July 2021
Paul Pagano		769,707	8 July 2021 – 8 July 2031
	US\$0.079	114,579	19 Sept 2020 – 19 Sept 2030
	US\$0.45	42,967	31 Dec 2019 – 31 Dec 2029
	US\$0.45	85,934	1 July 2019 – 1 July 2029
	US\$2.70	2,777	1 May 2016 – 1 May 2026
David Anderson	£1.76	386,703	8 July 2021 – 8 July 2031
	US\$0.079	2,777	17 Sept 2020 – 17 Sept 2030
	US\$0.45	2,777	1 July 2019 – 1 July 2029
Sara Barrington	US\$0.079	61,014	31 March 2021 – 31 March 2031
	US\$0.45	71,612	1 July 2019 – 1 July 2029
James McCullough	US\$0.79	88,182	31 March 2021 – 31 March 2031
	US\$0.45	36,110	31 Dec 2019 – 31 Dec 2029
	US\$0.45	8,333	1 July 2019 – 1 July 2029

Directors' interests in the share capital of the Company are disclosed in the Directors' Report on page 23.

Approved by the Board on 25 March 2022 and signed on its behalf by:

#### Andrew Boteler Non-Executive Director, Chair of the Remuneration Committee

#### Report of the audit of the financial statements for the year ended 31 December 2021

#### INDEPENDENT AUDITOR'S REPORT TO THE SHAREHOLDERS OF LUNGLIFE AI, INC.

#### Opinion

We have audited the non-statutory financial statements of LungLife AI, Inc. (the "Company") for the year ended 31 December 2021 which comprise the Statement of Profit or Loss and Other Comprehensive Income, the Statement of Financial Position, the Statement of Cash Flows, the Statement of Changes in Equity and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and UK adopted International Accounting Standards (UK IFRS).

In our opinion, the financial statements:

- give a true and fair view of the state of the Company's affairs as at 31 December 2021and of its loss for the year then ended; and
- have been properly prepared in accordance with UK IFRS

#### **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (UK) ("ISAs (UK)") and applicable law.

Our responsibilities under those standards are further described in the auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Conclusions relating to going concern

In auditing the financial statements, we have concluded that the Directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the Directors' assessment of the Company's ability to continue to adopt the going concern basis of accounting included the following procedures:

- Obtaining the going concern assessment year used by the Directors covering a period of at least 12 months from the date of the approval of the financial statements.
- Assessing the appropriateness of the approach, assumptions and arithmetic accuracy of the model used by management when performing their going concern assessment.
- Evaluating the Directors' assessment of the Company's ability to continue as a going concern, including challenging the underlying data and key assumptions used to make the assessment.
- Reviewing and challenging the results of management's stress testing, to assess the reasonableness of economic assumptions in light of the impact of Covid-19 on the Company's solvency and liquidity position.

Further details of the Directors' assessment of going concern is provided in Note 2.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Company's ability to continue as a going concern for a year of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

# Report of the audit of the financial statements for the year ended 31 December 2021 *(continued)*

#### Overview of our audit approach

#### Materiality

In planning and performing our audit we applied the concept of materiality. An item is considered material if it could reasonably be expected to change the economic decisions of a user of the financial statements. We used the concept of materiality to both focus our testing and to evaluate the impact of misstatements identified.

Based on our professional judgement, we determined overall materiality for the financial statements as a whole to be \$250,000 based on approximately 5% of the expected loss before tax at the planning stage, which we normalised by adjusting for IPO costs included in expenses and for non-recurring legal expenses. We did not consider it appropriate subsequently to amend our assessment. Profit or loss before tax is a generally accepted auditing benchmark.

We use a different level of materiality, performance materiality, to determine the extent of our testing for the audit of the financial statements. Performance materiality is set based on the audit materiality as adjusted for the judgements made as to the entity risk and our evaluation of the specific risk of each audit area having regard to the internal control environment. Performance materiality was set at \$175,000.

Where considered appropriate, performance materiality may be reduced to a lower level, such as for related party transactions and Directors' remuneration.

We agreed with the Audit Committee to report to it all identified errors in excess of \$12,500. Errors below that threshold would also be reported to it if, in our opinion as auditor, disclosure was required on qualitative grounds.

#### Overview of the scope of our audit

The Company's operations are based in the USA. In view of the early stage of development of the Company's business activities the audit team performed a full scope audit on the Company from the UK as a single component.

#### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) that we identified. These matters included those which had the greatest effect on the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

# Report of the audit of the financial statements for the year ended 31 December 2021 *(continued)*

#### Key audit matters (continued)

This is not a complete list of all risks identified by our audit.

Key audit matter	How the scope of our audit addressed the key audit matter
Mount Sinai license	
Note 13 In June 2021 the Company entered into an option to obtain a non-exclusive licence in relation to de-identified participant data and other IP belonging to Mount Sinai. The Company made an initial cash payment f \$1.8m followed by the issue of shares with a fair value of \$4.0m to acquire the licence. The Mount Sinai option is carried as an intangible asset at book value \$5.8m at 31 December 2021, so is a material component of the Company's statement of financial position. At the reporting date the licence had not yet been formally entered into so was not available for use so amortisation has not yet commenced. There is a risk that the expenditure may be inappropriately accounted for as an intangible asset or the intangible asset may be impaired	We obtained a copy of the licence option agreement, confirmed the basis of recognition of the cost of the asset and the appropriateness of the accounting treatment in accordance with IAS38 We considered the commercial substance of the license arrangement and management's assessment of the nature and probability of the flows of future economic benefits to the Company from the licence We discussed the likely benefits of the licence arrangement to the Company with management and considered whether there are indicators of impairment We ensured the disclosures in relation to the licence arrangement in the financial statements are appropriate

# Report of the audit of the financial statements for the year ended 31 December 2021 *(continued)*

#### Other information

The Directors are responsible for the other information contained within the annual report. The other information comprises the information included in the Annual Report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

#### Responsibilities of the Directors for the financial statements

As explained more fully in the Directors' responsibilities statement, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the Directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

#### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below:

We obtained an understanding of the legal and regulatory frameworks within which the Company operates, focusing on those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The laws and regulations we considered in this context were the US Federal and State law as it impacts on corporations and relevant taxation legislation. Technical, clinical or regulatory laws and regulations which are inherent risks in drug development are mitigated and managed by the Board and management in conjunction with expert regulatory consultants in order to monitor the latest regulations and planned changes to the regulatory environment.

