



26 September 2022

LungLife AI, Inc.  
(the “Company” or “LungLife”)

### Half-year Report

LungLife AI (AIM: LLA1), a developer of clinical diagnostic solutions for the early detection of lung cancer announces its unaudited half-year report for the six months ended 30 June 2022.

#### Summary and Highlights (including post-period end):

- Cash as of 30 June 2022 of \$10.63m
- Loss before tax of \$4.47m and EBITDA loss of \$4.31m
- Six sites participating in the Company’s LungLB® validation study, up from three at time of preliminary results in March, with more in the pipeline
- New York Clinical Laboratory Evaluation Programme (“CLEP”) permit awarded
- CPT® Proprietary Laboratory Analyses (PLA code), a key component towards reimbursement in the US market, awarded and became effective on 1 April 2022
- Appointment of Dr Drew Moghanaki, an internationally recognised lung cancer specialist, to the Company’s Scientific Advisory Board
- With the existing sites participating in the validation study and the additional sites already in the pipeline, there is a continued expectation that we will complete enrolment of our validation study by end of March 2023 and initial commercialisation with nominal revenues of LungLB® later in 2023

**Commenting on outlook, Paul Pagano, Chief Executive Officer of LungLife, said:** *“I am proud of the progress that the team has made over this six-month period. Our validation study is well underway, having enrolled our first participant in February, and we are where we expected to be at this time point to be able to complete enrolment by the end of Q1 2023.*

*“Beyond the continued enrolment of participants into the LungLB® validation study, over the remainder of the year we are focused on progressing towards commercial reimbursement. Following the grant of a CPT® PLA code in January, we now look ahead to the processes of pricing and coverage for the LungLB® test.”*

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#### About LungLife

LungLife AI is a developer of clinical diagnostic solutions designed to make a significant impact in the early detection of lung cancer, the deadliest cancer globally. Using a minimally invasive blood draw, the Company’s LungLB® test is designed to deliver additional information to clinicians who are evaluating indeterminate lung nodules. For more information visit [www.lunglifeai.com](http://www.lunglifeai.com)

## **CHAIRMAN'S STATEMENT**

The six months ended 30 June 2022 was a period of good progress for LungLife, as we achieved several milestones to keep us on track with our mission to make a significant impact in the early detection of lung cancer through our LungLB® test.

### **Our LungLB® test**

LungLB® is a blood-based test that uses circulating tumour cells to stratify indeterminate lung nodules as either cancerous or benign following their identification by CT scan. Biopsy is currently part of the standard of care pathway for lung nodules, but it has significant drawbacks. Approximately 40% of biopsies result in a benign nodule, and an adverse event rate of approximately 20% means that many patients are unnecessarily put at risk. The LungLB® test is designed to support the physician's decision to biopsy only when necessary, or to monitor non-invasively using additional imaging.

In 2021, we completed a 149-participant pilot study in which we observed a well-balanced performance and a Positive Predictive Value ("PPV") of 89% by LungLB®. This PPV value means that in the case of a positive result from the LungLB® test, the subject's indeterminate nodule was cancerous 89% of the time. We have now embarked on our clinical validation study and hope those results will mirror those found in our pilot study.

There are estimated to be over 1.5 million indeterminate lung nodules identified each year in the United States<sup>1</sup> by CT scan and LungLife's estimated one week turnaround from receipt of the blood sample to results can save a significant amount of stressful waiting time for the patient as well as avoid unnecessary costly, and often dangerous, procedures.

### **Progress in the period**

In February 2022, we enrolled the first participant into our multi-centre clinical validation study for LungLB®. The validation study will enrol up to 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, taking participants who present with indeterminate lung nodules.

Since my last report in March, we have added a further three sites to our validation study, including a further two medical centres of the Veterans Affairs ("VA") and most recently, University of California, Los Angeles ("UCLA"). There are a number of further sites currently in the pipeline and which are expected to come onstream in the coming weeks and months.

The VA has the United States' largest integrated health care system, providing care at nearly 1,300 facilities and serving nine million veterans each year. Lung cancer is the leading cause of cancer-related deaths among US veterans, and it is believed that veterans are at higher risk in part due to environmental exposures during military service. An estimated 900,000 US veterans are at-risk for lung cancer, and VA hospitals diagnose around 7,700 new lung cancer cases each year, making the three VA sites in our study population an important addition.

