RNS Number : 2308J
LungLife AI, INC
04 April 2024

4 April 2024

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

Preliminary audited results for year ended 31 December 2023

LungLife AI (AIM: LLAI), a developer of clinical diagnostic solutions for lung cancer, announces its audited preliminary results for the year ended 31 December 2023.

Summary and Highlights for the year and post-period end:

- Cash as of 31 December 2023 of $2.83m (2022: $8.01m).
- Loss before tax of $5.41m (2022: $7.60m).
- Adjusted EBITDA[1] loss of $5.19m (2022: $6.84m).
- Effective 1 January 2023, LungLB PLA code 0317U was added to Medicare's Clinical Laboratory Fee Schedule ("CLFS") at a National price of $2,030 per test.
- LungLife's cost effectiveness analysis was published in the Journal of Medical Economics, providing evidence that LungLB is cost effective when used to evaluate indeterminate lung nodules when integrated into the current clinical care pathway. This is a key publication for payors, including Medicare, when considering coverage for LungLB.
- The Company's lead-in multi-site validation of LungLB was published in Nature-Springer's BMC Pulmonary Medicine, demonstrating high performance in smaller lung nodules and outperforming PET scan and Mayo Nodule Calculator tools, and indicating the potential to reduce delays in treatment from earlier detection using LungLB.
- Successful clinical validation of the Company's LungLB test following conclusion of the multi-site validation trial with a positive predictive value ("PPV") of 81% for those indeterminate nodules less than 15mm in size and outperformed PET scan and Mayo Nodule Calculator tools, replicated the findings from the lead-in validation study.
- In March 2024, the Company raised gross proceeds of $2.28m (GBP1.81m) from the issue of 5,172,621 shares at 35 pence.

Commenting, Paul Pagano, Chief Executive Officer of LungLife, said *"2023 was a year of considerable achievement culminating in the conclusion of our multi-site clinical validation study, which was the primary objective at our IPO. A positive predictive value of over 80% in smaller indeterminate nodules is significant. This is where physicians consistently indicate the greatest unmet need and where currently available tools fall short.*

"In March 2024 we concluded our fund raising to commence the commercialisation of our test. This enables us to initiate our Early Access Program, submit forms to MolDX for technical assessment for Medicare coverage consideration, and continue other matters necessary for commercialisation. We have also started the process of considering all strategic options to get the LungLB test into the hands of patients who need it most.

"Our revised cash runway to April 2025 has required significant cost reductions, the largest being to headcount and salaries for the executive team. We are now a smaller team focussed on the key commercialisation activities. Those who have left the Company played an important role in delivering our achievements to date and on behalf of the whole Board, I would like to thank them for their efforts."

For further information please contact:

LungLife AI, Inc. Paul Pagano, CEO David Anderson, CFO	www.lunglifeai.com **Via Walbrook PR**
Investec Bank plc (Nominated Adviser & Broker) Virginia Bull / Cameron MacRitchie / Lydia Zychowska	**Tel: +44 (0)20 7597 5970**
Goodbody (Joint Broker) Tom Nicholson / Cameron Duncan / Will Hall	**Tel: +44 (0) 20 3841 6208**
Walbrook PR Limited Stephanie Cuthbert / Alice Woodings / Phillip Marriage	**Tel: +44 (0)20 7933 8780** or **LungLifeAI@walbrookpr.com** Mob: 07980 541 893 / 07407 804 654 / 07867 984 082

[1] Earnings before interest, tax, depreciation and amortisation, adjusted to exclude exceptional items, share based payments and other operating income.

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

Our Purpose is to be a driving force in the early detection to lung cancer. And our Vision is to invert the 20:80 ratio such that in years to come at least 80% of lung cancer is detected early.

Chairman's Statement

I am delighted to report on the Company's results for the year ended 31 December 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 through the completion of our LungLB® test multi-centre clinical validation study.

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 asymptomatically.

LungLB® is a blood-based test that uses Circulating Genetically Abnormal Cells ("CGAC"), which include 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.

