

bioAffinity
TECHNOLOGIES

NASDAQ: BIAF / BIAFW

Company Presentation

CyPath[®] Lung

Noninvasive, Accurate Lung Cancer Detection

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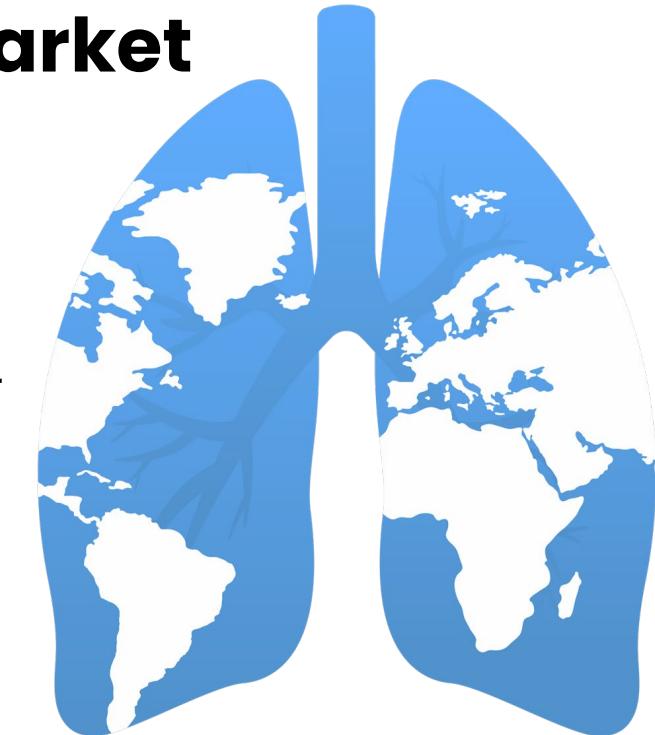
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Lung Cancer Is A Global Problem and Large Market

Most common cancer and leading cause of cancer-related deaths

- 2.48 million new cases of lung cancer worldwide in 2022, with 1.8 million deaths annually¹
 - An estimated **19.3 million Americans** should have annual lung cancer screening, according to the American Cancer Society²
 - Up to ~**34 million people in the European Union** were at high risk for lung cancer in 2018³
 - **China reported 1,060,600 new cases** of lung cancer in 2022⁴



Lung cancer diagnostic market is ever increasing

- Estimated at **\$20 billion in 2023** and projected to reach **\$38 billion by 2034**
 - CAGR of 7.23% over 2025-2033⁵

1. The Cancer Atlas, Third Edition, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <https://canceratlas.cancer.org/the-burden/lung-cancer/> and Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21834> 2. NBC News. "Lung cancer screening guidelines: Quit smoking, annual test." NBC News Health. Accessed Nov. 2023. <https://nbcnews.to/3QmWv6w> 3. Lung Cancer Burden in EU. European Union Joint Research Centre. Jan. 2021. <https://bit.ly/EUStats> and Estimation of the adult population at high risk of developing lung cancer in the European Union, Cancer Epidemiology, <https://doi.org/10.1016/j.canep.2018.10.007> 4. Cancer incidence and mortality in China, 2022, Journal of the National Cancer Center, <https://doi.org/10.1016/j.jncc.2024.01.006> 5. Research and Markets <https://www.researchandmarkets.com/reports/5941158/lung-cancer-diagnostics-market-size-share>

Early Detection of Lung Cancer Saves Lives

92% of Stage I patients survive 10 years if treated within 1 month of diagnosis¹

Accurate, early cancer detection can lead to

- Curative treatment
- Long-term survival
- Improving the positive predictive value of screening

In 2025, less than **30%** of patients survived 5 years²

- Most patients are diagnosed with late-stage (Stages III-IV) when survival is much lower²



1. Survival of patients with stage I lung cancer detected on CT screening, NEJM, October 26, 2006, <https://www.nejm.org/doi/full/10.1056/NEJMoa060476>

2. American Lung Association, State of Lung Cancer 2025, [State of Lung Cancer 2025](#)

Improving Lung Health by Tackling the Most Difficult Problem First: Detecting Lung Cancer with **Noninvasive** CyPath[®] Lung