# Report of the audit of the financial statements for the year ended 31 December 2021 *(continued)*

#### Auditor's responsibilities for the audit of the financial statements (continued)

We identified the greatest risk of material impact on the financial statements from irregularities, including fraud, to be the override of controls by management. Our audit procedures to respond to these risks included enquiries of management about their own identification and assessment of the risks of irregularities, sample testing on the posting of journals and reviewing accounting estimates for biases.

Owing to the inherent limitations of an audit, there is an unavoidable risk that we may not have detected some material misstatements in the financial statements, even though we have properly planned and performed our audit in accordance with auditing standards. We are not responsible for preventing non-compliance and cannot be expected to detect non-compliance with all laws and regulations.

These inherent limitations are particularly significant in the case of misstatement resulting from fraud as this may involve sophisticated schemes designed to avoid detection, including deliberate failure to record transactions, collusion or the provision of intentional misrepresentations.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

#### Use of our report

This report is made solely to the company's members, as a body. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

**Stephen Bullock** (Senior Statutory Auditor) for and on behalf of Crowe U.K. LLP Statutory Auditor, London 25 March 2022

# Statement of profit or loss and other comprehensive income for the year ended 31 December 2021

Note	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
4	195,566 (96,269)	205,180 (188,178)
	99,297	17,002
6 6	(5,903,738) (323,758) (1,101,370)	(3,458,984) (282,654) (337,201)
	(7,229,569)	(4,061,837)
6 9 9	206,164 12,017 (416,928)	- - (777,186)
	(7,428,316)	(4,839,023)
10	(15,872)	-
	(7,444,188)	(4,839,023)
	-	-
	(7,444,188)	(4,839,023)
11		
	(\$0.469)	(\$0.743)
	4 6 6 9 9 9	31 December 2021 US\$           4         195,566 (96,269)           99,297         99,297           6         (5,903,738) (323,758) (1,101,370)           6         (206,164 9           9         (7,229,569)           6         206,164           9         (416,928)           (7,428,316)         10           10         (15,872)           (7,444,188)         -           11         11

The results reflected above relate to continuing operations

The notes on pages 44 to 68 form part of these financial statements.

#### Statement of financial position as at 31 December 2021

	Note	2021 US\$	2020 US\$
Assets Current assets			
Trade and other receivables	14	740,865	169,801
Cash and cash equivalents	5	14,628,351	127,628
		15,369,216	297,429
Non-current assets	10	705 000	400 407
Property, plant and equipment Intangible assets	12 13	765,983 5,818,359	463,437
Other receivables	14	13,235	13,235
		6,597,577	476,672
Tatalasaata			
Total assets		21,966,793	774,101
Liabilities			
Current liabilities	45	000 700	4 005 000
Trade and other payables Lease liabilities	15 17	803,738	1,225,836
Discontinued operations	17	207,280 174,057	169,955 174,057
Convertible notes	18	-	10,086,616
Borrowings and loans	16	-	206,164
		1,185,075	11,862,628
Non-current liabilities		.,,	,002,020
Lease liabilities	17	601,622	167,488
Provisions	19	50,000	50,000
Total liabilities		1,836,697	12,080,116
NET ASSETS		20,130,096	(11,306,015)
Issued capital and reserves attributable to			
owners of the parent			
Share capital	21	2,548	8,665
Share premium reserve	22	91,264,305	52,194,390
Other equity	22	-	843,137
Share based payment reserve Accumulated losses		960,312 (72,097,069)	550,511 (64,902,718)
		(12,031,003)	(0 <del>4</del> ,302,710)
TOTAL EQUITY		20,130,096	(11,306,015)
		<u></u>	

The financial statements on pages 39 to 68 were approved and authorised for issue by the Board of Directors on 25 March 2022 and were signed on its behalf by:

#### Paul Pagano - Director

**David Anderson - Director** 

The notes on pages 44 to 68 form part of these financial statements.

# Statement of cash flows for the year ended 31 December 2021

	Note	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Cash flows from operating activities Loss for the year Adjustments for:		(7,444,188)	(4,839,023)
Adjustments for: Depreciation of property, plant and equipment Forgiveness of Paycheck Protection Program Loan Gain on sale of tangible assets Finance income Finance expense Taxation Share-based payments expense		323,758 (206,164) (35,752) (12,017) 416,928 15,872 409,801	282,654 - - 777,186 - 225,635
		(6,531,762)	(3,553,548)
(Increase) / decrease in trade and other receivables (Decrease) / increase in trade and other payables Income taxes paid		(569,143) (422,097) (15,872)	82,127 597,396 
Net cash outflow from operating activities		(7,538,876)	(2,874,025)
<b>Cash flows from investing activities</b> Purchases of tangible assets Proceeds from sale of tangible assets Landlord improvement contribution Purchase of intangibles		(47,365) 35,752 15,588 (1,800,000)	(5,328) - - -
Net cash used in investing activities		(1,796,025)	(5,328)
Cash flows from financing activities Issue of Convertible Notes Issue of Common Stock Expenses of issue of Common Stock Interest received Interest paid Paycheck Protection Program Ioan Repayment of Ioans Repayment of Iease liabilities		1,612,421 23,444,129 (1,000,354) 10,097 (107,601) - - (123,068)	2,290,899 90,510 - (6,297) 205,822 (120,368) (180,379)
Net cash from financing activities		23,835,624	2,280,187
Net increase / (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of year		14,500,723 127,628	(599,166) 726,794
Cash and cash equivalents at end of year	5	14,628,351	127,628

The notes on pages 44 to 68 form part of these financial statements.