Earlier this month we were delighted to be awarded the New York Clinical Laboratory Evaluation Programme ("CLEP") permit following their audit. The CLEP permit allows LungLife to perform clinical utility studies and offer the LungLB® test commercially in New York state, in addition to the 46 other states permitted by the Company's existing Clinical Laboratory Improvement Amendments ("CLIA") certification. The audit was performed to ensure that the premises, laboratory practice, equipment, personnel, and record-keeping methods meet state requirements. Issuance of the CLEP permit follows a rigorous, independent scientific review of both analytical and clinical data for LungLB®, as well as evaluation of adherence to the Company's quality management system.

This is an important step in LungLife's commercialisation plan, given our relationship with the Icahn School of Medicine at Mount Sinai in New York, a key site in the ongoing pivotal validation trial, and from which the Company is now able to accept study participants in future utility studies.

In January 2022, we announced that we had been successfully granted a Proprietary Laboratory Analyses (PLA) CPT® code by the American Medical Association, marking the first step on the path for commercial reimbursement. CPT® codes offer healthcare professionals a uniform language for coding medical services and procedures and allows clinical

laboratories to more specifically identify their tests when billing Medicare and commercial insurers. The Centers for Medicare & Medicaid Services (“CMS”) recently issued their Calendar Year 2023 Clinical Laboratory Fee Schedule (CLFS) preliminary payment determination for the LungLB® as crosswalk. There is now a public comment period for 30 days and the final determination will be announced in November 2022. There is no guarantee the final payment determination will be crosswalk.

As a reminder, crosswalk applies if the new test is comparable to an existing test (that may use a similar technology but for a different indication, for example), in which case it is assigned the market-based payment rate of that comparable existing test. Gapfill applies if there are no comparable existing tests, in which case the Medicare Administrative Contractor determines the pricing.

## **People**

In March, we announced the appointment of Dr Drew Moghanaki, MD, MPH, an internationally recognised lung cancer specialist, to our Scientific Advisory Board. Dr Moghanaki is Professor and Chief of Thoracic Oncology at the UCLA Department of Radiation Oncology. He has brought extensive leadership to our Scientific Advisory Board as the Director of the VA Partnership to increase Access to Lung Cancer Screening programme (VA-PALS), and the co-chair of the VA Lung Cancer Surgery or Stereotactic Radiotherapy (VALOR) Phase III study, investigating treatment options for stage I lung cancer.

## **Outlook**

Our key focus is meeting our enrolment target by end of March 2023. Once enrolment is complete, we will then start the process of evaluating the results which we expect to be concluded by June 2023. With our CLIA license and CLEP permit, we expect to be able to begin commercialisation of LungLB® in parallel with our preparation and submission to the FDA.

We continue to carefully manage our cash resources with an anticipated cash runway to first half of 2024.

I would like to thank our shareholders, staff and partners for their support over this period, and look ahead to the remainder of 2022 and beyond, which is set to bring further progress for the Company.

**Roy Davis**  
**Non-Executive Chairman**  
**26 September 2022**

<sup>1</sup> Gould MK *et al.* Am J Respir Crit Care Med. 2015 PMID: 26214244.3

## FINANCIAL REVIEW

In the period total cash outflow was \$4.0m (six months to 30 June 2021 - \$0.07m), of which \$3.8m was consumed by operating activities (six month to 30 June 2021 - \$1.6m) with the balance mainly being repayment of lease liabilities, which includes the rent on our CLIA laboratory. The prior period was before our IPO on 8 July 2021 whereupon the business was funded by the issue of convertible loan notes, all of which, principal and interest, were subsequently converted into new common shares.

Revenues of \$10k related to royalties earned under our arrangement with our partner in China. In the six months to 30 June 2021 revenue was \$107k which related wholly to the sale of consumable items to our partner in China. The EBITDA loss for the period was \$4.31m (six months to 30 June 2021 - \$2.2m), which includes the share-based payment charge of \$0.4m (six months to 30 June 2021 - \$0.16m). The biggest contributors to the EBITDA loss were employment costs of \$1.3m (six months to 30 June 2021 - \$0.43m) and research and development of \$1.3m (six months to 30 June 2021 - \$0.19m). The research and development costs are those incurred on our clinical validation study and continued development of the AI algorithm. In the period we increased our headcount, and we now have 14 full time employees.

