

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

Half-year Report

LungLife AI (AIM: LLAI), 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 2024.

Strong progress with our LungLB® product

- Successful clinical validation of the Company's LungLB® test following conclusion of the multi-site validation trial. This completes all of the major milestones set out at the time of the Company's admission to AIM, including regulatory approval from Clinical Laboratory Improvement Amendments ("CLIA") / New York State Department of Health ("NYSDOH"), obtaining a reimbursement code, and the securing of a favourable National Medicare price. Collectively, these achievements lay important foundations for commercial readiness.
- LungLB® test highlighted at the National Cancer Institute's ("NCI") Early Detection Research Network meeting, and now included on their list of biomarker tests available in CLIA-approved laboratories. The recognition from the NCI raises the profile of the test nationally to physicians searching for early detection solutions like LungLB®.
- Initial orders for LungLB® have been placed by physicians through the Early Access Program ("EAP"), and test results have been provided back to them to help with nodule evaluation and patient care.
- Two abstracts supporting evidence for analytical and clinical validity of LungLB submitted for presentation at the Association for Molecular Pathology annual meeting, to be held in November 2024.
- A manuscript detailing the analytical validation of LungLB® submitted for peer review. Publication of this validation study will form an important part of our Technical Assessment ("TA") for LungLB® insurance coverage by public and commercial payors. It provides evidence to physicians that LungLB® is robust and appropriate for everyday clinical use.
- Post period end, the foundational Local Coverage Determination ("LCD") for indeterminate lung nodules was published in August 2024. Following this publication, we plan to submit a Technical Assessment for coverage under the LCD in order to receive payment from Medicare. Having the Foundational LCD in place provides an accelerated pathway for this process. This is a key step towards commercialisation for LungLife, having already received a billing code and established a price of \$2,030 per LungLB® test.

Continued operational delivery

- Cost control and headcount restructuring following completion of the clinical trial allows the Company to focus on commercialisation activities.
- Appointed an advisor with expertise in diagnostics and an extensive network to assist with the identification of a suitable strategic partner.
- Continued the build of the required infrastructure in order to start billing for tests.
- Created marketing collateral to engage patients, healthcare professionals and insurance companies.
- Started the process of contacting commercial payors.
- Fifth internally generated patent application since IPO has entered PCT phase, the path to providing international protection for the latest advancements in the Company's technology.

Financial Highlights:

- Cash as of 30 June 2024 of \$2.62m (31 December 2023: \$2.83m)
- Equity funding in March raising gross proceeds of \$2.28m through the issue of 5,172,621 common shares
- Cash outflow from operating activities of \$1.94m (six months to 30 June 2023: \$2.70m)
- EBITDA loss of \$1.77m (six months to 30 June 2023: \$2.78m)

Commenting Paul Pagano, Chief Executive Officer of LungLife, said:

"The successful clinical validation of the LungLB® test and other achievements in this period reflect our commitment to advancing early detection of lung cancer and the team remains dedicated to making a significant impact in this critical area of healthcare.

We are delighted with the increasing recognition for LungLB® as evidenced by the positive clinician feedback together with the first orders being received under our Early Access Program. Whilst we progress towards commercialisation, we are

also actively seeking opportunities for a suitable strategic partner who aligns with our vision and has the capability to accelerate the adoption of LungLB®."

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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

CHAIRMAN'S STATEMENT

I am pleased to report on the Company's results for the six months ended 30 June 2024. These demonstrate strong delivery in our mission to be a driving force in the early detection of lung cancer.

Strategic update

This period is significant in that it marks the start of the next phase of our company as we look to transition from a clinical-stage company to a commercial entity.

We started the year delighted to announce the results from our successful validation of LungLB in our multi-site, prospective clinical study. This very important milestone marks the completion of all major objectives set out at the time of Company's admission to AIM in July 2021, including regulatory approval from CLIA/NYSDOH, obtaining a reimbursement code, and confirmation of the National Medicare price. Collectively, these achievements lay important foundations for the Company's commercial readiness.