# Statement of changes in equity for the year ended 31 December 2021

	Share capital US\$	Share premium US\$	Share-based payment reserve US\$	Other equity US\$	Accumulated losses US\$	Total attributable to equity holders of parent US\$	Total equity US\$
1 January 2020	8,483	52,104,062	324,876	828,318	(60,063,695)	(6,797,956)	(6,797,956)
<b>Comprehensive income for the year</b> Loss Other comprehensive Income	:	:	:	:	(4,839,023) -	(4,839,023) -	(4,839,023) -
Total comprehensive Income for the year					(4,839,023)	(4,839,023)	(4,839,023)
Contributions by and distributions to owners Issue of common stock Issue of Convertible Loan Note Share-based payment	 182 - -	90,328		- 14,819 -		90,510 14,819 225,635	90,510 14,819 225,635
Total contributions by and distributions to owners	182	90,328	225,635	14,819		330,964	330,964
31 December 2020	8,665	52,194,390	550,511	843,137	(64,902,718)	(11,306,015)	(11,306,015)

# Statement of changes in equity for the year ended 31 December 2021 *(continued)*

	Share capital US\$	Share premium US\$	Share-based payment reserve US\$	Other equity US\$	Accumulated losses US\$	Total attributable to equity holders of parent US\$	Total equity US\$
1 January 2021	8,665	52,194,390	550,511	843,137	(64,902,718)	(11,306,015)	(11,306,015)
<b>Comprehensive income for the year</b> Loss Other comprehensive Income	-	-	-	-	(7,444,188)	(7,444,188)	(7,444,188)
Total comprehensive Income for the year	<u>-</u>				(7,444,188)	(7,444,188)	(7,444,188)
Contributions by and distributions to owners Issue of Convertible Loan Notes Reverse split Issue of common shares on conversion	(8,184)	8,184	 - -	99,263		99,263	99,263
of preference shares and Convertible Loan Notes Issue of share capital Transfer of balance following conversion of Convertible Loan Note	935 1,132 -	12,600,730 27,461,355 -	- - -	(942,400)	- - 249,837	12,601,665 27,462,487 (692,563)	12,601,665 27,462,487 (692,563)
Share issue costs Share-based payments	-	(1,000,354) -	- 409,801	-	-	(1,000,354) 409,801	(1,000,354) 409,801
Total contributions by and distributions to owners	(6,117)	39,069,915	409,801	(843,137)	249,837	38,880,299	38,880,299
31 December 2021	2,548	91,264,305	960,312	-	(72,097,069)	20,130,096	20,130,096

#### Notes forming part of the financial statements for the year ended 31 December 2021

#### **1** General Information

LungLife AI, Inc, (the **"Company"**) is a company based in Thousand Oaks, California which is developing a diagnostic test for the early detection of lung cancer. The Company was incorporated under the laws of the state of Delaware, USA, on 30 December 2009.

The Company's costs associated with developing and commercialising its test include costs associated with the development of intellectual property, optimising the technology, and obtaining regulatory approval. To complete clinical trials the Company will continue to require additional operating funds. The Company has raised funds through offerings of debt, common stock and Series A Preferred Shares.

There are no restrictions on the Company's ability to access or use its assets and settle its liabilities.

#### 2 Basis of preparation

The financial statements have been prepared in accordance with UK adopted International Accounting Standards ("**UK IFRS**").

These financial statements are prepared in accordance with UK IFRS under the historical cost convention, as modified by the use of fair value for financial instruments measured at fair value. The historical financial information is presented in United States Dollars ("**US\$**") except where otherwise indicated.

The principal accounting policies adopted in the preparation of the financial statements are set out below. The policies have been consistently applied to all the yearspresented, unless otherwise stated.

#### (a) Going concern

These financial statements have been prepared on the going concern basis.

The directors of the Company have a reasonable expectation that the Company has adequate resources, to continue in operational existence for the foreseeable future and for at leastone year from the date of the financial statements. For that reason, they continue to adopt the going concern basis in preparing the Company's financial statements.

#### (b) New standards, amendments and interpretations

New standards are not expected to impact the Company as they are either not relevant to the Company's activities or require accounting which is consistent with the Company's current accounting policies.

The Directors have considered those standards and interpretations which have not been applied in these financial statements but which are relevant to the Company's operations that are in issue but not yet effective and do not consider that they will have a material effect on the future results of the Company.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### **2 Basis of preparation** (continued)

#### (c) **Revenue recognition**

#### Sale of goods

Revenue comprises the fair value of the sale of FISH probes used to identify the properties of blood samples under the terms of a sub license agreement with a third party, net of applicable sales taxes. Revenue is recognised on the sale of goods when the significant risks and rewards of ownership of the goods have passed to the buyer and the amount of revenue can be measured reliably. Revenue on goods delivered is recognised when the customer accepts delivery and on services when those services have been rendered.

#### Royalty income

Under the terms of a patent and technology sub license agreement the company is entitled to receive royalty income at 6% of the quarterly net sales invoiced by the sub licensee in the relevant quarter. Income is recognized in the period in which the underlying net sales are generated.

Cash is received from revenues recognised according to terms of trade within the relevant contractual relationship, usually in accordance with agreed events such as placing of order, fulfilment of order and delivery.

#### (d) Intangible assets

Research expenditure is recognised as an expense when incurred. Development expenditure is recognized as an expense except those costs incurred on development projects are capitalised as long term assets to the extent that such expenditure is expected to generate future economic benefits. Development expenditure is capitalised only if it meets the criteria for capitalisation under IAS 38. Capitalised development expenditure is measured at cost less accumulated amortisation and impairment losses, if any. Development expenditure initially recognised as an expense is not recognised as an asset in future years. Capitalised development expenditure is amortised on a straight-line basis over the estimated useful life of the asset when the asset is available for use.

#### (e) **Property, plant and equipment**

#### Owned assets

Items of property, plant and equipment are stated at cost or deemed cost less accumulated depreciation and impairment losses. Cost includes the original purchase price of the assetand the costs attributable to bringing the asset to its working condition for its intended use. When parts of an item of property, plant and equipment have different useful lives, those components are accounted for as separate items of property, plant and equipment.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Company and the cost of the item can be measured reliably.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognised in the income statement.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 2 Basis of preparation (continued)

#### (e) **Property, plant and equipment** (continued)

#### Depreciation

Depreciation is charged to profit or loss on a straight-line basis over the estimated useful lives of each part of an item of property, plant and equipment. The estimated useful lives are as follows:

- computer and IT equipment 33 per cent. straight line
- leasehold improvements shorter of lease term and useful life
- plant and machinery 20 per cent. straight line
- laboratory equipment 20 per cent. straight line

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, or if there is an indication of a significant change since the last reporting date.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognised within "other operating income" in the statement of income.