**STATEMENT OF COMPREHENSIVE INCOME**  
**For the period ended 30 June 2022**

	<i>Note</i>	<b>6 months ended 30 June 2022 US\$'000 Unaudited</b>	<b>6 months ended 30 June 2021 US\$'000 Unaudited</b>	<b>Year ended 31 December 2021 US\$'000 Audited</b>
Revenue	(3)	10	107	195
Cost of sales		-	(92)	(96)
<b>Gross profit</b>		<b>10</b>	<b>15</b>	<b>99</b>
Administrative expenses		(4,322)	(2,247)	(5,904)
Exceptional costs – costs of listing		-	(2,084)	(1,101)
Depreciation		(155)	(139)	(323)
<b>Operating loss</b>		<b>(4,467)</b>	<b>(4,455)</b>	<b>(7,229)</b>
Other operating income		-	206	206
Finance income		26	-	12
Finance charges		(27)	(317)	(417)
<b>Loss before taxation</b>		<b>(4,468)</b>	<b>(4,566)</b>	<b>(7,428)</b>
Taxation		(1)	-	(16)
<b>Loss for the period / year</b>		<b>(4,469)</b>	<b>(4,566)</b>	<b>(7,444)</b>
Other comprehensive income		-	-	-
<b>Total comprehensive loss for the period / year</b>		<b>(4,469)</b>	<b>(4,566)</b>	<b>(7,444)</b>
<b>Loss per share from continuing activities attributable to the ordinary equity holders of the Company</b>				
Basic and diluted (US Dollars per share)	(4)	(0.175)	(0.960)	(0.469)

**STATEMENT OF FINANCIAL POSITION**  
As at 30 June 2022

	<i>Note</i>	<b>30 June 2022 US\$'000 Unaudited</b>	<b>30 June 2021 US\$'000 Unaudited</b>	<b>31 December 2021 US\$'000 Audited</b>
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment		693	309	766
Intangible assets		5,818	-	5,818
Other receivables	(5)	13	13	13
<b>Total non-current assets</b>		<b>6,524</b>	<b>322</b>	<b>6,597</b>
<b>Current assets</b>				
Trade and other receivables	(5)	526	137	741
Cash and cash equivalents		10,633	121	14,628
<b>Total current assets</b>		<b>11,159</b>	<b>258</b>	<b>15,369</b>
<b>Total assets</b>		<b>17,683</b>	<b>580</b>	<b>21,966</b>
<b>Equity and liabilities</b>				
<b>Equity</b>				
Called up share capital		3	9	3
Share premium		91,264	52,194	91,264
Other equity		-	942	-
Share based payment reserve		1,358	714	960
Accumulated losses		(76,566)	(69,469)	(72,097)
<b>Total equity</b>		<b>16,059</b>	<b>(15,610)</b>	<b>20,130</b>
<b>Non-current liabilities</b>				
Lease liabilities		477	75	601
Provisions		50	50	50
		<b>527</b>	<b>125</b>	<b>651</b>
<b>Current liabilities</b>				
Trade and other payables	(7)	706	3,810	804
Lease liabilities		217	172	207
Discontinued operations		174	174	174
Convertible notes		-	11,909	-
<b>Total current liabilities</b>		<b>1,097</b>	<b>16,065</b>	<b>1,185</b>
<b>Total liabilities</b>		<b>1,624</b>	<b>16,190</b>	<b>1,836</b>
<b>Total equity and liabilities</b>		<b>17,683</b>	<b>580</b>	<b>21,966</b>