Progress this year

2023 has been an important year in the development of the Company, concluding with the announcement of the results of our multi-site, prospective clinical study on 2 January 2024.

Clinical validation study

We completed enrolment of the 425 participants in our clinical validation study in May and its findings were concluded by year end, being announced on 2 January 2024.

We were delighted by the findings showing a strong positive predictive value of 81% in discriminating benign from cancerous lung nodules in patients with smaller nodules (< 15mm).

Publications - 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 guidelines. 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 $2,030 per test. ICERs remain below WTP thresholds at prices up to $3,647 per test.

Publication - 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.

We are very pleased to have been able to achieve these important milestones in this year.

People

Our revised cash runway to April 2025 has required significant cost reductions, the largest being to headcount and salaries for the executive team. We are now a smaller team focussed on the key commercialisation activities. Those who have left the company played an important role in delivering our achievements to date and on behalf of the whole Board, I would like to thank them for their efforts.

Post balance sheet and outlook

On 22 March 2024 the Company issued 5,172,621 new common shares at a price of 35 pence per share, raising gross proceeds of US$2,280,000 (GBP1,810,000).

The Company intends to use the net proceeds of the funding, along with the Company's existing cash resources 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 ("EAP") and clinical utility studies, 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.

The net proceeds of the Fundraising will allow the Company to consider all of its strategic options in order to maximise shareholder value and, in conjunction with the implementation of certain cost-cutting actions, is expected to provide the Company with a cash runway to early April 2025.

This is our focus in 2024 and we look forward to updating shareholders on our progress.

Roy Davis
Chairman

3 April 2024

Financial Review

The financial performance of the Company in the year to 31 December 2023 reflects the costs incurred in concluding the clinical validation study, and the continued groundwork in laying the foundations for commercialisation.

Statement of Comprehensive Income

The Company generated revenues of US$46,000 in the year (2022 - US$34,000) comprising wholly of royalty income from its sub licensee in China. The royalty income is calculated at 6% of underlying net sales, and the Company pays a 3% royalty on this income to MD Anderson Cancer Center.

The largest cost incurred in the year was employee expenses of US$2,908,000 (2022 - $3,264,000) followed by research and development costs US$1,308,000 (2022 - US$1,981,00), being those external costs incurred on our clinical validation trial and in the continued development of our LungLB® test. In the year, one of our part time employees was offered a full-time position, bringing our operational headcount to 15.

Other operating income of US$44,000 (2022 - US$102,000) relates to claims made under the US Government Employee Retention Credits scheme, designed as COVID related support for businesses. Finance income of US$223,000 (2022 - US$88,000) was generated from funds held on deposit, benefiting from high interest rates, and we incurred finance expense of US$41,000 (2022 - US$52,000). Finance expense in both years related to that arising on lease liabilities for certain tangible assets and the leasehold premises.

EBITDA loss for 2023 excluding share-based payments was $5,192,000 (2022 - EBITDA loss $6,841,000).

Statement of Financial Position

Cash and cash equivalents at the end of the year was US$2,724,000 (2022 - US$3,088,000). In addition, the Company holds money on short term deposit, on which notice is 95 days with the balance at year end US$104,000 (2022 - US$4,922,000). We continue to hold the cost of acquiring the option under the License Agreement with the Icahn School of Medicine of Mount Sinai ("Mount Sinai") at its original purchase cost, without amortisation. 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.

Statement of Cash Flows

The net outflow from operating activities was US$5,020,000 (2022 - US$5,845,000), with minimal outflows for investing and financing activities such that net cash outflow for the year was US$364,000 (2022 - outflow of $6,129,000).

