



NASDAQ: BIAF / BIAFW

## Company Presentation

**CyPath<sup>®</sup> Lung**

***Noninvasive, Accurate Lung Cancer Detection***

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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 annually<sup>1</sup>
  - An estimated **19.3 million Americans** should have annual lung cancer screening, according to the American Cancer Society<sup>2</sup>
  - Up to ~**34 million people in the European Union** were at high risk for lung cancer in 2018<sup>3</sup>
  - **China reported 1,060,600 new cases** of lung cancer in 2022<sup>4</sup>



## 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 2025-2033<sup>5</sup>

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 diagnosis<sup>1</sup>

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 years<sup>2</sup>

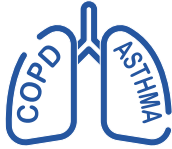
- Most patients are diagnosed with late-stage (Stages III-IV) when survival is much lower<sup>2</sup>



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<sup>®</sup>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)



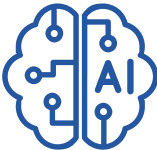
**92% Sensitivity<sup>1</sup>**

**87% Specificity<sup>1</sup>**

**99% Negative Predictive Value<sup>1</sup>**

**88% Accuracy<sup>1</sup>**

- CyPath<sup>®</sup> 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<sup>®</sup> Lung in Action: Patient Case Studies\*

## CyPath<sup>®</sup> Lung Finds Cancer at Curative Stage 1A; Averts Risky Procedures

“**Gloria**” case: CyPath<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](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](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-SAVES.pdf](https://www.cypathlung.com/wp-content/uploads/2025/08/BIO25_1012_R6_CP-25011-CyPath-Lung-Case-Study-Leavebehind-SAVES.pdf)



# CyPath<sup>®</sup>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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](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](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](https://www.cypathlung.com/wp-content/uploads/2025/10/CyPath_case-study_Helen_ground-glass_FINAL.pdf)



# CyPath<sup>®</sup>Lung Compares Favorably to Standards of Care

Proven Clinical Utility To Help Detect Lung Cancer Noninvasively

Lung Cancer Diagnostic Procedure or Test	Sensitivity	Specificity
<b>CyPath<sup>®</sup> Lung<sup>1</sup></b> (individuals at high risk with nodules <20mm)	<b>92%</b>	<b>87%</b>
<b>FDG PET imaging<sup>2</sup></b> (individuals with suspicious lung nodules)	89%	75%
<b>Bronchoscopy<sup>3</sup></b> (individuals with suspicious lung nodules)	88%	47%
<b>Fine Needle Biopsy<sup>4</sup></b> (individuals with suspicious lung nodules)	90%	75%
<b>Core Needle Biopsy<sup>4</sup></b> (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<sup>®</sup> Lung

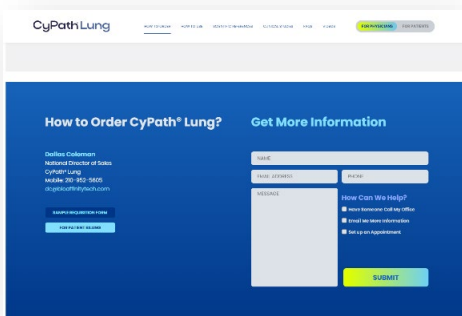
***Physician-Focused, Patient-Friendly, Reimbursed by Insurance***

@ Clinic

@ Home

@ Laboratory

@ Clinic



Physician orders  
**CyPath<sup>®</sup> Lung** test to ship  
to patient or deliver in clinic



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



ships  
overnight



**AI-driven** automated  
data analysis of flow  
cytometry data



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

## Actionable Results = Greater Confidence in Patient Care

AI=artificial intelligence.

**bioAffinity**  
TECHNOLOGIES

# Interpreting the CyPath<sup>®</sup>Lung Report



CyPath<sup>®</sup>Lung

Patient: DOE, JANE

DOB / Age / Sex: 01/06/1955 , 71 , Female

Accession Number: 10460303

Result ID: CY26-000035

Collection Date: 01/08/2026

Received Date: 01/09/2026

Report Date:

ICD 10 Codes:

CPT Codes:

Facility: Precision Pathology Laboratory Services - Nacogdoches

Client ID Number: PPS

Ordering Physician: Roby Joyce, MD

Copies To:

Results Interpretation: **LIKELY** malignancy in the lung

Note: This test does not differentiate between primary and metastatic cancer in the lung.

