



8 August 2023

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 2023.

Operational Highlights:

- Completed enrolment of the Company’s 425-participant pivotal clinical validation study in May, in line with expectations.
- Health economics study highlighting the cost-effectiveness of LungLB® when added to the clinical care pathway for indeterminate lung nodule management peer-reviewed and published in the *Journal of Medical Economics*.
- Peer-reviewed publication of LungLB® study in the Nature-Springer journal *BMC Pulmonary Medicine* demonstrating high test performance, successfully detecting lung cancer in its earliest stages when it is most curable.

Financial Highlights:

- Cash as of 30 June 2023 of \$5.36m (30 June 2022: \$10.63m, 31 December 2022: \$8.01m)
- Cash outflow from operating activities \$2.70m (six months to 30 June 2022: \$3.26m)
- Loss before tax of \$2.81m (six months to 30 June 2022: \$4.47m) and EBITDA loss of \$2.78m (six months to 30 June 2022: \$4.31m)

Commenting Paul Pagano, Chief Executive Officer of LungLife, said: *“This has been an important six months for the Company as we continue to meet our milestones. We have concluded participation in our clinical validation study and published two important reports that will assist with the commercialisation of LungLB®. Our present focus is the analysis of the results of our clinical validation study which we continue to expect to report on by the end of September.”*

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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 delighted to report on the Company's results for the six months ended 30 June 2023. 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.

Our LungLB® 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 asymptotically.

LungLB® 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® 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 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 participant as well as unnecessary costly and often dangerous procedures.

Three important milestones achieved in the period

Our focus in this period was to conclude enrolment into our clinical validation study and take further steps towards the commercialisation of our test.

Clinical validation study

We completed enrolment of the 425 participants in our clinical validation study in May. The Company is now focused on preparing the data for detailed analysis, including working with each clinical site to finalise monitoring of study data before it is unblinded. Monitoring ensures complete, accurate, and high-quality information will be received for all participants in the study prior to final analyses and results interpretation. We continue to expect this to be concluded by end of September 2023.

Health economics study

We published two important documents in the period, both of which are important components in establishing the ability of the Company to be paid for its tests, known as "coverage".

The first publication was a cost-effectiveness analysis ("CEA") model on LungLB® which provides evidence that the test can be utilised as a cost-effective tool within the current diagnostic pathway.

The principal aim of the research was to explore the incremental cost-effectiveness of LungLB® when added to the current clinical diagnostic pathway for patients with lung nodules, as described in guidelines¹. The greater cost savings in the model were demonstrated by a reduction in unnecessary procedures and better patient outcomes from reduced delays in treatment.

Incremental Cost-Effectiveness Ratio (ICER) is a key metric used in the publication to demonstrate cost effectiveness. Integration of LungLB® leads to improvement in outcomes and results in an ICER that was 25% below the willingness to pay (WTP) threshold commonly considered by US commercial payors, suggesting overall savings when LungLB® is priced at \$2,300 per test. ICERs remain below WTP thresholds at prices up to \$3,647 per test.

¹Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and Management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines.

Peer reviewed publication of our test

We also announced the peer-reviewed publication of the successful performance results for the Company's LungLB[®] test from a multi-site prospective study in patients with indeterminate pulmonary nodules. The pilot study was performed in collaboration with MD Anderson Cancer Center (Houston, TX) and Icahn School of Medicine at Mount Sinai (New York, NY) and appears in the journal *BMC Pulmonary Medicine*. The primary objective of the study was to compare the LungLB[®] test result with a lung biopsy diagnosis and assess performance in a patient cohort where commonly used nodule evaluation tools were not informative.

Key points from the study include:

- 151 study participants scheduled for CT-guided lung biopsy, 70% of whom were found to have “intermediate risk” nodules that represent the most challenging diagnostic subtype
- The LungLB[®] test outperformed commonly used evaluation tools, including the Mayo Clinic risk model and PET scan
- The test demonstrated robust performance in smaller nodules (<2 cm in diameter) and in early-stage cancer
- The LungLB[®] biomarker was found to be the strongest independent predictor of cancer in this study, exceeding commonly known strong predictors such as nodule size and smoking status
- The LungLB[®] test performed equally well in current, former, and never smokers
- The data support potential clinical utility of LungLB[®] in reducing delays in treatment, in which positive LungLB[®] test results were available months ahead of lung cancer diagnosis in three highlighted cases

We are delighted to have been able to achieve these important milestones in this six-month period.

Outlook

Our immediate focus is determining the results of our test in the clinical validation study. Alongside this we continue to prepare the necessary documentation and applications to support the commercialisation of our test.