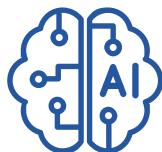
Growing Platform Technology

- Our commercial noninvasive lung cancer test is the **first in a pipeline** that includes development of companion diagnostics for asthma and chronic obstructive pulmonary disease (COPD)



92% Sensitivity¹ **87% Specificity¹** **99% Negative Predictive Value¹** **88% Accuracy¹**

- CyPath[®] Lung shows **high sensitivity and specificity** in detecting lung cancer in people with small, indeterminate pulmonary nodules*



Proprietary AI Analysis of Flow Cytometry Data

- AI-driven algorithm** analyzes complex flow cytometric data from patient sputum samples
- Profiles the lung microenvironment to differentiate between patients with or without lung cancer



Patient-friendly / Physician-focused

- At-home collection** (no needles, no blood) with results 3 days after sample arrives at lab.

*Nodules detected by low-dose computed tomography. Test performance for patients with pulmonary nodules less than 20 mm also resulted in 88% accuracy, 95% Area Under the Curve; 95% Confidence Interval; 99% Negative Predictive Value, 44% Positive Predictive Value.

1. Lemieux ME, Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning. *Respir Res.* 2023;24(1):23. doi:10.1186/s12931-023-02327-3

CyPath® Lung in Action: Patient Case Studies*

CyPath® Lung Finds Cancer at Curative Stage 1A; Averts Risky Procedures

“Gloria” case: CyPath® Lung returned a “likely” malignancy result for a patient with **Stage 1A** mucinous adenocarcinoma later confirmed by biopsy. PET scan and serum markers were non-diagnostic. Patient is doing well after surgery.

“Paula” case: CyPath® Lung returned a “likely” result for a patient with a **Stage 1A** neuroendocrine tumor later confirmed by biopsy. Bronchoscopy and a non-diagnostic PET scan missed the cancer. These rare tumors can be difficult to diagnose. Patient is doing well after surgery.

“James” case: CyPath® Lung returned an “unlikely” result in an 85-year-old at high risk for lung cancer from heavy tobacco use and asbestos exposure. The result supported delaying invasive testing, sparing the patient a high-risk biopsy. The **pulmonary nodules resolved** on follow-up.

*Patient names are changed to protect privacy

Gloria: https://www.cypathlung.com/wp-content/uploads/2025/08/CyPath_case-study_Gloria_Stage-1A.pdf

Paula: https://www.cypathlung.com/wp-content/uploads/2025/08/CyPath_case-study_Paula_Stage-1A.pdf

James: https://www.cypathlung.com/wp-content/uploads/2025/08/BIO25_1012_R6_CP-25011-CyPath-Lung-Case-Study-Leavebehind_JAMES.pdf



CyPath® Lung in Action: Patient Case Studies*

Detects Cancer In Surveillance Period; Malignant Ground Glass Nodule Detected Earlier

"Joan" case: **Surveillance** in high-risk survivors is challenging. CyPath® Lung returned a "likely" result during monitoring after initial lung cancer treatment, leading to a confirming biopsy and treatment for a new second lung cancer.

"Carol" case: CyPath® Lung is a **useful tool after treatment** for lung and non-lung primary cancers. A "likely" result for a new pulmonary nodule discovered post-treatment for breast and lung cancer led to a mammogram, biopsy and treatment for recurrent breast cancer metastatic to the lung.

"Helen" case: CyPath® Lung returned a "likely" result for incidentally detected **ground glass nodules** with no suspicious characteristics on imaging. The result led to **early diagnosis** and treatment, avoiding 3-5 years of "watchful waiting."