David Anderson
Chief Financial Officer
3 April 2024

Statement of Profit or Loss and Other Comprehensive Income

For the year ended 31 December 2023

	Note	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Revenue	4	**46**	24
Cost of sales		**-**	-
Gross margin		**46**	24
Administrative expenses	6	**(5,238)**	(6,865)
Share-based payments	6	**(186)**	(614)
Depreciation	6	**(254)**	(285)
Loss from operations		**(5,632)**	(7,740)
Other operating income	6	**44**	102
Finance income	9	**223**	88
Finance expense	9	**(41)**	(52)
Loss before tax		**(5,406)**	(7,602)
Tax expense	10	**(7)**	(4)

Loss from continuing operations		**(5,413)**	(7,606)
Other comprehensive income		**-**	-
Loss and total comprehensive income attributable to the owners of the Company		**(5,413)**	(7,606)
Earnings per share attributable to the ordinary equity holders of the parent	11		
Loss per share			
Basic and diluted (US$ cents)		**(21.2)**	(29.8)

Statement of Financial Position

As at 31 December 2023

	Note	2023 US$'000	2022 US$'000
Assets			
Current assets			
Trade and other receivables	14	**474**	613
Short term deposits	5	**104**	4,922
Cash and cash equivalents	5	**2,724**	3,088
		3,302	8,623
Non-current assets			
Property, plant and equipment	12	**389**	566
Intangible assets	13	**5,818**	5,818
Other receivables	14	**13**	13
		6,220	6,397
Total assets		**9,522**	15,020
Liabilities			
Current liabilities			
Trade and other payables	15	**1,213**	1,229
Lease liabilities	16	**233**	255
		1,446	1,484
Non-current liabilities			
Lease liabilities	16	**113**	346
Provisions	17	**50**	50
Total liabilities		**1,609**	1,880
NET ASSETS		**7,913**	13,140
Issued capital and reserves attributable to owners of the parent			
Share capital	19	**3**	3
Share premium reserve	20	**91,266**	91,266
Share based payment reserve		**1,760**	1,574
Accumulated losses		**(85,116)**	(79,703)
TOTAL EQUITY		**7,913**	13,140

Statement of Cash Flows

For the year ended 31 December 2023

	Note	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Cash flows from operating activities			

Loss for the year		**(5,413)**	(7,606)
Adjustments for:			
Depreciation of property, plant and equipment		**254**	285
Gain on sale of tangible assets		**-**	(43)
Foreign exchange loss on short term deposits		**-**	562
Finance income		**(223)**	(88)
Finance expense		**41**	52
Taxation		**7**	4
Share-based payments expense		**186**	614
		(5,148)	(6,220)
(Increase) / decrease in trade and other receivables		**151**	128
(Decrease) / increase in trade and other payables		**(16)**	251
Income taxes paid		**(7)**	(4)
Net cash outflow from operating activities		**(5,020)**	(5,845)
Cash flows from investing activities			
Purchases of tangible assets		**(77)**	(85)
Interest received		**212**	88
Proceeds from sale of tangible assets		**-**	43
Short term deposits		**4,817**	(73)
Net cash generated by / (used in) investing activities		**4,952**	(27)
Cash flows from financing activities			
Issue of Common Stock		**-**	2
Interest paid		**(41)**	(52)
Repayment of lease liabilities		**(255)**	(207)
Net cash (used in) / from financing activities		**(296)**	(257)
Net decrease in cash and cash equivalents		**(364)**	(6,129)
Cash and cash equivalents at beginning of year		**3,088**	9,217
Cash and cash equivalents at end of year	5	**2,724**	3,088

Statement of changes in equity
for the year ended 31 December 2023

	Share capital US$'000	Share premium US$'000	Share-based payment reserve US$'000	Accumulated losses US$'000	attrit to hol U
1 January 2022	**3**	**91,264**	**960**	**(72,097)**	
Comprehensive income for the year					
Loss	-	-	-	(7,606)	
Other comprehensive Income	-	-	-	-	
Total comprehensive Income for the year	-	-	-	(7,606)	
Contributions by and distributions to owners					
Exercise of options	-	2	-	-	
Share-based payment	-	-	614	-	
Total contributions by and distributions to owners	-	2	614	-	
31 December 2022	**3**	**91,266**	**1,574**	**(79,703)**	

Statement of changes in equity
for the year ended 31 December 2023 *(continued)*

for the year ended 31 December 2023 (continued)