This is a pivotal moment for the Company. 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 the six months to 30 June 2023 our cash outflow from operating activities was \$2.70m (six months to 30 June 2022: \$3.26m), resulting in a period end total cash balance of \$5.36m, compared to the total cash balance at the start of the period of \$8.01m. We continue to hold monies on notice deposit, with the longest notice period being 95 days, which is shown as our short-term deposit balance on the balance sheet. At 30 June 2023 this represented \$2.77m of our total cash balance, and \$4.92m at 31 December 2022.

Minimal capital expenditure in the period, and a total of \$0.13m spent on the repayment of lease liabilities (six months to 30 June 2022: \$0.11m), being a combination of the payments on our financing of two microscopes and the rent on our premises in Thousand Oaks California, being the right of use asset.

Revenues of \$23k (six months to 30 June 2022: \$10k) related to royalties earned under our arrangement with our partner in China. The EBITDA loss for the period was \$2.78m (six months to 30 June 2022: \$4.31m), which includes the share-based payment charge of \$0.12m (six months to 30 June 2022: \$0.39m). The biggest contributors to the EBITDA loss were employment costs of \$1.34m (six months to 30 June 2022: \$1.29m) and research and development of \$0.81m (six months to 30 June 2022: \$1.31m). The lower research and development costs reflect mainly the completion of work on our AI algorithm in the prior period. In the current period we moved one of our part time employees to full time, and as such we now have 15 full time employees in the business.

David Anderson
Chief Financial Officer

STATEMENT OF COMPREHENSIVE INCOME
For the period ended 30 June 2023

	<i>Note</i>	6 months ended 30 June 2023 US\$'000 Unaudited	6 months ended 30 June 2022 US\$'000 Unaudited	Year ended 31 December 2022 US\$'000 Audited
Revenue	(3)	23	10	24
Cost of sales		-	-	-
Gross profit		23	10	24
Administrative expenses		(2,687)	(3,924)	(6,865)
Share-based payments		(120)	(398)	(614)
Depreciation		(125)	(155)	(285)
Operating loss		(2,909)	(4,467)	(7,740)
Other operating income		-	-	102
Finance income		127	26	88
Finance charges		(22)	(27)	(52)
Loss before taxation		(2,804)	(4,468)	(7,602)
Taxation		(3)	(1)	(4)
Loss for the period / year		(2,807)	(4,469)	(7,606)
Other comprehensive income		-	-	-
Total comprehensive loss for the period / year		(2,807)	(4,469)	(7,606)
Loss per share from continuing activities attributable to the ordinary equity holders of the Company				
Basic and diluted (US Dollars per share)	(4)	(0.11)	(0.175)	(0.298)

STATEMENT OF FINANCIAL POSITION
As at 30 June 2023

	<i>Note</i>	30 June 2023 US\$'000 Unaudited	30 June 2022 US\$'000 Unaudited	31 December 2022 US\$'000 Audited
Assets				
Current assets				
Trade and other receivables	(5)	484	526	613
Short term deposits		2,772	4,884	4,922
Cash and cash equivalents		2,589	5,749	3,088
Total non-current assets		5,845	11,159	8,623
Non-current assets				
Property, plant and equipment		445	693	566
Intangible assets		5,818	5,818	5,818
Other receivables	(5)	13	13	13
Total current assets		6,276	6,524	6,397
Total assets		12,121	17,683	15,020
Current liabilities				
Trade and other payables	(7)	(970)	(706)	(1,055)
Lease liabilities	(8)	(290)	(217)	(255)
Discontinued operations		(174)	(174)	(174)
Total current liabilities		(1,434)	(1,097)	(1,484)
Non-current liabilities				
Lease liabilities	(8)	(184)	(477)	(346)
Provisions		(50)	(50)	(50)
Total liabilities		(1,668)	(1,624)	(1,880)
Net assets		10,453	16,059	13,140
Issued share capital and reserves attributable to owners to the parent				
Called up share capital		3	3	3
Share premium		91,266	91,264	91,266
Share based payment reserve		1,694	1,358	1,574
Accumulated losses		(82,510)	(76,566)	(79,703)
Total equity		10,453	16,059	13,140

STATEMENT OF CHANGES IN EQUITY
As at 30 June 2023

	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 2022	3	91,264	960	(72,097)	20,130
Comprehensive income:					
Loss for the period	-	-	-	(4,469)	(4,469)
Transactions with owners:					
Share based payments	-	-	398	-	398
Balance at 30 June 2022	3	91,264	1,358	(76,566)	16,059
Balance at 1 January 2023	3	91,264	1,358	(76,566)	16,059
Comprehensive income:					
Loss for the period	-	-	-	(3,137)	(3,137)
Transactions with owners:					
Exercise of share options	-	2	-	-	2
Share based payments	-	-	216	-	246
Balance at 31 December 2022	3	91,266	1,574	(79,703)	13,140
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