This shift to a commercial focus brings with it a range of strategic opportunities which the Board are actively pursuing, including seeking a potential strategic partner to help us commercialise the LungLB test. To support the Board in this, we have engaged the services of an advisory firm, known for its industry expertise and network, to explore strategic avenues for our company's growth.

In addition, we are working towards creating a direct sales platform and have launched an Early Access Program building on positive clinician feedback. This will provide the Company with strategic and commercial flexibility, as well as allowing us to demonstrate "proof of concept" during any discussions with potential strategic partners.

Commercialisation readiness

The Company has made progress in readiness for the commercialisation phase with key highlights in the period including:

- Launched the Early Access Programme. We have already received a small number of samples through this programme. The response from early adopters is encouraging and we have been able to incorporate our learnings from the programme into our ordering and reporting processes with the goal of making them more streamlined for full commercial launch. As a reminder we do not currently have the resources for a full launch, and we continue to explore options including actively seeking a strategic partner.
- To broaden the user base and enhance market penetration, we have initiated a targeted marketing campaign aimed at smaller hospital centres. This strategy has already generated a flow of new inquiries, which our limited team is actively pursuing.
- Submitted our analytical validation report for peer review, which is an important component of securing coverage from public and private payors.
- Concluded the infrastructure required by the billing provider necessary to start billing.
- Created a range of marketing collateral to engage patients, healthcare professionals and insurance companies.

Post period end, the finalised Local Coverage Determination titled "Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy" (L39654), was published by the Medicare Administrative Contractor (MAC) Noridian Healthcare Solutions, LLC, which has jurisdiction over LungLife's California laboratory. The Medicare coverage criteria are effective for medical insurance claims with dates of service on or after September 22, 2024. This enables LungLife to apply for coverage under the LCD in order to receive payment from Medicare. This is a key step towards commercialisation for LungLife, having already received a billing code (allowing clinicians to identify the test) and established a price of \$2,030 per LungLB® test.

The next step to obtain Medicare coverage is the preparation of a clinical dossier and its submission to the Medicare Contractor for Technical Assessment ("TA"). A key part of the TA is the inclusion of peer reviewed publications which include evidence of clinical utility. As noted above, peer-reviewed publications have already been made covering the test's health economics and clinical validity, and the Company also intends to publish the results of its analytical validity and recent clinical validation study, as well as utility data derived from the EAP. The nature and scope of the evidence required of clinical utility is subjective and, as part of the usual process, the Company will work with its Medicare contractor to define evidence for coverage.

One of the factors determining the nature and scope of the clinical utility evidence required for coverage is the pathway to the award of an LCD. There are two possible pathways, a foundational LCD (based on evidence of utility from an existing diagnostic test) or a specific LCD for LungLB®. The main difference between the two is the likely timeframe within which an award could be granted, with the former (the foundational LCD) being the quicker option. The other difference between the two pathways could be the nature and scope of the accompanying clinical utility study required for coverage. The recently finalized foundational LCD covering indeterminate lung nodules following non-diagnostic bronchoscopy represents a solid entry point for LungLB® testing, as it further demonstrates an area where clinicians have limited diagnostic testing options. Medicare is currently examining evidence that may lead to expansion of coverage criteria, demonstrating the ability of current Medicare policies and LCDs to be broadened. Additional data, from LungLife and other test manufacturers, may serve to further expand coverage in the future.

Clinical validation

The successful validation of LungLB® in our multi-site, prospective clinical study at the start of the year demonstrated that we have a test with stronger performance in the most challenging case of smaller nodules detected by CT scan. This underlines our goal of inverting the current unsatisfactory 20:80 ratio such that in years to come at least 80% of lung cancer is detected early.

The clinical study enrolled 425 patients across 17 hospital study sites who were scheduled to receive a lung nodule biopsy, of which 347 provided data that could be analysed. These results were driven by a 98-patient small nodules (<15 mm) group, which represent a major challenge to physicians practicing in lung cancer detection and treatment. When developing a precision medicine test it is common practice to identify a specific indicated use in order to maximise the impact on a given patient population, which in turn helps physicians to know exactly when to use the test. The small nodules group is the most important indication for LungLB®.