**STATEMENT OF CHANGES IN EQUITY**  
**As at 30 June 2022**

	Share capital US\$'000	Share premium US\$'000	Other equity US\$'000	Share based payment reserve US\$'000	Accumulated losses US\$'000	Total equity US\$'000
<b>Balance at 1 January 2021</b>	9	52,194	843	551	(64,903)	(11,306)
<b>Comprehensive income:</b>						
Loss for the period	-	-	-	-	(4,566)	(4,566)
<b>Transactions with owners:</b>						
Convertible debt	-	-	99	-	-	99
Share based payments	-	-	-	163	-	163
<b>Balance at 30 June 2021</b>	<b>9</b>	<b>52,194</b>	<b>942</b>	<b>714</b>	<b>(69,469)</b>	<b>(15,610)</b>
<b>Balance at 30 June 2021</b>	9	52,194	942	714	(69,469)	(15,610)
<b>Comprehensive income:</b>						
Loss for the period	-	-	-	-	(2,878)	(2,878)
<b>Transactions with owners:</b>						
Reverse stock split	(8)	8	-	-	-	-
Issue of common stock	2	40,062	-	-	-	40,064
Conversion of Loan Notes	-	-	(942)	-	250	(692)
Share issue costs	-	(1,000)	-	-	-	(1,000)
Share based payments	-	-	-	246	-	246
<b>Balance at 31 December 2021</b>	<b>3</b>	<b>91,264</b>	<b>-</b>	<b>960</b>	<b>(72,097)</b>	<b>20,130</b>
<b>Balance at 1 January 2022</b>	3	91,264	-	960	(72,097)	20,130
<b>Comprehensive income:</b>						
Loss for the period	-	-	-	-	(4,469)	(4,469)
<b>Transactions with owners:</b>						
Share based payments	-	-	-	398	-	398
<b>Balance at 30 June 2022</b>	<b>3</b>	<b>91,264</b>	<b>-</b>	<b>1,358</b>	<b>(76,566)</b>	<b>16,059</b>

**STATEMENT OF CASH FLOWS**  
**For the period ended 30 June 2022**

	6 months ended 30 June 2022 US\$'000 Unaudited	6 months ended 30 June 2021 US\$'000 Unaudited	Year ended 31 December 2021 US\$'000 Audited
<b>Cash flows from operating activities</b>			
Loss for the period / year	(4,469)	(4,566)	(7,444)
Adjustments for non-cash/non-operating items:			
Depreciation	155	139	323
Gain on sale of tangible assets	-	(36)	(36)
Other operating income	-	(206)	(206)
Finance income	(26)	-	(12)
Finance expense	27	317	417
Taxation	1	-	16
Share based compensation	398	163	409
	<b>(3,914)</b>	<b>(4,189)</b>	<b>(6,533)</b>
<b>Changes in working capital</b>			
(Increase)/ decrease in trade and other receivables	221	32	(569)
(Decrease)/increase in trade and other payables	(98)	2,585	(422)
<b>Cash outflow from operations</b>	<b>(3,791)</b>	<b>(1,572)</b>	<b>(7,524)</b>
<b>Taxation paid</b>	<b>(1)</b>	<b>-</b>	<b>(16)</b>
<b>Net cash outflow from operating activities</b>	<b>(3,792)</b>	<b>(1,572)</b>	<b>(7,540)</b>
<b>Cash inflow / (outflows) from investing activities</b>			
Proceeds from sale of tangible assets	-	36	36
Purchase of tangible assets	(82)	-	(47)
Landlord improvement contribution	-	15	15
Purchase of intangible assets	-	-	(1,800)
<b>Net cash flows from investing activities</b>	<b>(82)</b>	<b>51</b>	<b>(1,796)</b>
<b>Cash flows from financing activities</b>			
Issue of Convertible Notes	-	1,612	1,612
Issue of common stock	-	-	23,444
Expenses of issue of common stock	-	-	(1,000)
Interest received	20	-	10
Interest paid	(27)	-	(107)
Repayment of lease liabilities	(114)	(98)	(123)
<b>Net cash inflow from financing activities</b>	<b>(121)</b>	<b>1,514</b>	<b>23,836</b>
Net increase/(decrease) in cash and cash equivalents	(3,995)	(7)	14,500
Cash and cash equivalents brought forward	14,628	128	128
<b>Cash and cash equivalents carried forward</b>	<b>10,633</b>	<b>121</b>	<b>14,628</b>

## **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 on 30 December 2009.

### ***Basis of preparation***

The accounting policies adopted in the preparation of the interim consolidated financial information are consistent with those of the preparation of the Group's annual consolidated financial statements for the period ended 31 December 2021. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2022.

### ***Statement of compliance***

This interim consolidated financial information for the six months ended 30 June 2022 has been prepared in accordance with UK adopted International Accounting Standards (UK IFRS) IAS 34, 'Interim financial reporting' as adopted by the European Union and the AIM Rules for UK Companies. This interim consolidated financial information is not the Group's statutory financial statements and should be read in conjunction with the annual financial statements for the period ended 31 December 2021, which have been prepared in accordance with UK IFRS and have been delivered to the Registrar of Companies. The auditors have reported on those accounts; their report was unqualified, did not include references to any matters to which the auditors drew attention by way of emphasis of matter without qualifying their report and did not contain any statements of emphasis or other matters.

