

LungLifeAI™

Annual Results to 31 December 2023

April | 2024 ●●●



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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



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.



Audited Financial Results for year ended 31 December 2023



- Cash at end of year **\$2.83m** (2022 - \$8.01m)
 - Cash outflow from operations **\$5.0m** (2022 - \$5.8m)
 - Implying monthly burn of c. **\$420k** (2022 – c. \$490k)
- Adjusted EBITDA (excluding share-based payments) **\$5.19m** (2022 - \$6.84m)
 - Slight increase in wage cost from \$2.69m to **\$2.74m** due to full year impact of starters in 2022.
 - Offset by reduction in research and development cost from \$1.98m to **\$1.30m** as we finished enrolment of the trial and no further development of the AI algorithm.
 - And reduction in other cost categories.
- Balance sheet
 - Mount Sinai license continue to be carried at cost - \$5.8m – without amortization as yet to access the underlying data asset



- Net proceeds from issue of 5,172,621 shares – net **\$1.8m**
 - Cash runway to **April 2025**
 - With opening cash of \$2.83m, gives an implied monthly burn of c. **\$290k**
- Cost reductions
 - Headcount reduced and salary reductions – reduces monthly cost in **half**



Urgent Unmet Need for Early Detection

High Prevalence



Someone is diagnosed with lung cancer every 2.5 mins in the US



Accounts for >20% of all cancer deaths in US (est. 130k deaths in 2023¹)

Poor Early Detection



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



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

Lack of Screening



c. 14.2m Americans eligible for free screening (2020: 6.8m)²



Only 5.8% of those eligible are screened each year

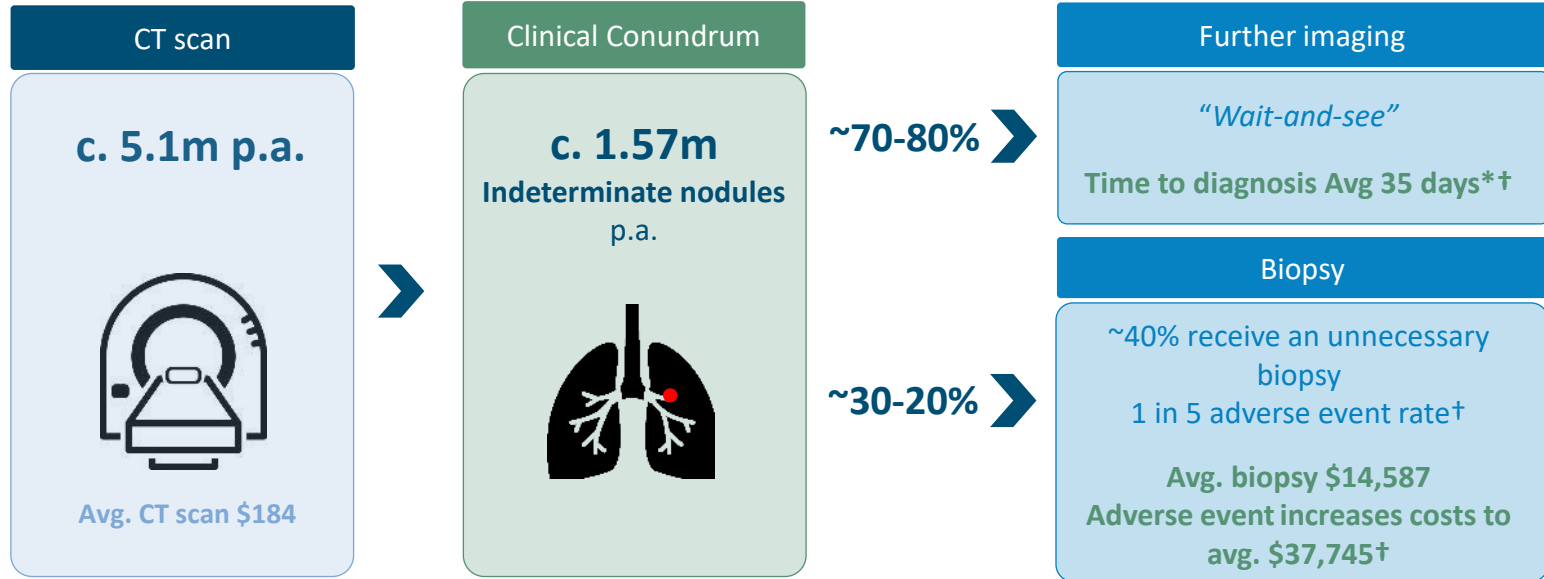
Nodules found incidentally by CT scan still account for majority of early diagnosis

¹SEER Program, National Cancer Institute (<https://seer.cancer.gov/statfacts/html/all.html>)