	Share capital US$'000	Share premium US$'000	Share-based payment reserve US$'000	Accumulated losses US$'000	attrik to hol U
1 January 2023	3	91,266	1,574	(79,703)	
Comprehensive income for the year					
Loss	-	-	-	(5,413)	
Other comprehensive Income	-	-	-	-	
Total comprehensive Income for the year	-	-	-	(5,413)	
Contributions by and distributions to owners					
Share-based payments	-	-	186	-	
Total contributions by and distributions to owners	-	-	186	-	
31 December 2023	**3**	**91,266**	**1,760**	**(85,116)**	

Notes to the financial statements

For the year ended 31 December 2023

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

Information in this preliminary announcement does not constitute statutory accounts of the company. The financial information presented in this preliminary announcement is based on, and is consistent with, that in the company's audited financial statements for the year ended 31 December 2023, which will be delivered to shareholders for approval at the Company's Annual General Meeting. The independent auditors have reported on those financial statements and their report is unqualified.

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 certain 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 years presented, unless otherwise stated.

(a) **Going concern**

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

On 2 January 2024, LungLife reported positive validation study results for its LungLB® test, a minimally invasive blood draw test used for the early detection of lung cancer. These results are the catalyst for the Company to begin its commercialisation process for the test. In view of the early stage of its commercial development the group currently funds its activities from existing cash resources. In addition, it expects to generate cash receipts from commercial revenues in future periods and if required, from additional equity or debt funding for future working capital needs.

At 31 December 2023 the Company had available cash resources and short term deposits of $2.8 million (2022 - $8.0 million. The Company is focused on the commercial proof of concept of its test and expects minimal revenues in 2024. As there are uncertainties in relation to the quantum and timing of cash receipts the financial projections have been prepared without including any assumed receipts from commercial revenues.

As set out in note 23, on 21 March 2024 a special meeting of the Company approved the issue of 5,172,621 new shares of common stock of the Company at a price of 35 pence per share. The new shares represent approximately

16.9 per cent. of the enlarged share capital of the company. The issue of shares raised approximately £1.8 million (approximately US$2.3 million) (before fees and expenses). The net proceeds of the fundraising, along with the Company's existing cash resources, are expected to be utilised to establish the commercial proof of concept of the Company's LungLB® test, including:

- funding of evidence generating activities, including the Early Access Program and clinical utility studies 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.

The net proceeds of the fundraising will allow the Company to consider all of its strategic options in order to maximise shareholder value and, in conjunction with the implementation of certain cost-cutting actions, is expected to provide the Company with a cash runway to early April 2025.

Having taken into account the information and estimates available at the date of approving these financial statements, the directors consider it is appropriate to adopt the going concern basis in preparing the financial statements. Although the company's projections, including expected levels of revenue generation, indicate sufficient funds through to the second quarter of 2025, it is reasonably possible that the group will require additional funding during, or shortly after a period of 12 months from the date of approval of these financial statements. The directors will seek to put in place funding arrangements which may from time to time be required but such arrangements are not presently committed. This represents a material uncertainty in relation to the group's funding arrangements.

(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 result of operations, statement of position or statement of cash flows of the Company.

(c) **Revenue recognition**

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 recognised 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**

Licenses are measured at cost less accumulated amortization and any accumulated impairment losses.

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

Owned assets

Items of property, plant and equipment are stated at cost less accumulated depreciation and impairment losses. Cost includes the original purchase price of the asset and 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.

(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 annually in the case of not being available for use, and 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).

(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.

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.

(i) **Financial liabilities**
Trade and other payables
Trade and other payables are initially recognised at fair value and subsequently measured at 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.

(j) **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.

(k) **Share capital**
Ordinary shares are classified as equity. There are various classes of ordinary shares in issue, as detailed in note 19. Incremental costs directly attributable to the issue of new shares are shown in share premium as a deduction from the proceeds.

(l) **Net finance costs**
Finance costs
Finance costs comprise interest payable on borrowings, direct issue costs and dividends on preference shares, and are expensed in the period in which they are incurred.

Finance income
Finance income comprises interest receivable on funds invested.
Interest income is recognised in the income statement as it accrues using the effective interest method.