#### (f) Impairment of non-financial assets

Non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are considered at the lowest levels for which there are separately identifiable cash flows (cash-generating units).

Non-financial assets other than goodwill that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

#### (g) Financial assets

#### Classification

The Company classifies its financial assets as loans and receivables. The classification depends on the purpose for which the investments were acquired. Management determines the classification of its investments at initial recognition.

#### Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments. They are initially recognised at fair value and are subsequently stated at amortised cost using the effective interest method.

#### Impairment of financial assets

Impairment provisions are recognised when there is objective evidence (such as significant financial difficulties on the part of the counterparty or default or significant delay in payment) that the Company will be unable to collect all of the amounts due under the term's receivable, the amount of such a provision being the difference between the net carrying amount and the present value of the future expected cash flows associated with the impaired asset.

#### (h) Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits with an original maturity of three months or less.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 2 Basis of preparation (continued)

#### (i) **Financial liabilities**

#### Trade and other payables

Trade and other payables are initially recognised at fair value and subsequently measuredat amortised cost. Accounts payable are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities.

#### Convertible debt

The proceeds received on issue of the Company's convertible debt are allocated into their liability and equity components. The amount initially attributed to the debt component equals the discounted cash flows using a market rate of interest that would be payable on similar debt instrument that does not include an option to convert. Subsequently, the debtcomponent is accounted for as a financial liability measured at amortised cost untilextinguished on conversion or maturity of the bond. The remainder of the proceeds is allocated to the conversion option and is recognised in the "Other equity" within shareholders' equity, net of income tax effects.

#### (j) Borrowings

Borrowings are recognised initially at fair value, net of transaction costs incurred. Borrowings are subsequently carried at amortised cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognised in the income statement over the period of the borrowings using the effective interest method.

Borrowings are de-recognised from the statement of financial position when the obligation specified in the contract is discharged, is cancelled or expires. The difference between the carrying amount of a financial liability that has been extinguished or transferred to anotherparty and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognised in the income statement as other operating income or finance costs.

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

#### (k) **Provisions**

A provision is recognised in the statement of financial position when the Company has a present legal or constructive obligation as a result of a past event, and it is probable that an outflow of economic benefits will be required to settle the obligation. If the effect is material, provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and, when appropriate, the risks specific to the liability. The increase in the provision due to the passage of time is recognised in finance costs.

#### (I) Share capital

Ordinary shares are classified as equity. There are various classes of ordinary shares in issue, as detailed in note 21. Incremental costs directly attributable to the issue of new shares are shown in share premium as a deduction from the proceeds.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 2 Basis of preparation (continued)

#### (m) Net finance costs

#### Finance costs

Finance costs comprise interest payable on borrowings, direct issue costs, dividends on preference shares and foreign exchange losses, and are expensed in the period in which they are incurred.

#### Finance income

Finance income comprises interest receivable on funds invested, and foreign exchange gains.

Interest income is recognised in the income statement as it accrues using the effective interest method.

#### (n) Leases

All leases are accounted for by recognising a right-of-use asset and a lease liability exceptfor:

- Leases of low value assets; and
- Leases with a duration of 12 months or less.

Lease liabilities are measured at the present value of the contractual payments due to thelessor over the lease term, with the discount rate determined by reference to the rate inherent in the lease unless (as is typically the case) this is not readily determinable, in which case the Company's incremental borrowing rate on commencement of the lease is used. Variable lease payments are only included in the measurement of the lease liability if theydepend on an index or rate. In such cases, the initial measurement of the lease liability assumes the variable element will remain unchanged throughout the lease term. Other variable lease payments are expensed in the period to which they relate.

On initial recognition, the carrying value of the lease liability also includes:

- amounts expected to be payable under any residual value guarantee
- the exercise price of any purchase option granted in favour of the Company if it is reasonably certain to assess that option
- any penalties payable for terminating the lease, if the term of the lease has been estimated on the basis of termination option being exercised.

Right of use assets are initially measured at the amount of the lease liability, reduced for any lease incentives received, and increased for:

- lease payments made at or before commencement of the lease
- initial direct costs incurred; and
- the amount of any provision recognised where the Company is contractually required todismantle, remove or restore the leased asset (typically leasehold dilapidations see note 19).

Subsequent to initial measurement lease liabilities increase as a result of interest chargedat a constant rate on the balance outstanding and are reduced for lease payments made. Right-of-use assets are amortised on a straight-line basis over the remaining term of the lease or over the remaining economic life of the asset if, rarely, this is judged to be shorterthan the lease term.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 2 Basis of preparation (continued)

#### (n) Leases (continued)

When the group revises its estimate of the term of any lease (because, for example, it re-assesses the probability of a lessee extension or termination option being exercised) it adjusts the carrying amount of the lease liability to reflect the payments to make over the revised term, which are discounted using a revised discount rate. The carrying value of lease liabilities is similarly revised when the variable element of future lease payments dependent on a rate or index is revised, except the discount rate remains unchanged. In both cases an equivalent adjustment is made to the carrying value of the right-of-use asset, with the revised carrying amount being amortised over the remaining (revised) lease term. If the carrying amount of the right-of-use asset is adjusted to zero, any further reduction is recognised in profit or loss.

#### (o) Income tax

Income tax for the years presented comprises current and deferred tax. Income tax is recognised in the income statement except to the extent that it relates to items recogniseddirectly in equity, in which case it is recognised in equity. Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the statement of financial position date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognised on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts.

The following temporary differences are not recognised if they arise from (a) the initial recognition of goodwill; and (b) for the initial recognition of other assets or liabilities in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. The amount of deferred tax provided is based on the expected manner of realisation or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the statement of financial position date.

A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the asset can be utilised. Deferred tax assets are reduced to the extent that it is no longer probable that the related tax benefit will be realised.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention settle the balances on a net basis.

#### (p) Foreign currency translation

#### *i)* Function and presentational currency

Items included in the financial statements of the Company are measured using USD, the currency of the primary economic environment in which the entity operates ('the functional currency'), which is also the Company's presentation currency.

#### *ii) Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates, of monetary assets and liabilities denominated in foreign currencies to USD, are recognised in the income statement.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 3 Critical accounting judgements and estimates

The preparation of the Company's historical financial information under UK IFRS requires the directors to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities. Estimates and judgements are continually evaluated and are based on historical experience and other factors including expectations of future events that are believed to be reasonable under the circumstances. Actual results may differ from these estimates.

