

# LungLifeAI™

Annual Results to 31 December 2022

February | 2023 ●●●

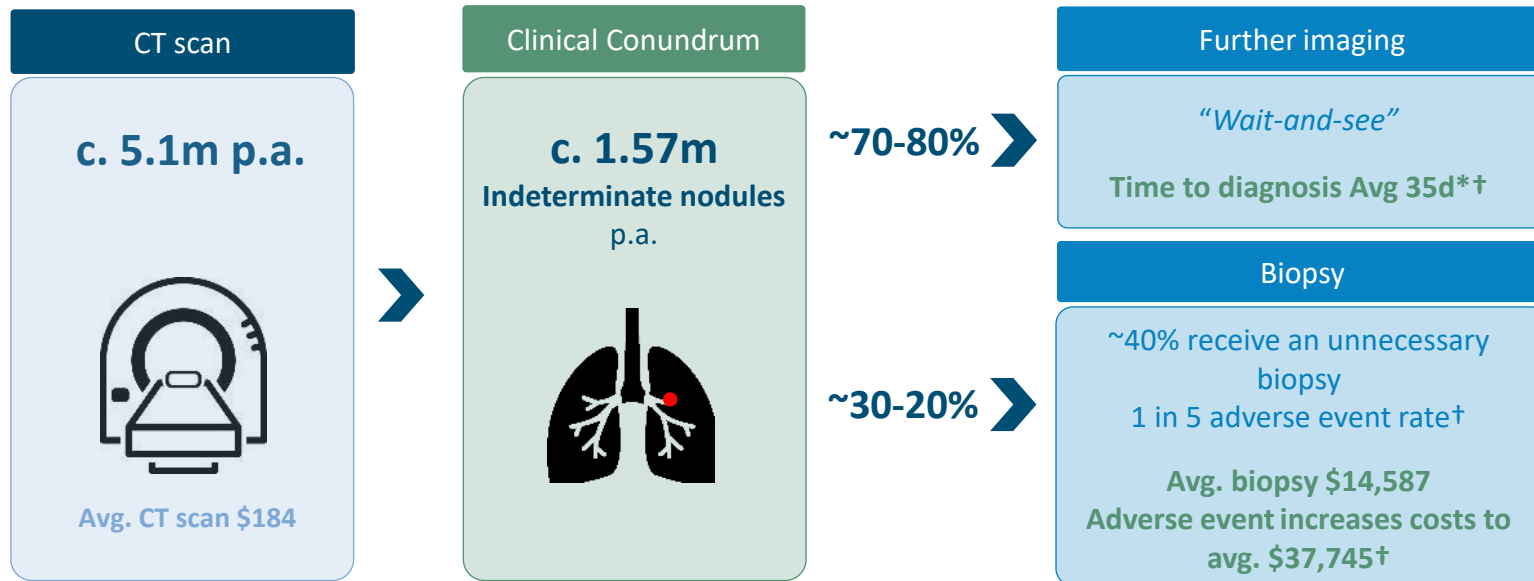
**LungLifeAI™** is a diagnostics company focused on the early detection of lung cancer from a **simple blood draw** enhanced by Artificial Intelligence.



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



### Primary Clinical Pathway



†Lokhandwala *et al* (2016), Handy *et al* (2020)    ‡Jemal and Fedewa 2017    # Gould *et al* (2015)

\*Average time to diagnosis incorporates both “wait-and-see” and biopsy pathways



**Last update (Sep 2022)**

**Actions Since**

**Ongoing**

Validation Study

- Six hospitals activated

- Thirteen total hospitals activated (+3 additional VAs)

- Onboard 2 additional hospitals
- Continue enrollment
- Data analysis/study readout

Regulatory

- New York State approval of LungLB® test

- Initiated FDA de novo application

- FDA submission

Reimbursement

- Presented at CMS Public Meeting for LungLB® pricing

- Final pricing determination issued by CMS – crosswalk awarded
- National Medicare price of \$2,030 for LungLB® assigned January 1<sup>st</sup>

- Enroll in key State Medicaid programs
- Build Early Access Program interest for LungLB®