In the study LungLB demonstrated:

- A strong positive predictive value (PPV) of 80% in discriminating benign from cancerous lung nodules in patients with smaller nodules (<15 mm). Smaller nodules are the most problematic area for early detection and represent the greatest challenge for physicians. Current clinical standards of care generate a ~60% PPV, leading to material delays in diagnosis of deadly cancers.
- This performance in smaller nodules, similarly demonstrated in LungLife AI's lead-in study published in June 2023, typically represents earlier detection capability and improved patient outcomes and highlights the test's consistency.
- The small nodule group in this study is of utmost importance because it is comprised of ~87% "intermediate" risk nodules, which are the most challenging to evaluate and diagnose. Previous studies lack sufficient numbers of intermediate-risk nodules and is the reason why existing diagnostic tools perform poorly in this group. We believe this will also be of significant value to physicians.
- In-line with a high percentage of intermediate risk nodules, the test also outperformed the highly-validated Mayo Risk Model nodule evaluation tool, which is a commonly used baseline comparator, with an area under the curve (AUC) of 72% for LungLB® compared to 62% for Mayo.
- The results were also compared to Positron Emission Tomography (PET) scan, another tool often employed in nodule evaluation clinics. LungLB® outperformed PET by ~21% (80% vs 67% PPV) in the small nodule group, providing physicians with a more robust diagnostic tool in this area.

These positive results have been met with favourable clinician reaction as the team engages with sites regarding participation in our Early Access Program.

Funding

In March 2024, the Company issued 5,172,621 new common shares at a price of 35 pence per share, raising gross proceeds of US\$2.28m. This allows us to establish the commercial proof of concept of the Company's LungLB® test, as detailed below:

- Funding of evidence generating activities, including the Early Access Program dependent on the factors noted below, to support reimbursement and test adoption;
- Increasing expenditure to support engagement with payors and clinicians, and support the wider need to raise clinical awareness via key opinion leaders, publications and conferences; and
- Accelerating the commercial pathway by pursuing licensing or other similar agreements.

In addition to the above, the Company undertook to consider all its strategic options in order to maximise shareholder value.

Outlook

Following the successful validation of our LungLB test at the start of the year, we are now actively transitioning into the commercial phase. This is an exciting time for the Company as we strive to transform the early detection of lung cancer and continue to deliver on our strategy.

At the time of the fundraise, we set out three priorities: evidence generating activities, increasing engagement and awareness, and accelerating the commercial pathway. In keeping with our strong financial discipline, and reflecting the amount raised, we have significantly reduced our expenditure to reflect the shift of focus from research towards commercialisation and reiterate our previous guidance regarding the cash runway into Q2 2025.

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

Roy Davis

Chairman

FINANCIAL REVIEW

In March we raised gross proceeds of \$2.28m from the issue of 5,172,621 shares. We have implemented significant cost reductions, predominantly through headcount reductions and are now a smaller team focussed on the key commercialisation activities. This reflects the Company entering its initial pre-commercial phase whilst still allowing us the ability to identify a strategic partner that will help LungLB reach meaningful revenues. In the six months to 30 June 2024 our cash outflow from operating activities was \$1.94m, down from \$2.70m in the comparable period, resulting in a period end total cash balance of \$2.62m.

Our EBITDA loss for the period was \$1.77m, down from \$2.78m in the comparable period. Our largest cost continues to be wages and salaries. We started the year with 15 people in the business, and we are now a team of 8 having reduced headcount in March, in part driven by the completion of the clinical research for the LungLB validation study. In addition to this cost saving all directors reduced their salaries from March, with the difference being accrued until such times as affordability allows it to be paid. Wages and salaries, excluding share-based payments charge, amounted to \$1.06m in the period, down from \$1.34m in the comparable period. With the conclusion of our clinical trial our research and development costs continue to fall, and amounted to \$0.22m in the period, down from \$0.81m in the comparable period.

As previously communicated, following our March 2024 fundraise we projected our cash runway to extend into Q2 2025, and our current financial position remains consistent with these expectations.