The Directors consider that the following estimates and judgements are likely to have the most significant effect on the amounts recognised in the financial information.

#### Carrying value of intangible assets, property, plant and equipment

In determining whether there are indicators of impairment of the Company's intangible assets, the directors take into consideration various factors including the economic viability and expected future financial performance of the asset and when it relates to the intangible assets arising on abusiness combination, the expected future performance of the business acquired.

#### Classification of the Mount Sinai License as an intangible asset

As set out in note 13, on 18 June 2021, the Company entered into the Mount Sinai License Agreement, pursuant to which Mount Sinai granted an option to the Company to obtain a licence, on a non-exclusive basis, to use certain information held by Mount Sinai. After considering the criteria in IAS38 the directors have judged that the recognition criteria therein have been met and classified the Mount Sinai license as an intangible asset.

#### 4 Segment analysis

IFRS 8 requires operating segments to be identified on the basis of internal reports about components of the Company that are regularly reviewed by the chief operating decision maker (which takes the form of the Board of Directors) as defined in IFRS 8, in order to allocate resources to the segment and to assess its performance.

The chief operating decision maker has determined that the Company has one operating segment, the development and commercialisation of its lung cancer early detection test. Revenues are reviewed based on the products and services provided.

The Company operates in the United States of America. Revenue by origin of geographical segment is as follows:

	Year to 31 December 2021	Year to 31 December 2020
	US\$	US\$
Revenue People's Republic of China	195,566	205,180
	195,566	205,180

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 4 Segment analysis (continued)

	2021 US\$	2020 US\$
Non-current assets United States of America	6,597,577	476,672
	6,597,577	476,672
	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
<b>Product and service revenue</b> Royalty income Consumable items	88,553 107,013	205,180
	195,566	205,180

#### 5 Financial instruments - Risk management

The Company is exposed through its operations to the following financial risks:

- Credit risk
- Foreign exchange risk and
- Liquidity risk

The Company is exposed to risks that arise from its use of financial instruments. This note describes the Company's objectives, policies and processes for managing those risks and the methods used to measure them. Further quantitative information in respect of these risks is presented throughout these financial statements.

#### (i) Principal financial instruments

The principal financial instruments used by the Company, from which financial instrument risk arises, are as follows:

- Cash and cash equivalents
- Trade and other payables

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

5	Financial instruments - Risk management (continued)		
	(ii) Financial instruments by category		
	Financial asset		
		Amortised cost 2021 US\$	Amortised cost 2020 US\$
	Cash and cash equivalents Trade and other receivables	14,628,351 740,865	127,628 169,801
	Total financial assets	15,369,216	297,429
	Financial liabilities		
		Amortised cost 2021 US\$	Amortised cost 2020 US\$

Trade and other payables and loan	803,738	1,225,836
Total financial liabilities	803,738	1,225,836

#### (iii) Financial instruments not measured at fair value

Financial instruments not measured at fair value includes cash and cash equivalents, trade and other receivables, and trade and other payables.

Due to their short-term nature, the carrying value of cash and cash equivalents, trade and other receivables, and trade and other payables approximates their fair value.

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 5 Financial instruments - Risk management (continued)

#### (iv) Financial instruments

#### General objectives, policies and processes

The Board has overall responsibility for the determination of the Company's risk management objectives and policies and, whilst retaining ultimate responsibility for them, it has delegated the authority for designing and operating processes that ensure the effective implementation of the objectives and policies to the Company's finance function.

The overall objective of the Board is to set policies that seek to reduce risk as far as possible without unduly affecting the Company's competitiveness and flexibility. Further details regarding these policies are set out below:

#### Credit risk

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations. Due to the current low level of revenue, the Company's exposure to credit risk is on cash at bank. The Company only deposits cash with major banks with high quality credit standing.

#### Cash in bank and short-term deposits

The credit quality of cash has been assessed by reference to external credit rating, based on Standard and Poor's long-term / senior issuer rating:

	2021	2021 Cash	2020	2020 Cash
	Rating	at bank US\$	Rating	at bank US\$
Bank A	A+	8,140,196	A+	127,628
Bank B	BBB+	6,425,645		-
Bank C	A+	62,510		-
		14,628,351		127,628

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 5 Financial instruments - Risk management (continued)

#### Foreign exchange risk

Foreign exchange risk arises when the Company enters into transactions denominated in a currency other than its functional currency. The Company's policy is, where possible, to settle liabilities denominated in its functional currency. Currently the Company's liabilities are either US dollar or UK sterling. No forward contracts or other financial instruments are entered into to hedge foreign exchange movements, with funds raised in the UK being transferred to fund US operations using spot rates.

As at 31 December 2021 assets held in Sterling amounted to US\$6,488,154 (2020 – US\$ Nil) and liabilities held in Sterling amounted to US\$65,772 (2020 – US\$340,371).

The effect of a 5% strengthening of the Sterling against US dollar at the reporting date on the Sterling denominated net assets carried at that date would, all other variables held constant, have resulted in a decrease in post-tax loss for the year and increase of net assets of US\$321,119. A 5% weakening in the exchange rate would, on the same basis, have increased post-tax loss and decreased net assets by US\$321,119.

#### Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty in meeting its financial obligations as they fall due. This risk is managed by the production of annual cash flow projections. The Company's continued future operations depend on its ability to raise sufficient working capital through the issue of share capital and generating revenue.

The following table sets out the contractual maturities (representing undiscounted contractual cash-flows) of financial liabilities which can all be met from the cash resources currently available:

		Between
	Up to 3	3 and 12
	months	months
At 31 December 2021	US\$	US\$
Trade and other payables	275,276	-
Total	275,276	-
		Between
	Up to 3	3 and 12
	months	months
At 31 December 2020	US\$	US\$
Trade and other payables	822,758	-
Loan	206,164	-
Total	1,028,922	-

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 5 Financial instruments - Risk management (continued)

#### Capital Disclosures

The Company monitors its capital which comprises all components of equity (i.e., share capital, share premium, and accumulated losses).

The Company's objectives when maintaining capital are to safeguard the entity's ability to continue as a going concern.