Additional Highlights

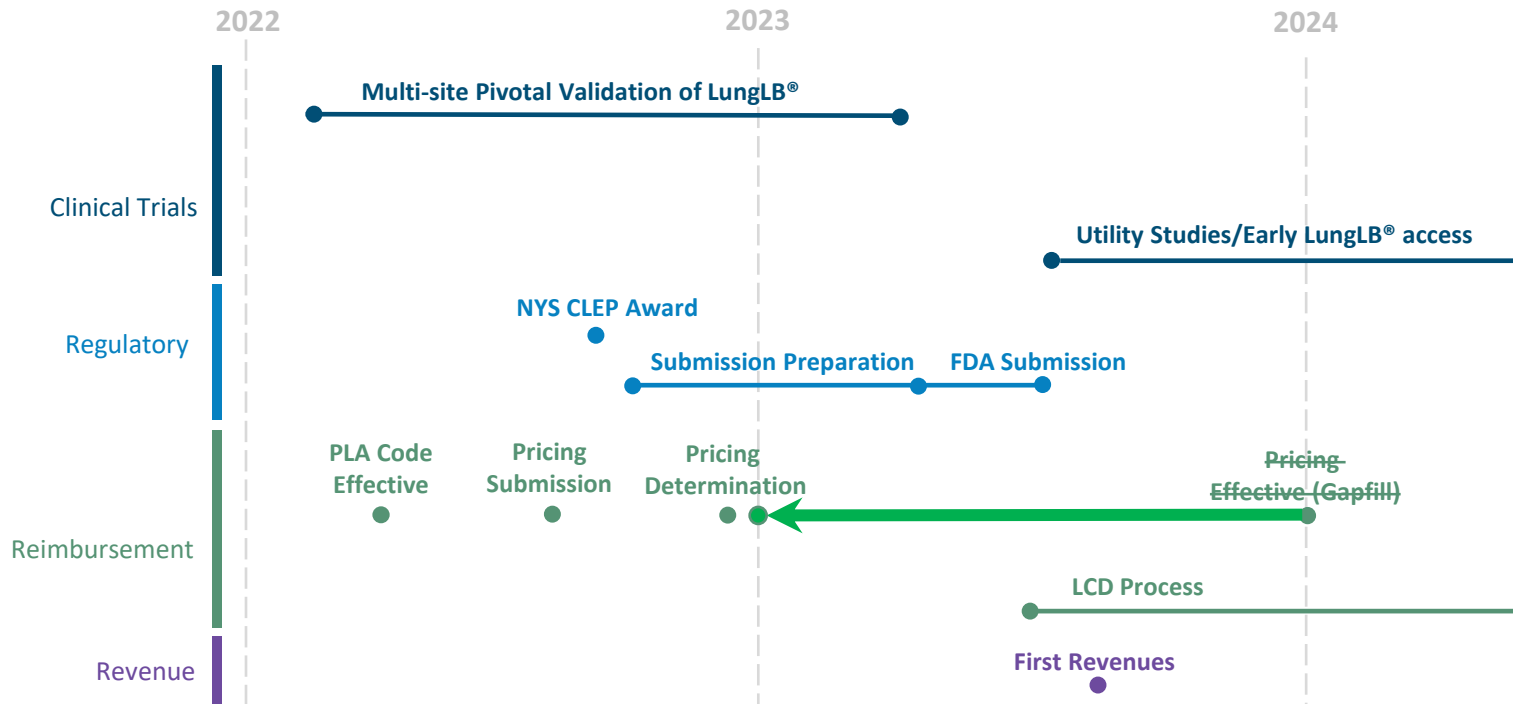
- Submitted pilot study publication for peer review publication
- Presentations accepted at two international conferences

- Partnered with UCLA and BU in prestigious EDRN program
- Submitted Health Economics manuscript for publication

- National EDRN presentation



Notional timeline





Pivotal Study  
Enrollment and  
Results



FDA de Novo  
submission



Expanded  
Reimbursement  
(Medicaid/  
Private Payor)



Initiate Clinical  
Utility Studies



Nominal First  
Revenues

**LungLifeAI™** aims to be a driving force in the early detection of lung cancer.

Our Vision is to invert the 20:80 ratio such that at least 80% of lung cancers are diagnosed early.