*Patient names are changed to protect privacy

Joan: https://www.cypathlung.com/wp-content/uploads/2025/08/BIO25_1013_R7_CP-25012-CyPath-Lung-Case-Study-Leavebehind_JOAN.pdf

Carol: https://www.cypathlung.com/wp-content/uploads/2025/08/BIO25_1014_R6_CP-25013-CyPath-Lung-Case-Study-Leavebehind_CAROL.pdf

Helen: https://www.cypathlung.com/wp-content/uploads/2025/10/CyPath_case-study_Helen_ground-glass_FINAL.pdf



CyPath[®] Lung Compares Favorably to Standards of Care

Proven Clinical Utility To Help Detect Lung Cancer Noninvasively

Lung Cancer Diagnostic Procedure or Test	Sensitivity	Specificity
CyPath[®] Lung¹ (individuals at high risk with nodules <20mm)	92%	87%
FDG PET imaging² (individuals with suspicious lung nodules)	89%	75%
Bronchoscopy³ (individuals with suspicious lung nodules)	88%	47%
Fine Needle Biopsy⁴ (individuals with suspicious lung nodules)	90%	75%
Core Needle Biopsy⁴ (individuals with suspicious lung nodules)	89%	89%

FDG=fluorodeoxyglucose; ;PET=positron emission tomography.

1. M. Lemieux, et al, Detection of early-stage cancer in sputum using automated flow cytometry and machine learning, *Respiratory Research*, Jan 2023.

2. Deppen et al, Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: A meta-analysis, *JAMA*, 2014. 3. Silvestri et al. A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer, *New England Journal of Medicine*, 2015. 4. Yao et al, Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review, *Current Oncology*, 2012



CyPath[®] Lung

Physician-Focused, Patient-Friendly, Reimbursed by Insurance

@ Clinic



Physician orders
CyPath® Lung test to ship
to patient or deliver in clinic

@ Home



Patient videos,
instructions, personal
coach assist with 3-day
collection **at home**

@ Laboratory



AI-driven automated data analysis of flow cytometry data

@ Clinic



Physician receives results
within **3 days** after lab
receives sample

Actionable Results = Greater Confidence in Patient Care

AI=artificial intelligence.

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Interpreting the CyPath Lung Report

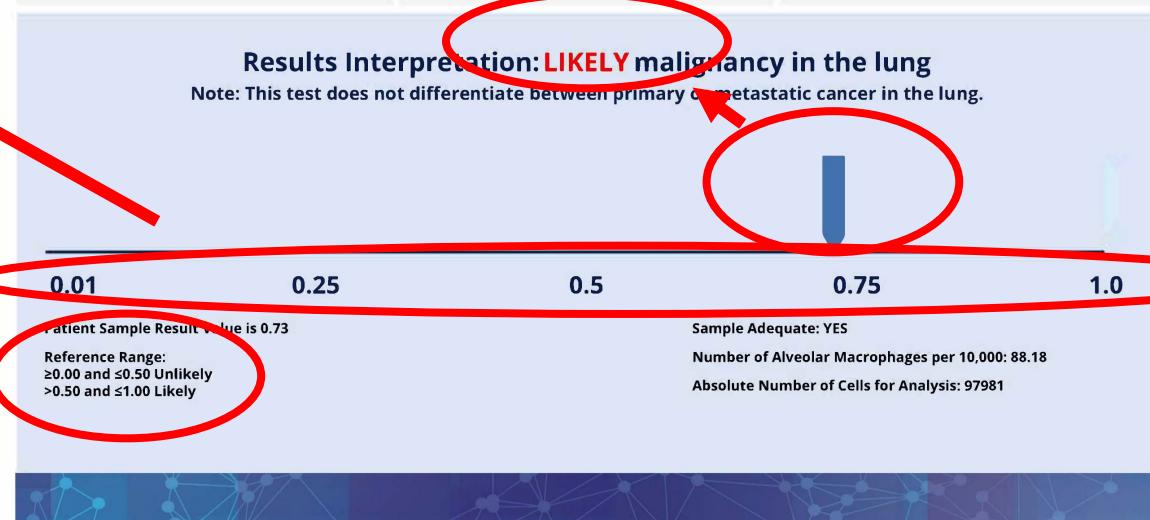


CyPath Lung

Scale reflects probability of cancer

Reference Range:
 $>0.00 \& <0.50$ Unlikely
 $>0.50 \& < 1.00$ Likely

Patient: DOE, JANE	Collection Date: 01/08/2026	Facility: Precision Pathology Services - Nacogdoches
DOB / Age / Sex: 01/06/1955 , 71 , Female	Received Date: 01/09/2026	Client ID Number: PPS
Accession Number: 10460303	Report Date:	Ordering Physician: Roby Joyce, MD
Result ID: CY26-000035	ICD 10 Codes:	Copies To:
	CPT Codes:	