David Anderson

Chief Financial Officer

STATEMENT OF COMPREHENSIVE INCOME

For the period ended 30 June 2024

	Note	6 months ended 30 June 2024 US\$'000 Unaudited	6 months ended 30 June 2023 US\$'000 Unaudited	Year ended 31 December 2023 US\$'000 Audited
Revenue	(3)	6	23	46
Cost of sales		-	-	-
Gross profit		6	23	46
Administrative expenses		(1,707)	(2,687)	(5,238)
Share-based payments		(67)	(120)	(186)
Depreciation		(132)	(125)	(254)
Operating loss		(1,900)	(2,909)	(5,632)
Other operating income		-	-	44
Finance income		53	127	223
Finance charges		(14)	(22)	(41)
Loss before taxation		(1,861)	(2,804)	(5,406)
Taxation		-	(3)	(7)
Loss for the period / year		(1,861)	(2,807)	(5,413)
Other comprehensive income				

Other comprehensive income	-	-	-
Total comprehensive loss for the period / year	(1,861)	(2,807)	(5,413)
Loss per share from continuing activities attributable to the ordinary equity holders of the Company			
Basic and diluted (US Dollars per share) (4)	(0.06)	(0.11)	(21.2)

STATEMENT OF FINANCIAL POSITION
As at 30 June 2024

	Note	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Assets				
Current assets				
Trade and other receivables (5)		347	484	474
Short term deposits		-	2,772	104
Cash and cash equivalents		2,619	2,589	2,724
Total non-current assets		2,966	5,845	3,302
Non-current assets				
Property, plant and equipment		262	445	389
Intangible assets		5,818	5,818	5,818
Other receivables (5)		13	13	13
Total current assets		6,093	6,276	6,220
Total assets		9,059	12,121	9,522
Current liabilities				
Trade and other payables (7)		(865)	(970)	(1,213)
Lease liabilities (8)		(182)	(290)	(233)
Discontinued operations		-	(174)	-
Total current liabilities		(1,047)	(1,434)	(1,446)
Non-current liabilities				
Lease liabilities (8)		(29)	(184)	(113)
Provisions		(50)	(50)	(50)
Total liabilities		(1,126)	(1,668)	(1,609)
Net assets		7,933	10,453	7,913
Issued share capital and reserves attributable to owners to the parent				
Called up share capital		3	3	3
Share premium		93,080	91,266	91,266
Share based payment reserve		1,827	1,694	1,760
Accumulated losses		(86,977)	(82,510)	(85,116)
Total equity		7,933	10,453	7,913

STATEMENT OF CHANGES IN EQUITY
As at 30 June 2024

	Share capital US\$'000	Share premium US\$'000	Share based payment reserve US\$'000	Accumulated losses US\$'000	Total equity US\$'000
Balance at 1 January 2023	3	91,266	1,574	(79,703)	13,140
Comprehensive income:					
Loss for the period	-	-	-	(2,807)	(2,807)
Transactions with owners:					
Share based payments	-	-	120	-	120
Balance at 30 June 2023	3	91,266	1,694	(82,510)	10,453

Balance at 1 July 2023

	3	91,266	1,694	(82,510)	10,453
Comprehensive income:					
Loss for the period	-	-	-	(2,606)	(2,606)
Transactions with owners:					
Share based payments	-	-	66	-	66
Balance at 31 December 2023	3	91,266	1,760	(85,116)	7,913
Balance at 1 January 2024	3	91,266	1,760	(85,116)	7,913
Comprehensive income:					
Loss for the period	-	-	-	(1,861)	(1,861)
Transactions with owners:					
Issue of shares	-	2,281	-	-	2,281
Cost of share issue	-	(467)	-	-	(467)
Share based payments	-	-	67	-	67
Balance at 30 June 2024	3	93,080	1,827	(86,977)	7,933