(m) **Leases**
All leases are accounted for by recognising a right-of-use asset and a lease liability except for:
- 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 the lessor 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. 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 to dismantle, remove or restore the leased asset (typically leasehold dilapidations - see note 17).

Subsequent to initial measurement lease liabilities increase as a result of interest charged at 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 shorter than the lease term.

(n) **Leases** *(continued)*
When the company 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 recognised directly 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

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 to 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.

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 judgement is likely to have the most significant effect on the amounts recognised in the financial information.

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. All revenue arises from the same customer in both years.

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

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Revenue		
People's Republic of China	**46**	24
	46	24

	2023 US$'000	2022 US$'000
Non-current assets		
United States of America	**6,220**	6,397
	6,220	6,397

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Product and service revenue		
Royalty income	**46**	24
	46	24

5 Financial instruments - Risk management

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

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
- Short term cash deposits
- Trade and other payables

(ii) Financial instruments by category

Financial asset

	Amortised Cost 2023 US$'000	Amortised cost 2022 US$'000
Cash and cash equivalents	**2,724**	3,088
Short term cash deposits	**104**	4,922
Trade and other receivables	**174**	155
Total financial assets	**3,002**	8,165

Financial liabilities

	Amortised Cost 2023 US$'000	Amortised cost 2022 US$'000
Trade and other payables	**1,039**	1,055
Total financial liabilities	**1,039**	1,055

(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.

See note 16 for information on lease liabilities.

(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:

Cash in bank	**2023 Rating**	**2023 Cash at bank US$'000**	**2022 Rating**	**2022 Cash at bank US$'000**
Bank A	**A+**	**58**	A+	981
Bank B	**BBB+**	**2,588**	BBB+	2,002
Bank C	**A+**	**78**	A+	105
		2,724		3,088

	2023	**2023**	**2022**	**2022**

Short term deposits

	Rating	US$'000	Rating	US$'000
Bank B	**BBB+**	**104**	BBB+	4,922
		104		4,922

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 2023 assets held in Sterling amounted to US$79,000 (2022 - US$5,275,000) and liabilities held in Sterling amounted to US$92,000 (2022 - US$65,000).

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 decrease of net assets of US$1,000 (2022 - increase US$260,000). A 5% weakening in the exchange rate would, on the same basis, have increased post-tax loss and decreased net assets by US$1,000 (2022 - US$260,000).

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:

At 31 December 2023	**Up to 3 Months US$'000**	**Between 3 and 12 months US$'000**
Trade and other payables	**454**	-
Total	**454**	-

At 31 December 2022	**Up to 3 Months US$'000**	**Between 3 and 12 months US$'000**
Trade and other payables	371	-
Total	371	-

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 2023 US$'000	**Year to 31 December 2022 US$'000**
Employee benefit expenses (see note 8)	**2,908**	3,264
Share-based payments charge - non-employee and directors	**17**	37
Depreciation of property, plant and equipment	**254**	285
Gain on disposal of equipment	**-**	(43)
Research and development expenditure	**1,308**	1,981
Professional costs	**609**	643
Foreign exchange (gains) / losses	**(146)**	659
Other costs	**728**	938

Other operating income is claims made for Employee Retention Credits.

7 Auditors' remuneration

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

	Year to 31 December 2023 US$'000	**Year to 31 December 2022 US$'000**
Fees payable to the Company's auditor for the audit of the Company	**56**	48
Total	**56**	48

8 Employee benefit expenses

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Employee benefit expenses (including Directors) comprise:		
Wages and salaries	**2,312**	2,262
Benefits	**185**	164
Share-based payments expense	**169**	577
Social security contributions and similar taxes	**171**	177
Pension	**71**	84
	2,908	3,264

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 2023 US$	Year to 31 December 2022 US$
Salary	**683**	696
Share based payment expense	**124**	495
	807	1,191

The average number of employees (including Directors) in the Company in the year was 19 (2022 - 18).