Signed By: Vibha Bhasin, MD

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CyPath[®] Lung

Significant Healthcare Savings

2024 study¹ authored by pulmonologists practicing at Audie L. Murphy Memorial VA Hospital and Brooke Army Medical Center evaluated CyPath[®] Lung's potential economic impact if added to the standard of care in 2022



Conclusion: Significant savings to individual patients and the overall healthcare system

\$2,733 per Medicare patient
for estimated annual
savings of
~\$370 million to the
healthcare system¹

**\$6,460 per patient covered
by commercial insurance**
for estimated annual savings of
~\$895 million to the healthcare
system¹

VA=US Department of Veterans Affairs.

1. Morris, M., Habib, S., Do Valle, M., & Schneider, J.; Economic Evaluation of a Novel Lung Cancer Diagnostic in a Population of Patients with a Positive Low-Dose Computed Tomography Result (2024)(Accepted for Publication, Journal of Health Economics and Outcomes)

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How the CyPath Lung Test Works



Flow cytometry interrogates the lung microenvironment

- Sputum samples are processed into a single-cell suspension and labelled before data acquisition with antibodies, reagents, labeling agents and TCPP, a synthetic porphyrin taken up by cancer and cancer-related cells



Proprietary AI-driven platform analyzes sample for cancer

- Automated analysis identifies cell populations of interest and eliminates debris, dead cells, and cell aggregates to distinguish between likely cancer and benign conditions



Quality control assures the sample is from the lungs

- Fluorescent antibody specifically identifies lung macrophages to ensure the sample comes from the lungs



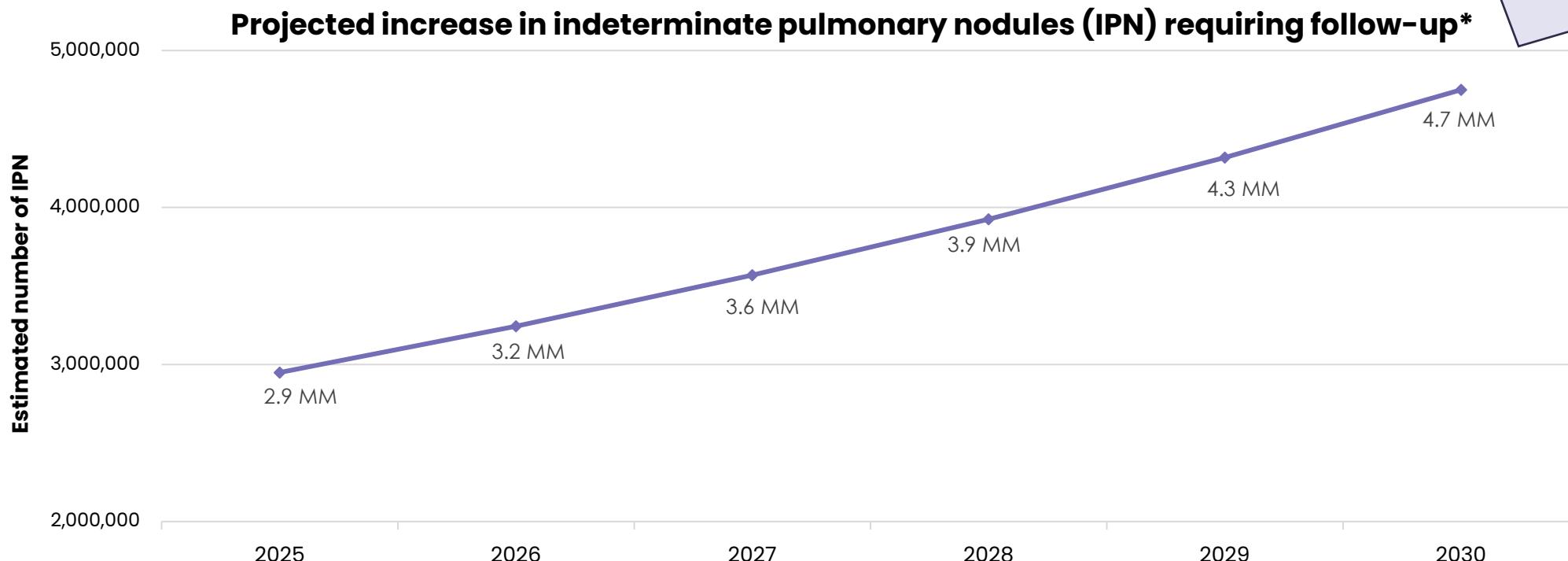
AI-driven analysis takes only minutes to identify lung cancer