²American Lung Association (<https://www.lung.org/media/press-releases/state-of-lung-cancer-2022>)

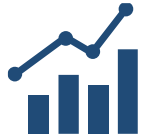


Primary Clinical Pathway

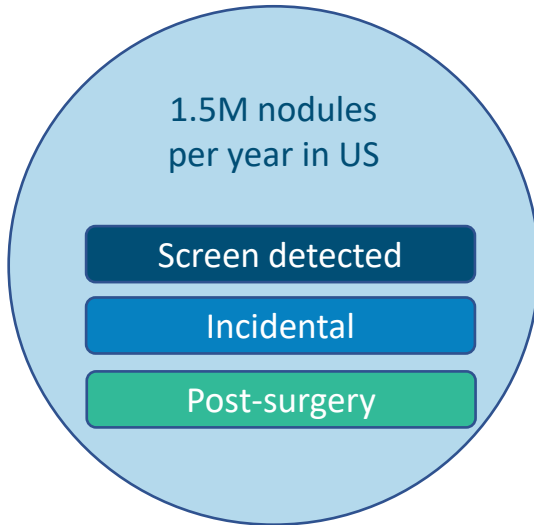


†Lokhandwala *et al* (2017), Handy *et al* (2020) ‡Jemal and Fedewa 2017 # Gould *et al* (2015)

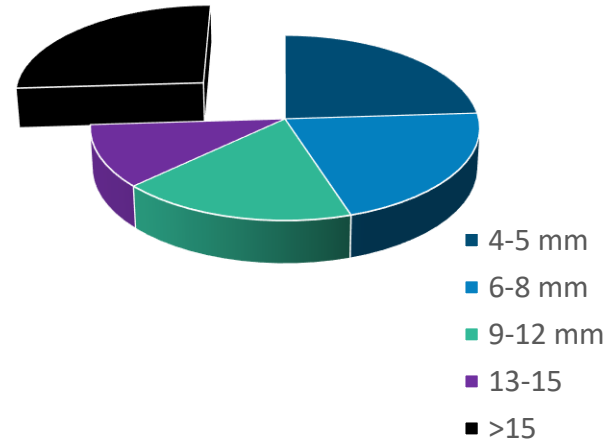
*Average time to diagnosis incorporates both “wait-and-see” and biopsy pathways



The market for early detection of lung cancer in the US estimated to exceed \$2 billion



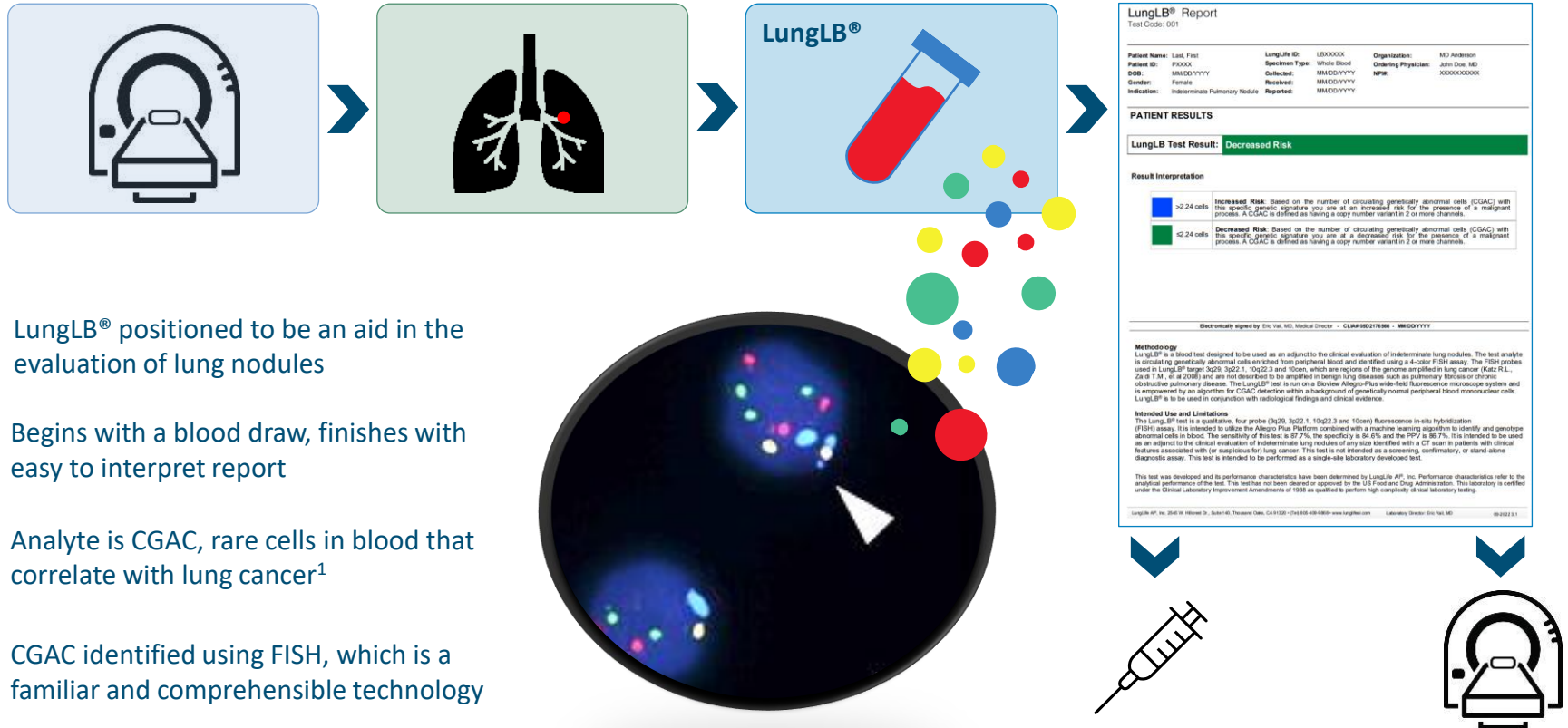
Entry point: nodules <15 mm make up ~70% TAM