# Audited Financial Results for year ended 31 December 2022



- Total cash balance: **\$8.0m** (Runway to mid-2024)
- Cash used by operations in the year: **\$5.8m**
- EBITDA loss (excluding share based payments charge): **\$6.8m**





Urgent Unmet Need for Early Detection

## High Prevalence



Someone in US diagnosed every 2.5 mins



Almost 25% of all cancer deaths in US, 130,180 deaths in 2022<sup>1</sup>

## Poor Early Detection



Surgery can cure – but only 20% of US cases diagnosed early



>1.5m lung nodules identified p.a. in US

## Lack of Screening



c. 14.2m Americans eligible for free screening (2020: 6.8m)

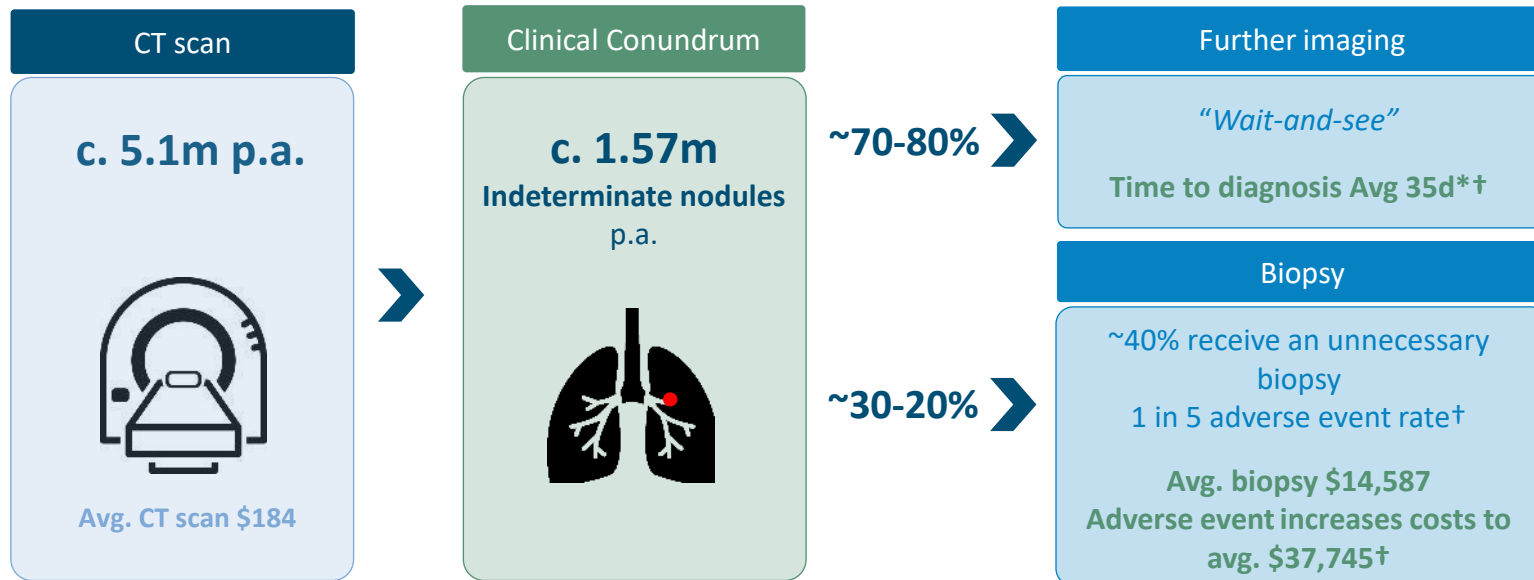


Only 5.8% of those eligible are screened

**Nodules found incidentally by CT scan still account for majority of early diagnosis**



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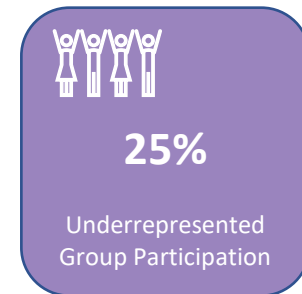
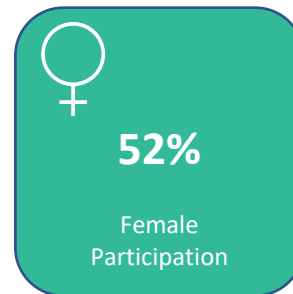
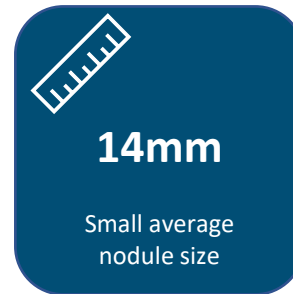
Why We Believe our LungLB<sup>®</sup> test is an  
Answer



Based on pilot study, which showed well balanced performance

“Real-world” patients enrolled in our study:

- Majority of nodules are small, which represent earliest cancers and most challenging to detect
- >65% of participants of Medicare age
- Good study demographics gives confidence in test performance across multiple patient types





## Simplicity



- Simple blood draw
- Familiar technologies: CTC and FISH
- Report: Positive/Negative

## Care Pathway



- Blood tests are already required prior to biopsy
- Aid in the decision-making process: biopsy vs wait-and-see

## LungLB<sup>®</sup> is an easy test to order and simple to understand

### Advocates



“We appreciate that LungLife’s test was developed without requirement for smoking history”

### Pulmonologists



“I’m starting a nodule clinic at our hospital and we’re looking for a technology like LungLB to help triage patients”

### Researchers



“EDRN members would be interested in LungLB’s potential to facilitate early detection of multiple cancer types”

### Pulmonologists



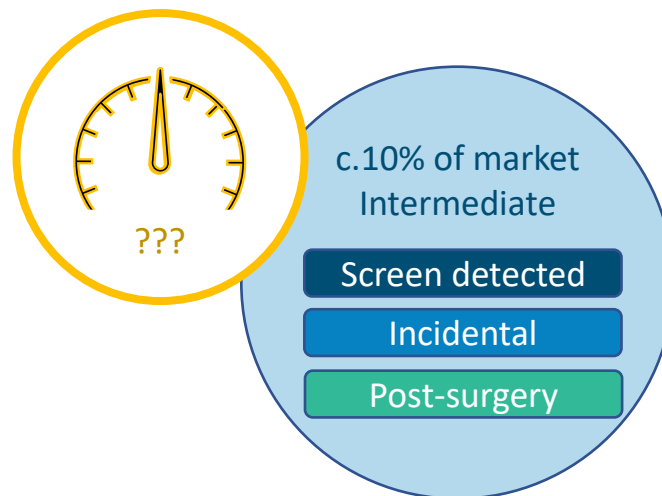
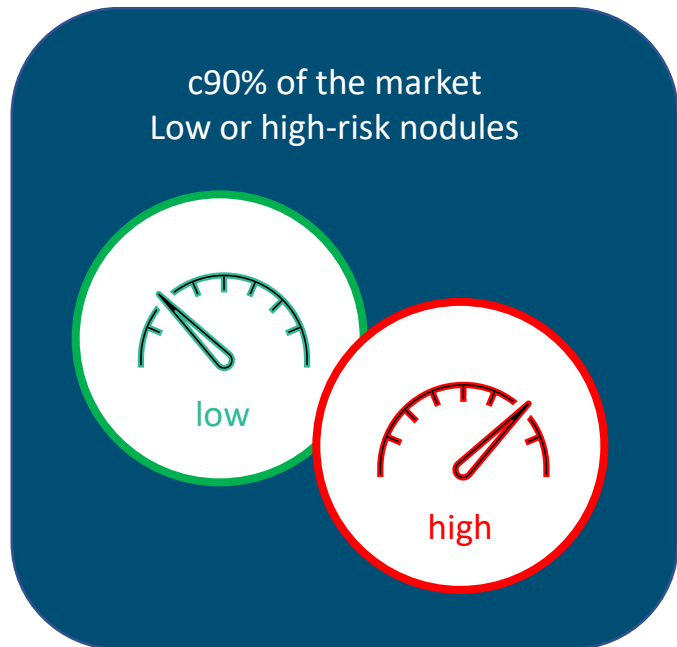
“Sometimes I need to convince other docs to take action on a suspected cancer: I think LungLB may be able to help with this”