9 Net finance costs

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Finance expense		
Interest expense on lease liabilities	**36**	52
Interest on short term funding	**5**	-
Total finance expense	**41**	52

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Finance income		
Bank interest	**223**	88
Total finance income	**223**	88

10 Tax expense

	Year to 31 December 2023 US$'000	Year to 31 December 2022 US$'000
Current tax expense		
Current tax on loss for the year	**-**	-
Withholding tax on royalties	**7**	4
Total current tax	**7**	4
Deferred tax asset		
On losses generated in the year	**-**	-
	7	4

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	Year to

	31 December 2023 US$'000	31 December 2022 US$'000
Loss for the year	**(5,413)**	(7,606)
Tax using 29.84%	**(1,615)**	(2,270)
Expenses not deductible for tax purposes	**37**	34
Unrecognised deferred tax assets for losses carried forward	**1,578**	2,236
Total tax expense	**-**	-

The unrecognised deferred tax is based on Federal taxable losses carried forward of US$56,623,000 (2022 - US$53,485,000) and a Federal capital loss of US$4,583,333 (2022 - 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. Of the total Federal losses carried forward US$35,281,000 (2022 - US$35,281,000) expire in 2030 and can only be used against trading profits from the same trade. Losses of US$21,342,000 (2022 - US$18,204,000) do not expire but can only offset against 80% of taxable profits from the same trade.

11 Loss per share

	Year to 31 December 2023 Total US$	Year to 31 December 2022 Total US$
Numerator		
Loss for the year used in basic EPS	**(5,413,213)**	(7,605,585)
Denominator		
Weighted average number of ordinary shares used in basic EPS	**25,485,982**	25,481,800
Resulting loss per share	**(US$0.212)**	(US$0.298)

The Company has one category of dilutive potential ordinary share, being share options (see note 21). 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 19, 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.

12 Tangible assets

	Leasehold improvements US$'000	Furniture and equipment US$'000	Computers and IT Equipment US$'000	Plant & machinery US$'000	Total US$
Cost or valuation					
At 1 January 2022	1,316	56	85	1,309	2,766
Additions	-	-	31	54	85
At 31 December 2022	1,316	56	116	1,363	2,851
Additions	-	-	-	77	77
At 31 December 2023	**1,316**	**56**	**116**	**1,440**	**2,928**
Accumulated depreciation and impairment					
At 1 January 2022	945	56	53	946	2,000
Depreciation	140	-	19	126	285
At 31 December 2022	1,085	56	72	1,072	2,285
Depreciation	131	-	22	101	254
At 31 December 2023	**1,216**	**56**	**94**	**1,173**	**2,539**
Net book value					
At 31 December 2023	**100**	**-**	**22**	**267**	**389**
At 31 December 2022	231	-	44	291	566

Included in leasehold improvements at 31 December 2023 are right of use assets with a cost of $1,282,000 (2022 - $1,282,000) and accumulated depreciation of $1,173,000 (2022 - $1,042,000).

13 Intangible assets

	License US$'000	Total US$'000
Cost		
At 31 December 2022 and 2023	**5,818**	**5,818**
Accumulated amortisation and impairment		
At 1 January 2022	-	-

Amortisation charge	-	-
At 31 December 2022	**-**	**-**
Amortisation charge		
At 31 December 2023	**-**	**-**
Net book value		
At 31 December 2023	**5,818**	**5,818**
At 31 December 2022	5,818	5,818

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.

14 Trade and other receivables

	2023 US$'000	2022 US$'000
Amounts falling due within one year		
Prepayments	**299**	458
Accrued income	**31**	5
Other debtors	**144**	150
	474	613

	2023 US$'000	2022 US$'000
Amounts falling due after one year		
Rent deposit	**13**	13
	13	13

15 Trade and other payables

	2023 US$'000	2022 US$'000
Trade payables	**439**	358
Accruals and other payables	**759**	858
Total financial liabilities classified as financial liabilities measured at amortised cost	**1,198**	1,216
Other payables - tax and social security payments	**15**	13
Total trade and other payables	**1,213**	1,229