#### 6 Expenses by nature

	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Employee benefit expenses (see note 8)	1,760,012	1,295,786
Share-based payments charge – non-employee and directors	86,602	83,657
Depreciation of property, plant and equipment	323,758	282,654
Research and development expenditure	1,343,132	647,147
Professional costs	720,232	811,660
Legal settlement	687,409	525,000
Foreign exchange losses	96,690	-
Other costs	1,209,661	179,391

Other operating income included the forgiveness of the Paycheck Protection Program Loan of US\$206,164 (2020 – US\$Nil)

#### 7 Auditors' remuneration

During the year the Company obtained the following services from the Company's auditor:

Fees payable to the Company's auditor for the audit of the Company Fees payable to the Company's auditor for other services:	Year to 31 December 2021 US\$ 47,472	Year to 31 December 2020 US\$
Services in connection with listing Taxation services	108,423	41,864 2,500
Total	155,895	44,364

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 8 Employee benefit expenses

Employee benefit expenses (including Directors) comprise:	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Wages and salaries Benefits Share-based payments expense Social security contributions and similar taxes Pension	1,304,022 75,350 323,199 52,601 4,840  1,760,012	911,560 79,433 141,978 79,158 - 1,212,129

#### Key management personnel compensation

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, including the Directors of the Company.

	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Salary Share based payment expense	599,232 312,706	299,042 126,175
	911,938	425,217

The average number of employees (excluding Directors) in the Company in the year was 8 (2020 – 10).

#### 9 Net finance costs

Finance expense	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Interest expense on lease liabilities Interest expense on liabilities measured at amortised cost Interest expense on other loans	107,601 309,327 -	23,390 747,157 6,639
Total finance expense	416,928	777,186

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 9 Net finance costs (continued)

Finance income	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Bank interest	12,017	-
Total finance income	12,017	-

#### 10 Tax expense

	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Current tax expense		
Current tax on loss for the year	-	-
Withholding tax on royalties	15,872	-
Total current tax	15,872	-
Deferred tax asset		
On losses generated in the year	-	-
	15,872	-

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### **10** Tax expense (continued)

There were no charges to current corporation taxation due to the losses incurred by the Company in the year. The reasons for the difference between the actual tax charge for the year and the US federal income tax rate of 21% and state of California income tax rate of 8.84% are as follows:

	Year to 31 December 2021 US\$	Year to 31 December 2020 US\$
Loss for the year	(7,428,316)	(4,839,023)
Tax using 29.84% Expenses not deductible for tax purposes Unrecognised deferred tax assets for losses carried forward	(2,216,610) 688,811 1,527,799	(1,443,964) 410,500 1,033,464
Total tax expense	-	-

The unrecognised deferred tax is based on total taxable losses carried forward of US\$49,393,180 (2020 – US\$44,940,832 and a capital loss of US\$4,583,333 (2020 – US\$4,583,333). No deferred tax asset is recognised for these losses due to early stage in the development of the Company's activities. The losses do not expire but can only be used against trading profits from the same trade.

#### 11 Loss per share

Numerator	Year to 31 December 2021 Total US\$	Year to 31 December 2020 Total US\$
Loss for the year used in basic EPS	(7,444,188)	(4,839,023)
Denominator		
Weighted average number of ordinary shares used in basic EPS	15,870,143	6,515,838
Resulting loss per share	(US\$0.469)	(US\$0.743)

The Company has one category of dilutive potential ordinary share, being share options (see note 23). The potential shares were not dilutive in the year as the Company made a loss per share in line with IAS 33. As described in note 21, between 2 July 2021 and 7 July 2021 the Company implemented a pre-Admission reorganisation of its capital which included the conversion of Series A and B Preferred Shares into Common Shares and a reverse share split by way of the issue of one new Common Share and Preferred Share for every 18 old Common Shares and Preferred Shares held.

As required by IAS33, the number of shares presented as the denominator in calculating loss per share has been adjusted from 1 January 2020, the beginning of the earliest period for which loss per share information is presented in order to maintain comparability.

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 12 Tangible assets

Tangible assets	Leasehold improvements US\$	Furniture and equipment US\$	Computers and IT equipment US\$	Plant & machinery US\$	Total US\$
Cost or valuation					
<b>At 1 January 2020</b> Re-classification Additions	981,613 - -	1,102,464 (1,045,962) -	49,831 - -	۔ 1,045,962 5,328	2,133,908 - 5,328
At 31 December 2020 Landlord contribution	981,613 (15,588)	56,502	49,831	1,051,290	2,139,236 (15,588)
Additions	349,338	-	35,126	257,428	641,892
At 31 December 2021	1,315,363	56,502	84,957	1,308,718	2,765,540
Accumulated depreciation and impairment					
<b>At 1 January 2020</b> Re-classification Depreciation	558,051 - 153,126	786,784 (730,282)	48,310 - 1,521	730,282 128,007	1,393,145 - 282,654
At 31 December 2020 Depreciation	711,177 233,253	56,502	49,831 3,173	858,289 87,332	1,675,799 323,758
At 31 December 2021	944,430	56,502	53,004	945,621	1,999,557
<i>Net book value</i> At 31 December 2021	370,933		31,953	363,097	765,983
At 31 December 2020	270,436	-	-	193,001	463,437

Included in leasehold improvements at 31 December 2021 are right of use assets with a cost of \$1,282,052 and accumulated depreciation of \$911,119.

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 13 Intangible assets

	License US\$	Total US\$
Cost		
<b>At 1 January 2020</b> Additions	-	-
At 31 December 2020 Additions	5,818,359	5,818,359
At 31 December 2021	5,818,359	5,818,359
Accumulated amortisation and impairment		
At 1 January 2020 Amortisation charge	-	-
At 31 December 2020 Amortisation charge		-
At 31 December 2021	-	-
Net book value		
At 31 December 2021	5,818,359	5,818,359
At 31 December 2020	-	

On 18 June 2021, the Company entered into the Mount Sinai Licence Agreement, pursuant to which the Icahn School of Medicine at Mount Sinai ("Mount Sinai") granted an option to the Company to obtain a licence, on a non-exclusive basis, to use certain information held by Mount Sinai. The Mount Sinai Licence Agreement automatically became effective on Admission. Exercise of the option contained in the Mount Sinai Licence Agreement is conditional on: (i) Admission; (ii) clearance by Mount Sinai's information security team; and (iii) IRB, data security and data use approvals. Mount Sinai is under an obligation to use commercially reasonable efforts to obtain such clearances and approvals (other than Admission). Pursuant to the Mount Sinai Licence Agreement, Mount Sinai has granted the Company an option to obtain a licence, on a non-exclusive basis, to use certain information held by Mount Sinai to be able to develop future products.