Source: Gould *et al* (2015), 13-15 mm range estimated by LLA
LungLB® National Medicare price of \$2,030/test
1.5M nodules * 70% * \$2,030/test = ~\$2B



Why We Believe our LungLB[®] test is the
Answer



- » LungLB[®] positioned to be an aid in the evaluation of lung nodules
- » Begins with a blood draw, finishes with easy to interpret report
- » Analyte is CGAC, rare cells in blood that correlate with lung cancer¹
- » CGAC identified using FISH, which is a familiar and comprehensible technology

LungLB [®] Report			
Test Code: 001			
Patient Name:	Last, First	LungLife ID:	LEXXXXX
Patient ID:	XXXXX	Specimen Type:	Whole Blood
DOB:	MM/DD/YYYY	Collection:	MM/DD/YYYY
Gender:	Female	Received:	MM/DD/YYYY
Indication:	Indeterminate Pulmonary Nodule	Reported:	MM/DD/YYYY
Organization:	MD Anderson	Ordering Physician:	John Doe, MD
		NPI#:	XXXXXX0000
PATIENT RESULTS			
LungLB Test Result: Decreased Risk			
Result Interpretation			
■	>24 cells	Increased Risk: Based on the number of circulating genetically abnormal cells (CGAC) with this specific genetic signature you are at an increased risk for the presence of a malignant process. A CGAC is defined as having a copy number variant in 2 or more chromosomes.	
■	≤24 cells	Decreased Risk: Based on the number of circulating genetically abnormal cells (CGAC) with this specific genetic signature you are at a decreased risk for the presence of a malignant process. A CGAC is defined as having a copy number variant in 2 or more chromosomes.	
Electronically signed by Eric Val, MD, Medical Director - CLIA# H0217686 - MM/DD/YYYY			
Methodology			
LungLB [®] is a blood test designed to be used as an adjunct to the clinical evaluation of indeterminate lung nodules. The test analyte is circulating genetically abnormal cells extracted from peripheral blood and identified using a 4-color FISH assay. The FISH probes used in LungLB [®] target 3p28, 3q22.1, 10q23.3 and 10cen, which are regions of the genome amplified in lung cancer (Katz, R.L., Zand, L.M. et al. 10/2018) and are not observed to be amplified in benign lung diseases such as pulmonary fibrosis or chronic obstructive pulmonary disease. The LungLB [®] test is run on a Biorad Axiom-Plus wide-field fluorescence microscope system and is empowered by an algorithm for CGAC detection within a background of genetically normal peripheral blood mononuclear cells. LungLB [®] is to be used in conjunction with radiological findings and clinical evidence.			
Intended Use and Limitations			
The LungLB [®] test is a qualitative, four probe (3p28, 3q22.1, 10q23.3 and 10cen) fluorescence in-situ hybridization (FISH) assay. It is intended to utilize the Axiom-Plus Platform combined with a machine learning algorithm to identify and genotype abnormal cells in blood. The sensitivity of this test is 87.7%, the specificity is 84.6% and the PPV is 96.7%. It is intended to be used as an adjunct to the clinical evaluation of indeterminate lung nodules of any size identified with a CT scan in patients with clinical features associated with (or suspicious for) lung cancer. This test is not intended as a screening, confirmatory, or stand-alone diagnostic assay. This test is intended to be performed as a single-site laboratory developed test.			
This test was developed and its performance characteristics have been determined by LungLife AI, Inc. Performance characteristics refer to the analytical performance of the test. This test has not been cleared or approved by the US Food and Drug Administration. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high-complexity clinical laboratory testing.			
LungLife AI, Inc. 2540 W. Howell Dr., Suite 100, Thousand Oaks, CA 91320 - (760) 438-8888 - www.lunglife.com Laboratory Director: Eric Val, MD (0002) 1.1			