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

16 Lease Liabilities

	Land and buildings US$'000	Plant and machinery US$'000	Total US$'000
At 1 January 2022	504	304	808
Interest expense	37	15	52
Repayments	(134)	(125)	(259)
At 31 December 2022	**407**	**194**	**601**
Repayments	(166)	(125)	(291)
Interest expense	27	9	36
At 31 December 2023	**268**	**78**	**346**

	2023 US$'000	2022 US$'000
Maturity of lease liabilities		
Within 3 months	**74**	75

Between 3 - 12 months	**179**	225
Between 1 - 2 years	**117**	253
Between 2 - 5 years	**-**	117
	370	**670**

17 Provisions

	Dilapidations US$'000	Total US$'000
At 1 January 2022	50	50
Movement	**-**	-
At 31 December 2022	**50**	**50**
Movement	-	-
At 31 December 2023	**50**	**50**

Provision is made for the anticipated cost of returning the Company's premises to their prior state on termination of the lease. The lease terminates in August 2025.

18 Net cash /(debt) reconciliation

	2023 US$'000	2022 US$'000
Cash and cash equivalents	**2,724**	3,088
Lease liabilities	**(346)**	(601)
Net cash / (debt)	**2,378**	**2,487**

	Cash and cash equivalents US$'000	Borrowings and loans US$'000	Net Debt US$'000
Net debt at 1 January 2022	9,217	(808)	8,409
Cash flows	(6,129)	-	(6,129)
Other non-cash movements:			
Lease liabilities	-	207	207
Net debt at 31 December 2022	3,088	(601)	2,487
Cash flows			
Other non-cash movements:	**(364)**		**(364)**
Lease liabilities	**-**	**255**	**255**
Net debt at 31 December 2023	**2,724**	**(346)**	**2,378**

19 Share capital

	Issued and fully paid Number	US$
Shares of US$0.0001 par value each		
At 1 January 2022	25,480,790	2,548
Exercise of 5,192 options in the year	5,192	5
Total issued share capital at 31 December 2022	25,485,982	2,553
Total issued share capital at 31 December 2023	**25,485,982**	**2,553**

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

As a result the Company only has common shares in issue.

20 Reserves

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.
Share based payment reserve	Amount charged to date in respect of share based payment expense
Accumulated losses	All other net gains and losses and transactions with owners (e.g., dividends) not recognised elsewhere.

21 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, non-executive 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 forty-eighth 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 quarter. 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 19, 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.

21 Share-based payment *(continued)*

	Weighted average exercise price US$	**Number**
Outstanding at 31 December 2021	**1.74**	**2,065,527**
Granted during 2022	2.37	75,000
Exercised during 2022	0.45	(5,192)
Expired during 2022	1.80	(18,356)
Outstanding at 31 December 2022 and 2023	1.76	2,116,979
Exercisable at 31 December 2022	**1.62**	**1,506,180**
Exercisable at 31 December 2023	**1.71**	**1,817,206**

The exercise price of options outstanding at 31 December 2023 ranged between US$0.08 and US$2.70 and their weighted

The exercise price of options outstanding at 31 December 2023 ranged between US$0.08 and US$2.70 and their weighted average remaining contractual life was 6.92 years and weighted average expected life was 3.55 years.

The Company recognised total expenses of US$186,000 (2022: US$614,000) within administrative expenses relating to equity-settled share-based payment transactions during the year.

22 Related party transactions

During the year an amount of US$85,000 (2022 - US$130,000) was invoiced by The Icahn School of Medicine at Mount Sinai for services rendered in the year. As of 31 December 2023 no amounts were owed to The Icahn School of Medicine at Mount Sinai (2022 - Nil).

During the year Paul Pagano and David Anderson, both directors of the Company, each purchased 7,123 shares in the Company using their own funds.

23 Events after the reporting date

On 21 March 2024 a special meeting of the Company approved the issue of 5,172,621 new shares of common stock of the Company at a price of 35 pence per share. The new shares represent approximately 16.9 per cent. of the enlarged share capital of the company. The issue of shares raised approximately £1.8 million (approximately US$2.3 million) (before fees and expenses).

END

FR SSDFWDELSEFL