STATEMENT OF CASH FLOWS
For the period ended 30 June 2023

	6 months ended 30 June 2023 US\$'000 Unaudited	6 months ended 30 June 2022 US\$'000 Unaudited	Year ended 31 December 2022 US\$'000 Audited
Cash flows from operating activities			
Loss for the period / year	(2,807)	(4,469)	(7,606)
Adjustments for non-cash/non-operating items:			
Depreciation	125	155	285
Gain on sale of tangible assets	-	-	(43)
Foreign exchange (gain) / loss on short term deposits	(100)	527	562
Finance income	(127)	(26)	(88)
Finance expense	22	27	52
Taxation	3	1	4
Share based compensation	120	398	614
	(2,764)	(3,387)	(6,220)
Changes in working capital			
(Increase)/ decrease in trade and other receivables	150	221	128
(Decrease)/increase in trade and other payables	(83)	(98)	251
Cash outflow from operations	(2,697)	(3,264)	(5,841)
Taxation paid	(3)	(1)	(4)
Net cash outflow from operating activities	(2,700)	(3,265)	(5,845)
Cash inflow / (outflows) from investing activities			
Proceeds from sale of tangible assets	-	-	43
Purchase of tangible assets	(5)	(82)	(85)
Short term deposits	2,250	-	(73)
Net cash flows from investing activities	2,245	(82)	(115)
Cash flows from financing activities			
Issue of common stock	-	-	2
Interest received	105	20	88
Interest paid	(22)	(27)	(52)
Repayment of lease liabilities	(127)	(114)	(207)
Net cash (outflow) / inflow from financing activities	(44)	(121)	(169)
Net decrease in cash and cash equivalents	(499)	(3,468)	(6,129)
Cash and cash equivalents brought forward	3,088	9,217	9,217
Cash and cash equivalents carried forward	2,589	5,749	3,088

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 2022. No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2023.

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 2022, 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 2023 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 2022 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 30 June 2023 US\$'000 Unaudited	6 months ended 30 June 2022 US\$'000 Unaudited	Year ended 31 December 2022 US\$'000 Audited
People's Republic of China	23	10	24
	23	10	24
Non-current assets	30 June 2023 US\$'000 Unaudited	30 June 2022 US\$'000 Unaudited	31 December 2022 US\$'000 Audited
United States of America	6,276	6,524	6,397
	6,276	6,524	6,397
Product and service revenue	6 months ended 30 June 2023 US\$'000 Unaudited	6 months ended 30 June 2022 US\$'000 Unaudited	Year ended 31 December 2022 US\$'000 Audited
Royalty income	23	10	24
	23	10	24

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 \$2,807,760 for the 6 months ended 30 June 2023 (6 months ended 30 June 2022 loss \$4,469,915; year ended 31 December 2022: loss \$7,605,585) and the weighted average number of shares in issue for the 6 months to 30 June 2023 of 25,485,982 (6 months to 30 June 2022: 25,480,790 and year to 31 December 2022: 25,481,800).

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.

5. TRADE AND OTHER RECEIVABLES

Amounts falling due within one year	30 June	30 June	31 December
	2023	2022	2022
	US\$'000	US\$'000	US\$'000
	Unaudited	Unaudited	Audited
Trade receivables	20	69	-
Other receivables	194	99	150
Prepayments	270	358	463
	484	526	613
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 1 January 2022 - audited	2,065,527	1.74
Granted	75,000	2.37
Exercised	(5,192)	0.45
Expired	(18,356)	1.80
Outstanding at 31 December 2022 - audited	2,116,979	1.76
No movements in the period		
Outstanding at 30 June 2023 - unaudited	2,116,979	1.69

7. TRADE AND OTHER PAYABLES

	30 June	30 June	31 December
	2023	2022	2022
	US\$'000	US\$'000	US\$'000
	Unaudited	Unaudited	Audited
Trade payables	369	368	358
Other payables – tax and social security	15	2	13
Accruals and other payables	586	336	684
	970	706	1,055

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 2022	504	304	808
Interest expense	19	8	27
Repayments	(79)	(62)	(153)
	—————	—————	—————
At 30 June 2022 - unaudited	444	250	694
Repayments	(55)	(63)	(118)
Interest expense	18	7	25
	—————	—————	—————
At 31 December 2022 – audited	407	194	601
Repayments	(82)	(65)	(147)
Interest expense	15	5	20
	—————	—————	—————
At 30 June 2023 - unaudited	340	134	474

9. SUBSEQUENT EVENTS

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