Definitive Diagnosis

Non-invasive Imaging

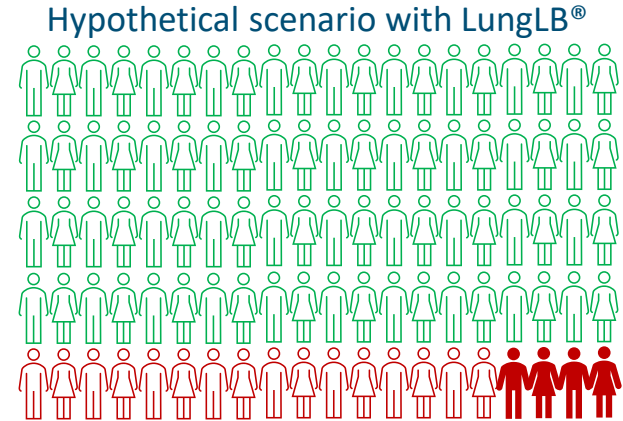
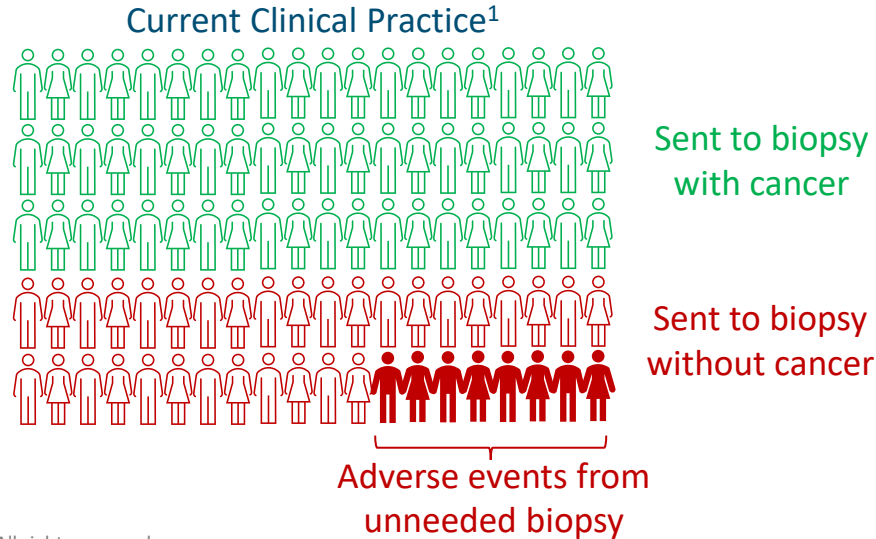
- » LungLB® performed significantly in participants with small (<15 mm) nodules, a known pain-point for physicians
- » Rigorous study: 87% in “intermediate” risk group. Previous studies lack sufficient numbers of intermediate-risk nodules
- » **Left over blood cells and plasma preserved for future LungLB® development**



PERFORMANCE

- **81% Positive Predictive Value (PPV)**
- 72% AUC Vs. 62% Mayo Model
- 81% PPV Vs. 67% PET Scan

When a physician sends someone with a lung nodule to biopsy because they suspect cancer...