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

14	Trade and other receivables	2021	2020
	Amounto folling due within and year	US\$	US\$
	Amounts falling due within one year		
	Prepayments and accrued income Other debtors	692,274 48,591	169,801
		740,865	169,801
		2021 US\$	2020 US\$
	Amounts falling due after one year		
	Rent deposit	13,235	13,235
		13,235	13,235
15	Trade and other payables		
		2021 US\$	2020 US\$
	Trade payables Accruals and other payables	211,718 570,920	786,018 439,818
	Total financial liabilities classified as financial liabilities measured at		
	amortised cost	782,638	1,225,836
	Other payables – tax and social security payments	21,100	-
	Total trade and other payables	803,738	1,225,836

The carrying value of trade and other payables classified as financial liabilities measured at amortised cost approximates fair value.

### Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 16 Borrowings and Loans

2021 US\$	2020 US\$
	206,164
	206,164
	US\$ 

In May 2020 the Company applied for and received a loan under the US Government Paycheck Protection Program. An application for forgiveness of the entire principal balance as permitted under the Program was made subsequent to 31 December 2020 and was granted in the year to 31 December 2021.

#### 17 Lease Liabilities

	Land and buildings US\$	Plant and machinery US\$	Total US\$
At 1 January 2020 Interest expense Repayments	349,803 23,390 (151,859)	144,629 (28,520)	494,432 23,390 (180,379)
At 31 December 2020	221,334	116,109	337,443
Additions Repayments Interest expense	349,338 (156,306) 89,625	245,189 (74,363) 17,976	594,527 (230,669) 107,601
At 31 December 2021	503,991	304,911	808,902

The Company acquired certain tangible assets under capital lease financing arrangements.

The Company operates from one office which is rented under a lease agreement ending on 1 July 2022 under which rent is payable monthly. During the year the Company extended this lease until 31 August 2025 commencing 1 July 2022 and with a two-month rent free period.

	2021 US\$	2020 US\$
Maturity of lease liabilities		
Within 3 months	56,727	40,951
Between 3 – 12 months	150,553	131,045
Between 1 – 2 years	255,070	108,346
Between 2 – 5 years	346,552	57,101
	909 002	227 442
	808,902	337,443

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 18 Convertible Notes

	2021 US\$	2020 US\$
Due within one year: Convertible Secured Promissory Notes		10,086,616
	-	10,086,616

On 26 October 2017 the Company issued a Convertible Secured Promissory Note Purchase Agreement (the "**Notes**") that provided for the issuance of up to a principal amount US\$3m on which interest of eight per cent. Accrued. Unless converted into shares the principal and accruedinterest are payable in full at the earlier of the maturity date of 26 January 2020 or the occurrenceof a defined corporate transaction.

On 31 December 2018 the total principal amount of Notes that could be issued increased to US\$6m and on 20 August 2019 the total principal amounts of Notes that could be issued increased to US\$7.5m. On 20 August 2019 the Company determined that the Notes issued before that date should be classified as Series A-1 Notes and those issued after that date SeriesA-2 Notes. The Series A-2 Notes have a different conversion term and are repayable in preference to the Series A-1 Notes.

As the conversion feature results in the conversion of a fixed amount of stated principal into a fixed number of shares, it satisfies the 'fixed for fixed' criterion and, therefore, it is classified as an equity instrument.

The value of the liability component and the equity conversion component were determined at the date the instrument was issued.

The fair value of the liability component, included above, at inception was calculated using a market interest rate for an equivalent instrument without conversion option. The discount rate applied was eight per cent.

On 15 June 2020 the Company entered into an agreement to extend the maturity date of the Notes to 30 June 2021.

Between 2 July 2021 and 7 July 2021 all the principal and accrued interest in the Convertible Notes was converted into new Common Stock shares.

The interests of the Directors and their connected persons in the Convertible Notes was:

	2021 US\$	2020 US\$
Simon Raab (resigned 1 July 2021) Frederick Gluck (resigned 1 July 2021)	-	3,232,380 1,711,953
	-	4,944,333

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

19	Provisions	Dilapidations US\$	Total US\$
	At 1 January 2020 Movement	50,000 -	50,000
	At 31 December 2020	50,000	50,000
	Additions	-	-
	At 31 December 2021	50,000	50,000

Provision is made for the anticipated cost of returning the Company's premises to their prior state on termination of the lease.

# Notes forming part of the financial statements for the year ended 31 December 2021 *(continued)*

#### 20 Net cash /(debt) reconciliation

•		2021 US\$	2020 US\$
	Cash and cash equivalents	14,628,351	127,628
	Convertible notes	-	(10,086,616)
	Other borrowings and loans	-	(206,164)
	Lease liabilities	(808,902)	(337,443)
	Net cash / (debt)	13,819,449	(10,502,595)

cash ai	rowings nd loans	Net Debt
US\$	US\$	US\$
		6,951,392) 2,975,519)
-	-	-
-	156,647 (732,331)	156,647 (732,331)
7,628 (10	,630,223) (1	0,502,595)
0,723	- 1	4,500,723
- 10		0,395,943
-	•	206,164 (471,459)
	(309,327)	(309,327)
8,351	(808,902) 1	3,819,449
	cash ai alents US\$ 26,794 (7 99,166) (2 - - - - 27,628 (10 - - - - - - - - - - - - - - - - - - -	cash alents       and loans         JS\$       JS\$         26,794       (7,678,186)       ()         (99,166)       (2,376,353)       ()         -       -       -         -       156,647       (732,331)         -       -       -         -       156,647       -         -       (732,331)       -         -       -       -         27,628       (10,630,223)       (1)         -       -       -         00,723       -       1         -       10,395,943       1         -       206,164       -         -       (471,459)       -         -       (309,327)       -