# Market Opportunity



Total lung cancer early detection market opportunity in US is significant



Source: American College of Radiology LungRADS





# Commercialisation Plan



▼ We have regulatory support to begin commercialisation



✔ **2019** - LungLB<sup>®</sup> qualified as a Laboratory Developed Test, LDT



✔ **2021**



✔ **2022**

▼ FDA is voluntary but is expected to support uptake



✔ **Submission targeted 2023** – provides confidence to all stakeholders, rigorous study design requirements and adjunct claim is a good entry point

▼ Reimbursement is the next most important step



✔ **Jan 2022** – PLA code granted



✔ **Nov 2022** - LungLB<sup>®</sup> assigned “crosswalk” by CMS – priced at \$2,030 per test



✔ **Coverage** – Assessment under MoIdx – supported by validation and clinical utility studies

### Current focus and priorities

Building our network of utility sites



Existing relationships



Word of mouth



Medicaid/private payor provider in strategic states



Peer reviewed publications supporting utility and economics of LungLB®

### Longer term growth drivers

LungLB® pipeline expansion



Other LC indications



Additional cancer types



Distribution in other countries with interest in early detection



Partnerships and collaborations

#### Established clinical partners





# Overview



Pivotal Study  
Enrollment and  
Results



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submission



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Reimbursement  
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# Appendix



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### Paul Pagano, PhD

CEO & CSO



Amgen  
CytomX



### David Anderson

CFO



Audit Partner BDO, Crowe  
FD Strategic Minerals Plc (AIM)  
FD Hakkasan and C|T Group



## Non-Executive Directors



### Roy Davis

Independent Non-Executive Chairman



Gyrus Group, Optos, Medica, Edinburgh Molecular Imaging,  
Foster & Freeman, RAIR Health



### Andrew Boteler

Independent Non-Executive Director



Riverford Organic Farmers Ltd, Octopus VCT plc,  
Gooch & Housego



### James McCullough

Independent Non-Executive Director



Current CEO of Renalytix AI,  
Verici Dx, Exosome Dx



### Sara Barrington

Non-Executive Director



Current CEO of Verici Dx,  
LungLife AI, Exosome Dx, Kantaro



## Steven M. Dubinett, MD

Dean of Medicine,  
Former Chief of Pulmonary Medicine  
University of California, Los Angeles

## Michael J. Donovan, PhD MD

University of Miami  
Mount Sinai Health Systems

## Claudia Henschke, PhD MD

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MD Anderson Cancer Center

## Ruth Katz, MD

Professor of Pathology/Cytopathology  
MD Anderson Cancer Center

## Max P. Rosen, MD MPH

Chair of Radiology  
UMass Memorial Medical System

## Drew Moghanaki, MD MPH

Chief of Thoracic Oncology  
University of California, Los Angeles



## Cash Flow Statement

	\$'000
Cash used by operating activities	(5,845)
Cash used by investing activities	(115)
Cash used by financing activities	(169)
Net movement in cash and deposits	(6,129)
Cash and deposits at 31 Dec 2022	8,010

## Income Statement

	\$'000
Revenue	24
Administrative expenses	(6,865)
Depreciation and share based charge	(899)
Other income	102
Finance income	88
Finance charge	(52)
Tax	(4)
Loss for year	(7,606)



## Balance Sheet

	\$'000
Receivables, incl long term	626
Cash and deposits	8,010
Tangible assets	566
Intangible assets	5,818
Trade and other payables	(1,055)
Leases and other liabilities	(825)
Share capital	(3)
Reserves	(92,840)
Accumulated losses	79,703