¹Lokhandwala et al (2017), 60% PPV from 40% biopsies in people w/o lung cancer



Commercialisation



▼ We have regulatory support to begin commercialisation



Department of Health



LungLB® qualified as a Laboratory Developed Test, LDT



2021



2022



Voluntary but important

▼ Reimbursement foundation in place



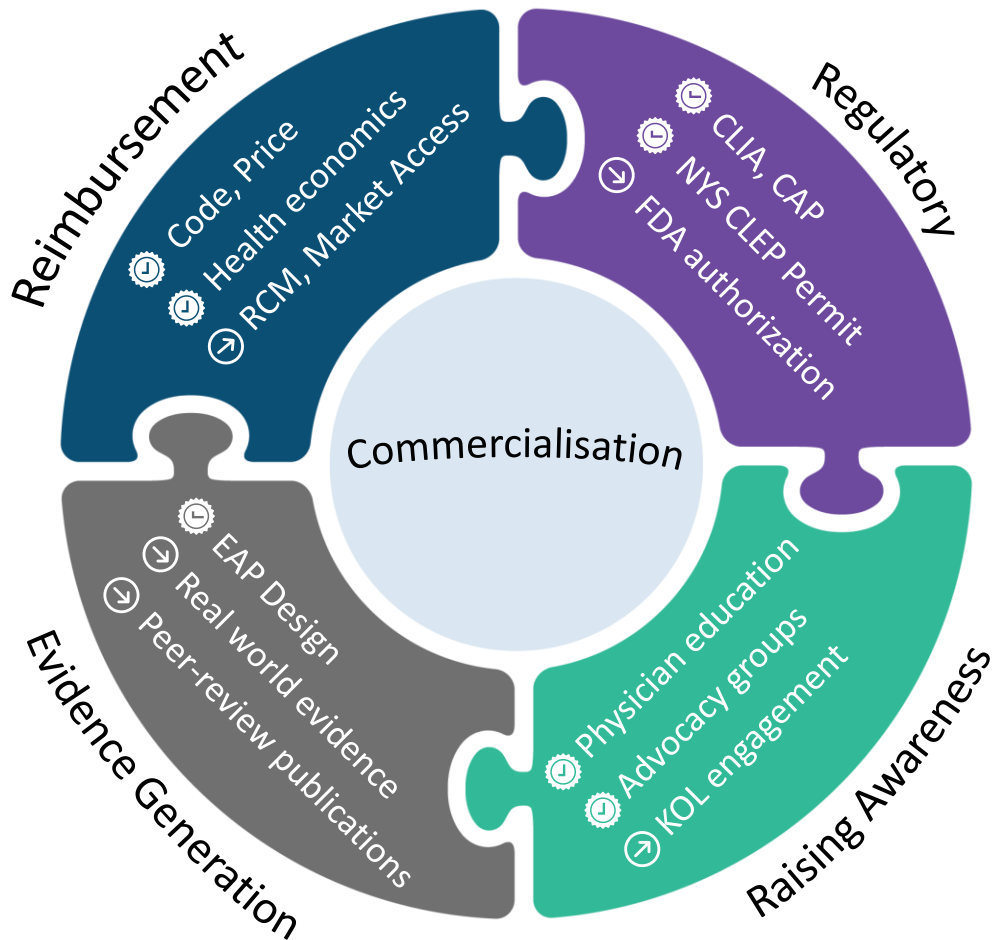
Jan 2022 – PLA code granted



Nov 2022 – LungLB® assigned national Medicare price at \$2,030 per test



Coverage – Assessment under MoIDX – supported by health economics, validation and clinical utility studies



Commercial Proof of Concept

- ✓ **Methodical** approach
- ✓ Prove and build **adoption** curve
- ✓ Adoption is about data and **trust**
- ✓ Test business/sales model in limited scope, low-cost setting
- ✓ Collect utility data and build **KOLs**
- ✓ Secure payor **reimbursement** through appeals process



Early Access Program – up to 20 patients per site from 5-10 sites, up to 100 patients. Physicians will be surveyed.

- Comprised of familiar sites that participated in validation study
- Refine “technical” aspects of test ahead of launch (ordering process, client services, results reporting)
- Understand clinical utility: effect on nodule evaluation and patient care

EAP on utility – understand adoption curve and provides additional evidence considered by payors for reimbursement





Foundational LCD Pathway

Headline:

MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy

DL39678

Expand All | Collapse All



PROPOSED LCD

Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor.

- Foundational LCD proposed by MolDx to cover tests for lung nodules
- We believe LungLB® would be eligible for coverage under this LCD, if finalized.
- MolDx has well defined technical assessment process
- Coverage under foundational LCD 8-12 months.