- Analysis developed by machine learning detects cell populations indicative of lung cancer

TCPP=tetra (4-carboxylphenyl) porphyrin.

CyPath® Lung Market Opportunity

The U.S. Market for CyPath® Lung is poised for significant growth

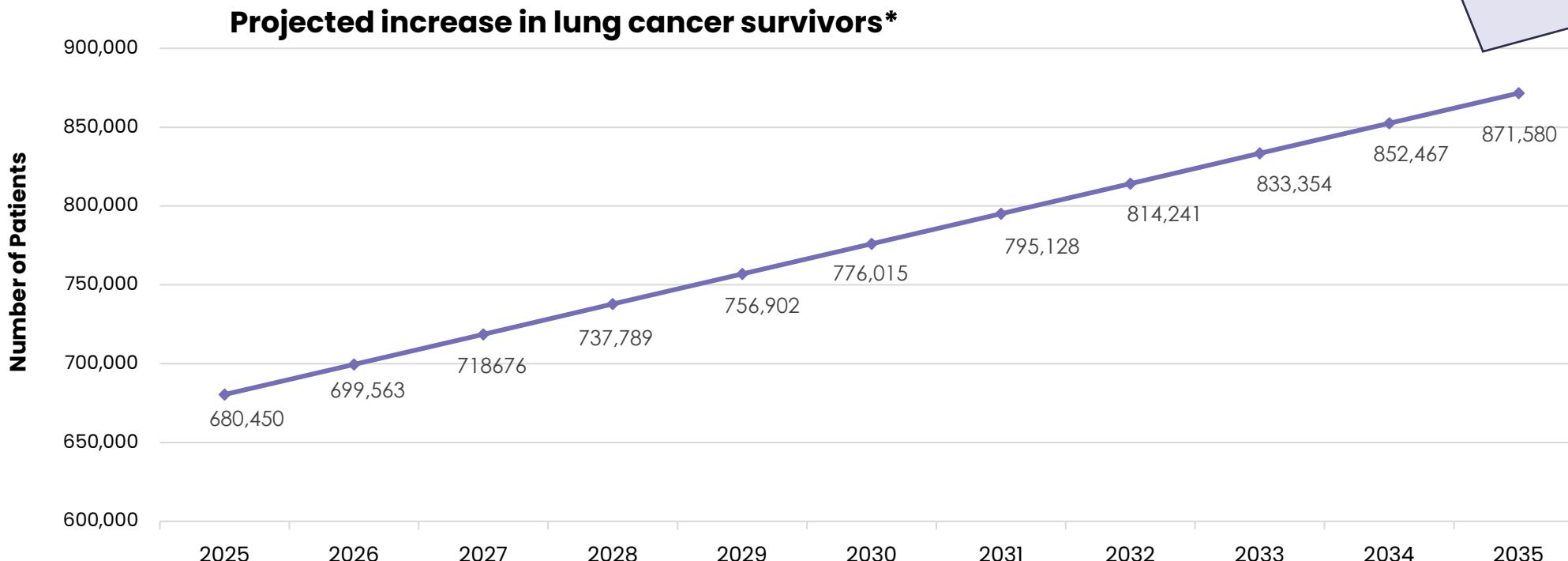


- The total number of indeterminate pulmonary nodules detected by lung cancer screening and incidentally by imaging for other conditions is projected to increase by 62% from 2.9 MM in 2025 to 4.7 MM in 2030*

*Projection assumes 10% compound annual growth for the 2024–2030 period based on 1) utilization of LCS increasing from 18.1% in 2023 to close to 50% by 2030 due to growing adoption and awareness with improved access, and 2) improved ability to detect IPN in CT and x-ray through greater adherence to guideline recommendations and use of AI.