The interim consolidated financial information for the six months ended 30 June 2022 is unaudited. In the opinion of the Directors, the interim consolidated financial information presents fairly the financial position, and results from operations and cash flows for the period. Comparative numbers for the six months ended 30 June 2021 are unaudited.

### ***Measurement convention***

The financial information has been prepared under the historical cost convention. Historical cost is generally based on the fair value of the consideration given in exchange for assets.

The preparation of the financial information in compliance with UK IFRS requires the use of certain critical accounting estimates and management judgements in applying the accounting policies. The significant estimates and judgements that have been made and their effect is disclosed in note 2.

## **2. 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 a business combination, the expected future performance of the business acquired.

## **3. 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 LungLife AI, Inc 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:

<b>Revenue</b>	<b>6 months ended 30 June 2022 US\$'000 Unaudited</b>	<b>6 months ended 30 June 2021 US\$'000 Unaudited</b>	<b>Year ended 31 December 2021 US\$'000 Audited</b>
People's Republic of China	10	107	195
	<b>10</b>	<b>107</b>	<b>195</b>
<b>Non-current assets</b>	<b>30 June 2022 US\$'000 Unaudited</b>	<b>30 June 2021 US\$'000 Unaudited</b>	<b>31 December 2021 US\$'000 Audited</b>
United States of America	6,524	322	6,597
	<b>6,524</b>	<b>322</b>	<b>6,597</b>
<b>Product and service revenue</b>	<b>6 months ended 30 June 2022 US\$'000 Unaudited</b>	<b>6 months ended 30 June 2021 US\$'000 Unaudited</b>	<b>Year ended 31 December 2021 US\$'000 Audited</b>
Consumable items	-	107	107
Royalty income	10	-	88
	<b>10</b>	<b>107</b>	<b>195</b>

#### 4. LOSS PER SHARE

The basic loss per share from continuing activities is based on a loss for the year attributable to equity holders of the Parent Company of \$4,469,915 for the 6 months ended 30 June 2022 (6 months ended 30 June 2021 loss \$4,566,267; year ended 31 December 2021: loss \$7,444,188) and the weighted average number of shares in issue for the 6 months to 30 June 2022 of 25,480,790 (6 months to 30 June 2021: 4,758,434 and year to 31 December 2021: 15,870,143).

The Company has one category of dilutive potential ordinary share, being share options. The potential shares were not dilutive in the period as the Company made a loss per share in line with IAS 33. Prior to the listing of its shares, 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 2021, the beginning of the earliest period for which loss per share information is presented in order to maintain comparability.

#### 5. TRADE AND OTHER RECEIVABLES

<b>Amounts falling due within one year</b>	<b>30 June 2022 US\$'000</b>	<b>30 June 2021 US\$'000</b>	<b>31 December 2021 US\$'000</b>
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	Unaudited	Unaudited	Audited
Trade receivables	69	67	-
Other receivables	99	-	49
Prepayments	358	70	692
	<b>526</b>	<b>137</b>	<b>741</b>

#### Amounts falling due after one year

Rent deposit	13	13	13
	<b>13</b>	<b>13</b>	<b>13</b>

All receivables are denominated in US dollars

#### 6. SHARE BASED PAYMENTS

The following is an analysis of movement in options issued and outstanding to purchase shares in the Company:

	Total options Number	Weighted average exercise price US\$
At 1 January 2021	14,499,482	
Reverse share split	(13,693,990)	
<b>Revised balance at 1 January 2021</b>	<b>805,492</b>	<b>0.74</b>
Exercised or expired	(13,913)	0.74
Granted	1,260,035	2.19
<b>At 31 December 2021 – Exercisable</b>	<b>2,065,527</b>	<b>1.74</b>
Granted	75,000	2.37
Expired	(18,356)	1.80
<b>At 30 June 2022 - Exercisable</b>	<b>2,122,171</b>	<b>1.76</b>

#### 7. TRADE AND OTHER PAYABLES

	30 June 2022 US\$'000 Unaudited	30 June 2021 US\$'000 Unaudited	31 December 2021 US\$'000 Audited
Trade payables	368	1,225	212
Other payables – tax and social security	2	-	21
Accruals and other payables	336	2,585	571
	<b>706</b>	<b>3,810</b>	<b>804</b>

Trade and other payables comprise amounts outstanding for trade purchases and on-going costs. All trade and other payables are due in less than a year.

#### 8. SUBSEQUENT EVENTS

There have been no events which require disclosure in these unaudited interim financial statements.