PALMETTO GBA®

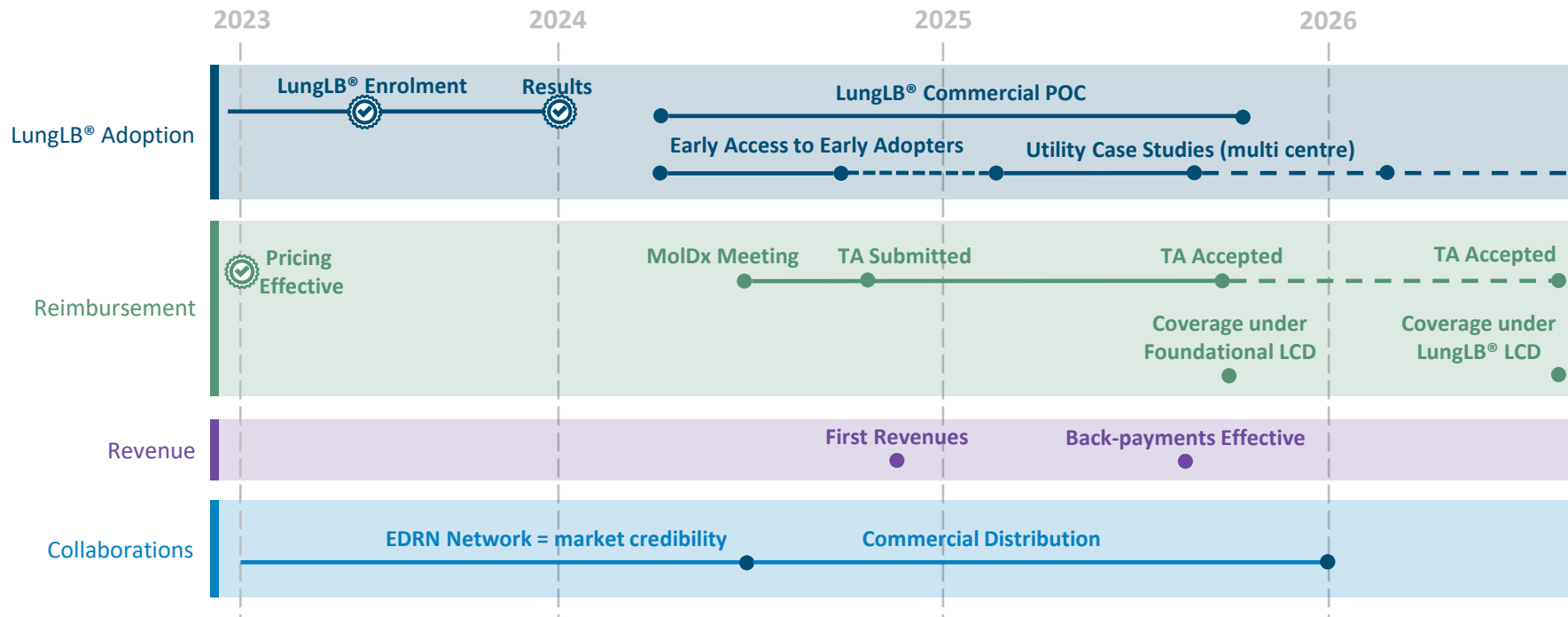
A CELERIAN GROUP COMPANY



MolDX



Notional timeline





Commercial launch: internal resource

1 Sales H/C per 10 centers

Increase number of tests per month:

- Clinical Trust
- Reimbursement
- Initial patient case studies for utility presented
- Case studies (multi center)

Sales and Distribution

Strategic collaborator options

Unique use fits with other portfolios

De-risked proposition for revenue growth “hungry” companies

Mature Sales

Leverage wider distribution

Leverage publications and usage

Additional uses of the product

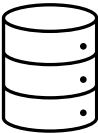




- LungLB uses peripheral blood cells isolated from ~2 mL whole blood and does not use plasma.
- Remaining blood cells and unused plasma are cryopreserved for future studies.



- >600 patient specimens stored representing early-stage lung cancer and benign indeterminate nodules.
- Patient demographic and clinical information collected with >400 matched CT scan images.
- Ongoing collection through EDRN partnership provides estimated +500 samples from lung nodule patients.



- Fully-paid data access license to de-identified patient records from Mount Sinai Hospital.
- Includes CT and PET scan images related to lung cancer and those at-risk for lung cancer.



In conclusion.....