CyPath® Lung Market Opportunity

CyPath® Lung Use for Surveillance of Lung Cancer Recurrence



- The total number of people living with lung cancer is projected to increase by 28% from 680,450 survivors in 2025 to 871,580 in 2035*

*Wagel, et al. *Cancer treatment and survivorship statistics*, 2025 [CA Cancer J Clin. 2025 Sep 13;75\(6\):683](https://doi.org/10.1200/JCO.2025.75.6683).

A Solid Foundation for Growth

Revenue Milestones Achieved in 2025

- 100% increase in year-over-year revenue and units sold
- Published multiple case studies and physician testimonials on the human impact of CyPath® Lung
- Entered major VA medical centers with lung nodule programs
- Phased field expansion in strategic regional markets in Northeast and Southern US
- Expanded indications for use of CyPath® Lung for surveillance after treatment and detection of metastatic cancer to the lung



VA=US Department of Veterans Affairs.

Longitudinal Clinical Trial Launches in 2026

- Longitudinal study supports inclusion of CyPath® Lung as part of the standard of care for pulmonary nodules
- Clinical study will evaluate CyPath® Lung performance to support risk stratification, clinical decision-making, detection and survivor surveillance
- 2000-patient longitudinal clinical trial with up to 20 collection sites including more than a dozen VA and military medical centers are qualified and ready
- Patient enrollment begins Q1 2026 with financial support from the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF), a nonprofit organization dedicated to advancing military medicine



VA=US Department of Veterans Affairs.

Building on a successful diagnostic platform

Next in our pipeline: companion diagnostics for asthma and COPD



Precision diagnostics match patients to effective treatments and monitor their effectiveness

- Companion diagnostic test panel offers a 'scorecard' for lung inflammation
- Test indication expanded to support identification of patients best suited for specific therapies
- An estimated 23 million adults in the US¹ and 27 million people in the European Union² have been diagnosed with **asthma** and an estimated 14.2 million US adults have chronic obstructive pulmonary disease (**COPD**)³
- The global market for asthma and COPD therapeutics is estimated at \$26 billion⁴

1. Asthma and Allergy Foundation of America; accessed 2.17.2025; <http://bit.ly/3X7edl>

2. Eurostat, Weckler H. et al. *World Allergy Organ. J.* 2023, 16(8) PMID: 37564904CDC

3. CDC Morbidity and Mortality Weekly Report (MMWR) 2023, 72(46), 1250-1256

4. <https://www.grandviewresearch.com/industry-analysis/asthma-therapeutics-market>;

Management— Innovative, Experienced, Dedicated



Maria Zannes, JD
Founder, CEO & President

30+ years C-suite executive in medical and engineering fields building high-performing corporate teams who build shareholder value



Michael Edwards,
MBA, CPA
CFO

30+ years in corporate finance including CFO at CytoBioscience and OncoVista Innovative Therapies



Gordon Downie, MD, PhD
Chief Medical Officer

30+ years in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology; 30 peer-reviewed publications, worked extensively in both academic medicine and private practice.



William Bauta, PhD
Chief Science Officer

30+ years directing R&D of multiple drugs and diagnostics for oncology, neuroscience, and immunology at big pharma including Ilex and Genzyme



Xavier Reveles, MS,
CG(ASCP)CM
Chief Operating Officer

25+ years experience creating, building and managing CAP/CLIA labs and creating and commercializing LDTs; clinical cytogeneticist

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Founded leading global healthcare marketing firm Healthworld with 32 offices worldwide; NASDAQ's 1999 "Entrepreneur of the Year"



Peter Knight, Director

Founding Partner of Generation Investment Mgmt. with >\$18B AUM; Campaign Manager for President Clinton's '96 re-election campaign



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BIAF founder; former President of The Energy Recovery Council, The Zannes Firm, Senior Executive at ECOS Corp.





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