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 21 Share capital

Share capital	Issued and fully paid Number US\$	
<i>Shares of US\$0.0001 par value each</i> At 1 January 2020 Common shares	5 002 820	510
Preference shares, Series A and B	5,092,839 79,738,560	510 7,973
Issue of common shares in the year	1,820,407	184
Total at 31 December 2020	86,651,806	8,665
	00,001,000	0,000
Reverse stock split, at ratio of 1 new common share	(81,837,883)	(8,184)
Issue of common shares on conversion of the Convertible Loan Notes and Warrants	9,350,888	935
Issue of common shares for cash	9,659,091	966
Issue of common shares for non-cash consideration	1,656,888	166
Total issued share capital at 31 December 2021	25,480,790	2,548

Between 2 July 2021 and 7 July 2021 the Company implemented a pre-Admission reorganisation of its capital which included, inter alia, the following:

- A reverse share split by way of the issue of one new Common or Preferred Share for every 18 old Common or Preferred Shares held
- Conversion of Series A-1 and Series A-2 Convertible Notes and related Warrants into Common Shares
- Conversion of Series A Preferred Shares and Series B Preferred Shares into Common Shares

#### 22 Reserves

The following describes the nature and purpose of each reserve within equity:

Reserve	Description and purpose
Share premium	Amount subscribed for share capital in excess of nominal value.
Other equity	Amount of proceeds on issue of convertible debt relating to the equity component (i.e., option to convert the debt into share capital).
Retained earnings	All other net gains and losses and transactions with owners (e.g., dividends) not recognised elsewhere.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

#### 23 Share-based payment

Prior to Admission to AIM the Company operated two share option plans: the 2010 Stock Incentive Plan and approved by the Board on 1 January 2010 and the 2020 Stock Incentive Plan was approved on 14 May 2020:

- (a) options granted under the 2010 Stock Incentive Plan fall into two groups:
  - (i) options granted in or before 2016 over a total of 2,183,634 shares, with exercise prices ranging from \$0.10 to \$0.16 per share, these options are now fully vested; and
  - (ii) options granted in 2019 over a total of 6,951,463 shares, with an exercise price of \$0.025 per share: these options generally vest on a monthly basis over three or four years from the date of grant. However, those granted to current employees of the Company were amended so that they became exercisable in full on Admission.
- (b) Options were granted in 2020 and 2021 under the 2020 Stock Incentive Plan over a total of 5,364,385 shares with an exercise price of \$0.0044 per share. These options vest over four years from the date of grant on a monthly basis, but certain of these options accelerated immediately before Admission, and became fully exercisable at Admission.

On 14 May 2021 the Board approved the Company's 2021 Omnibus Long-Term Incentive Plan ("LTIP") and it was approved by shareholders on 27 May 2021 to become effective approximately three days prior to Admission. The LTIP provides for the grant of both EMI Options and non-tax favoured options. Options granted under the LTIP are subject to exercise conditions as summarised below.

The LTIP has a non-employee sub-plan for the grant of Options to the Company's advisors, consultants, nonexecutive directors, and entities providing, through an individual, such advisory, consultancy, or office holder services and a US sub-plan for the grant of Options to eligible participants in the LTIP and the Non-Employee Sub-Plan who are US residents and US taxpayers.

With the exception of options over 384,924 shares, which vested immediately on Admission, the options issued under the LTIP vest 25% on the first anniversary of the vesting commencement date and an additional one fortyeighth of the total number of options after each subsequent calendar month for employees. For consultants options issued under the LTIP vest 25% on the first anniversary of the vesting commencement date and an additional one sixteenth of the total number of options after each subsequent guarter. If options remain unexercised after the date one day before the tenth anniversary of grant such options expire. Vesting shall accelerate in full in the event of a change of control of the Company.

As described in note 21, between 2 July 2021 and 7 July 2021 the Company implemented a pre-Admission reorganisation of its capital which included a reverse share split by way of the issue of one new Common or Preferred Share for every 18 old Common or Preferred Shares held.

At the date of the reorganisation there were 14,499,482 pre-Admission options outstanding to 32 option holders comprising Directors, former Directors and employees with exercise prices between \$0.0044 and \$0.16 per share. Those options were varied to reflect the reverse share split so that they were replaced with 805,492 options with exercise prices of between \$0.0792 and \$2.88 per share. The directors consider that this was a mechanical variation modification of the awards and not a modification for the purposes of IFRS2. Comparative figures have been adjusted to restate numbers and values of share options issued as if the reverse share split had been in effect from 1 January 2020.

On Admission on 8 July 2021 the Board approved grants of 769,707 to Paul Pagano and 386,703 options to David Anderson and on 23 November 2021 and 27 December 2021 the Board approved further grants, of 112,500 and 5,000 options respectively, to employees and consultants.

# Notes forming part of the financial statements for the year ended 31 December 2021 (continued)

23	Share-based payment (continued)	Weighted average exercise price US\$	Number
		price 035	
	Outstanding at 1 January 2020 Granted during the year Cancelled Exercised during the year		12,230,198 2,345,845 (25,000) (51,561)
	Outstanding at 31 December 2020 and 1 January 2021		14,499,482
	Reverse share split		(13,693,990)
	Revised balance outstanding at 31 December 2020	0.74	805,492
	Granted during the year Exercised or expired during the year	2.19 0.74	1,260,035 (13,913)
	Outstanding at 31 December 2021	1.74	2,065,527
	Vested at 31 December 2021	1.35	1,030,627

The exercise price of options outstanding at 31 December 2021 ranged between US\$0.08 and US\$2.70 and their weighted average contractual life was 7.66 years and weighted average expected life was 1.8 years. The fair value of each share option granted has been estimated using a Black-Scholes model. The inputs into the model are share prices of between US\$0.08 and US\$2.51, exercise prices of between US\$0.45 and US\$2.77, expected volatility of 57.9%, expected dividend yield of 0%, expected lives of between 1.25 and 3.75 years and a risk-free interest rate of 0.29%. In the absence of historic volatility data available at the grant date the expected volatility of 57.9% was estimated based on comparable companies.

The Company recognised total expenses of US\$409,801 (2020: US\$225,635) within administrative expenses relating to equity-settled share-based payment transactions during the year.

#### 24 Events after the reporting date

There have been no events subsequent to the year-end that require disclosure in these financial statements.

# LungLifeAl

#### **Our Vision.**

To invert the 20:80 ratio such that in years to come at least 80% of lung cancer is detected early