Proven test performance



Large addressable market



Vital entry point in small nodules



Regulatory and reimbursement foundations



Path to first revenues

LungLifeAI™

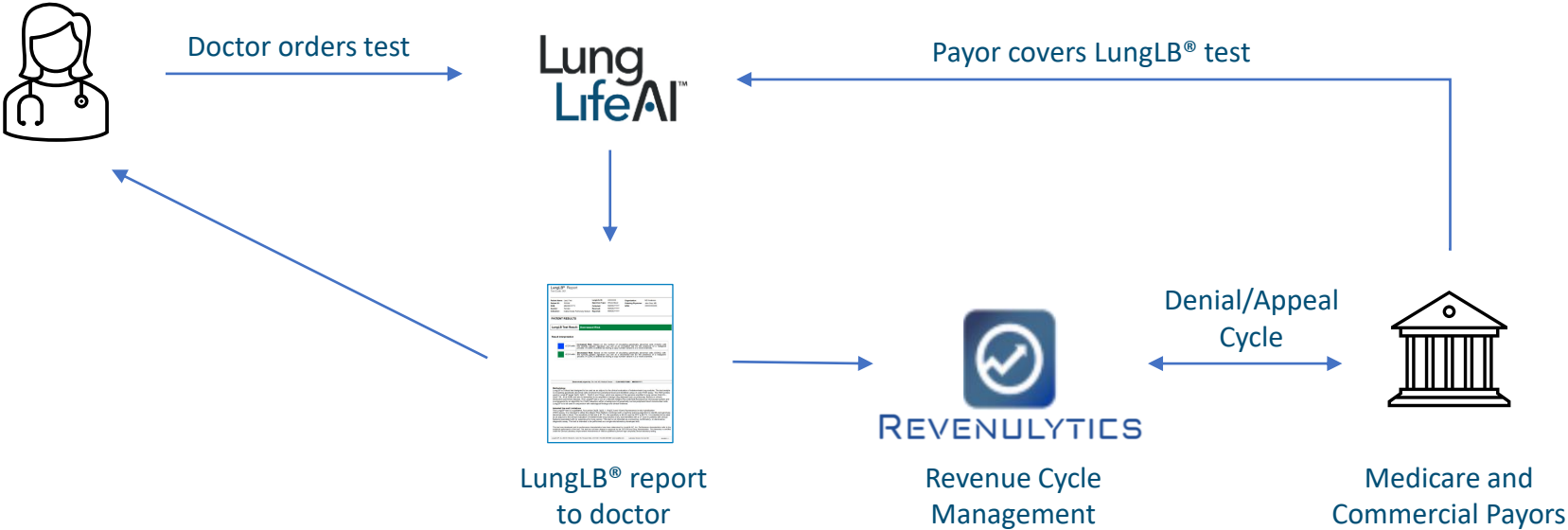
aims to be a driving force in the early detection of lung cancer.

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





Appendices



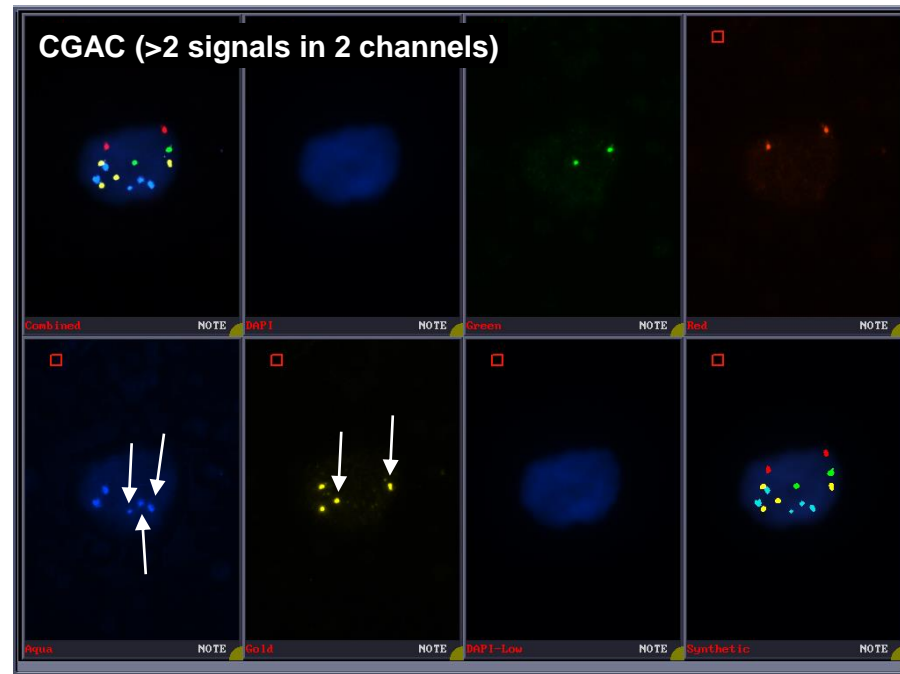
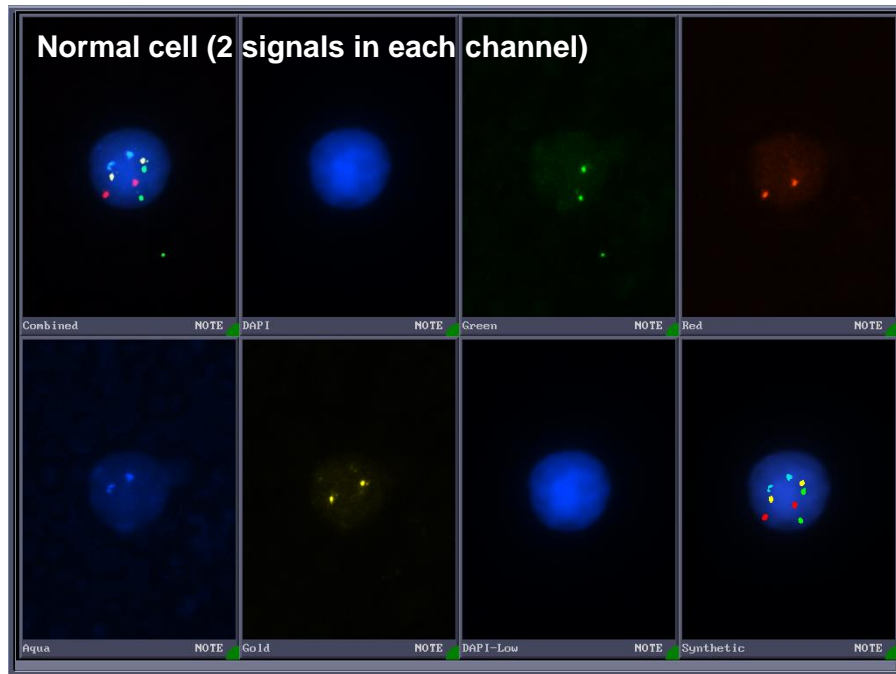