STATEMENT OF CASH FLOWS

For the period ended 30 June 2024

	6 months ended 30 June 2024 US\$'000 Unaudited	6 months ended 30 June 2023 US\$'000 Unaudited	Year ended 31 December 2023 US\$'000 Audited
Cash flows from operating activities			
Loss for the period / year	(1,861)	(2,807)	(5,413)
Adjustments for non-cash/non-operating items:			
Depreciation	132	125	254
Foreign exchange (gain) / loss on short term deposits	-	(100)	-
Finance income	(53)	(127)	(223)
Finance expense	14	22	41
Taxation	-	3	7
Share based compensation	67	120	186
	(1,701)	(2,764)	(5,148)
Changes in working capital			
Decrease in trade and other receivables	105	150	151
(Decrease)/increase in trade and other payables	(348)	(83)	(16)
Cash outflow from operations	(1,944)	(2,697)	
Taxation paid	-	(3)	(7)
Net cash outflow from operating activities	(1,944)	(2,700)	(5,020)
Cash inflow / (outflows) from investing activities			
Interest received	75	105	212
Purchase of tangible assets	(5)	(5)	(77)
Short term deposits	104	2,250	4,817
Net cash inflows from investing activities	174	2,350	5,164
Cash flows from financing activities			
Issue of common stock, net of expenses	1,814	-	-
Interest paid	(14)	(22)	(41)
Repayment of lease liabilities	(135)	(127)	(255)
Net cash inflow / (outflow) from financing activities	1,665	(149)	(508)
Net decrease in cash and cash equivalents	(105)	(499)	(364)
Cash and cash equivalents brought forward	2,724	3,088	3,088
Cash and cash equivalents carried forward	2,619	2,589	2,724

1. GENERAL INFORMATION

LungLife AI, Inc. (the "Company") is a company based in Thousand Oaks, California which is developing 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 2023. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2024.

Statement of compliance

This interim consolidated financial information for the six months ended 30 June 2023 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 2023, 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 include references to 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 2024 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 2023 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.

Classification of the Mount Sinai License as an intangible asset

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.

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:

Revenue	6 months ended	6 months ended	Year ended 31
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	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	December 2023 US\$'000 Audited
People's Republic of China	6	23	46
	6	23	46
Non-current assets	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
United States of America	6,093	6,276	6,220
	6,093	6,276	6,220
Product and service revenue	6 months ended 30 June 2024 US\$'000 Unaudited	6 months ended 30 June 2023 US\$'000 Unaudited	Year ended 31 December 2023 US\$'000 Audited
Royalty income	6	23	46
	6	23	46

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 \$1,861,293 for the 6 months ended 30 June 2024 (six months ended 30 June 2023 loss \$2,807,760; year ended 31 December 2023: loss \$5,413,213) and the weighted average number of shares in issue for the 6 months to 30 June 2024 of 28,373,362 (six months to 30 June 2023: 25,485,982 and year to 31 December 2023: 25,485,982).

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.

5. TRADE AND OTHER RECEIVABLES

Amounts falling due within one year	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Trade receivables	-	20	-
Other receivables	179	194	174
Prepayments	168	270	299
	347	484	474
Amounts falling due after one year			
Rent deposit	13	13	13
	13	13	13

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\$
Outstanding at 30 June and 31 December 2023	2,116,979	1.76
Granted	53,872	
Outstanding at 30 June 2024 - unaudited	2,170,851	1.72

7. TRADE AND OTHER PAYABLES

	30 June 2024 US\$'000 Unaudited	30 June 2023 US\$'000 Unaudited	31 December 2023 US\$'000 Audited
Trade payables	284	369	439
Other payables - tax and social security	8	15	15
Accruals and other payables	573	586	759
	865	970	1,213

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 LEASE LIABILITIES

	Land and buildings US\$'000	Plant and machinery US\$'000	Total US\$'000
At 1 January 2023	407	194	601
Interest expense	15	5	20
Repayments	(82)	(65)	(147)
At 30 June 2023 - unaudited	340	134	474
Repayments	(84)	(60)	(144)
Interest expense	12	4	16
At 31 December 2023 - audited	268	78	346
Repayments	(84)	(62)	(146)
Interest expense	9	2	11
At 30 June 2024 - unaudited	193	18	211

9. SUBSEQUENT EVENTS

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

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