- Medicare is the largest US public health insurance payor.
- Medicare is administered by multiple MACs (Medicare Administrative Contractors) whose jurisdiction is based on geographical region.
- LungLife is under a jurisdiction that uses the MoIDx program, which has a well-defined process for applying for coverage called Technical Assessment.
- A clinical dossier that contains analytic validity, clinical validity, and clinical utility is compiled and submitted to MoIDx.
- Your test is deemed “Not Covered” until the technical assessment is complete.
- Coverage is given if Medicare approves your clinical dossier (called a Local Coverage Determination).
- A foundational LCD has been proposed by MoIDx for indeterminate lung nodules. An alternative path, should the proposal be finalized, is LungLB gains coverage under the Foundational LCD rather than a LungLB-specific LCD.



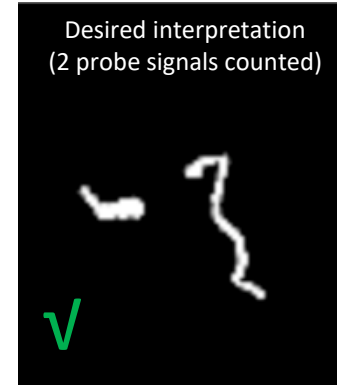
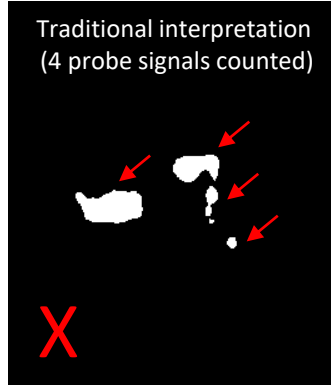
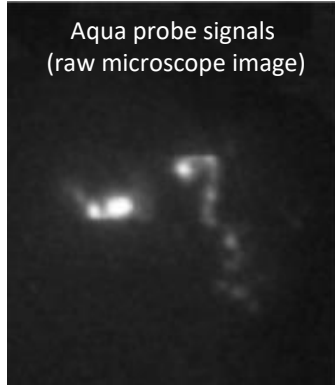
The successful commercialization of our LungLB test will be achieved by a **methodical, deliberate** approach. To date we have built some of the foundations. This next phase is to drive adoption of the test which starts with clinicians finding the test useful

- We have 2 sources of revenue by payor:
 - Commercial payors
 - Expectation of ramp up in volume as utilization will generate greater utilization
 - Coverage will be very low in early period
 - Reimbursement is a function of utilization, as utilization increases, reimbursement should follow
 - Medicare
 - Limited reimbursement until Local Coverage Determination in place
 - Once in place, reimbursement backdated to acceptance of complete Technical Assessment
 - Based on our validation study, 68% of participants are of Medicare age.





Not all FISH images are easily interpreted



Our AI algorithm co-developed with Persistent Systems provides:

- Enhanced sensitivity: A 4-point improvement in the cancer detection rate
- Enhanced specificity: >60% reduction in miscategorised CGAC vs standard FISH microscope software
- Improved objectivity and reproducibility: Algorithm defines “true” probe signal parameters



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

Radiology
Mount Sinai Health Systems

David Yankelevitz, MD

Interventional Radiology
Mount Sinai Health Systems

Joshua D. Kuban, MD

Interventional Radiology
MD Anderson Cancer Center

Ruth Katz, MD

Former 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



Executive Team

Paul Pagano, PhD

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Non-Executive Directors



Roy Davis

Independent Non-Executive Chairman



Inspiration Healthcare, Futura Medical, Foster + Freeman



Andrew Boteler

Independent Non-Executive Director



Octopus AIM VCT PLC



James McCullough

Independent Non-Executive Director



Current CEO of Renalytix,
Verici Dx



Sara Barrington

Non-Executive Director



Current CEO of Verici Dx,
LungLife AI