Reference Range:  
>0.00 & <0.50 Unlikely  
≥0.50 & < 1.00 Likely

Scale reflects probability of cancer

0.01 0.25 0.5 0.75 1.0

Patient Sample Result Value is 0.73

Reference Range:  
≥0.00 and ≤0.50 Unlikely  
>0.50 and ≤1.00 Likely

Sample Adequate: YES

Number of Alveolar Macrophages per 10,000: 88.18

Absolute Number of Cells for Analysis: 97981

Signed By: Vibha Bhasin, MD

bioAffinity  
TECHNOLOGIES

# CyPath<sup>®</sup> Lung

## Significant Healthcare Savings

2024 study<sup>1</sup> authored by pulmonologists practicing at Audie L. Murphy Memorial VA Hospital and Brooke Army Medical Center evaluated CyPath<sup>®</sup> 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 system<sup>1</sup>

**\$6,460 per patient covered  
by commercial insurance**  
for estimated annual savings of  
**~\$895 million** to the healthcare  
system<sup>1</sup>

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)



# How the CyPath<sup>®</sup>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

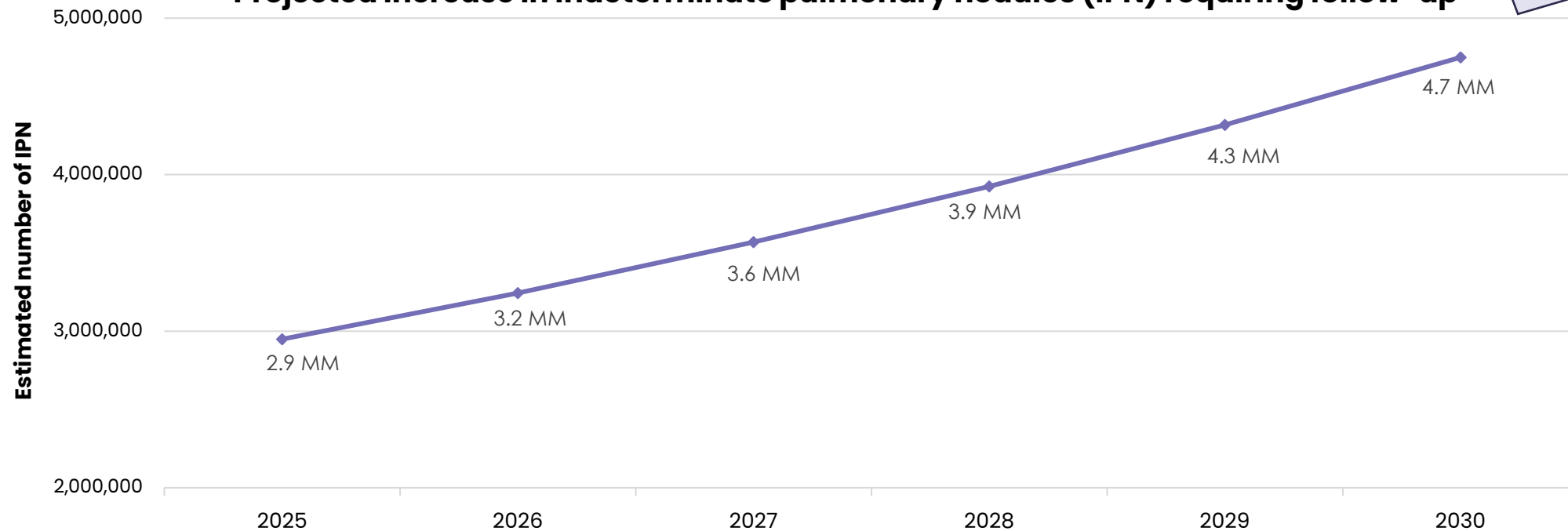
TCPP=tetra (4-carboxylphenyl) porphyrin.

# CyPath<sup>®</sup>Lung Market Opportunity

***The U.S. Market for CyPath<sup>®</sup> Lung is poised for significant growth***

10%  
2030 Market  
Share = \$470  
MM

**Projected increase in indeterminate pulmonary nodules (IPN) requiring follow-up\***



- 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\*

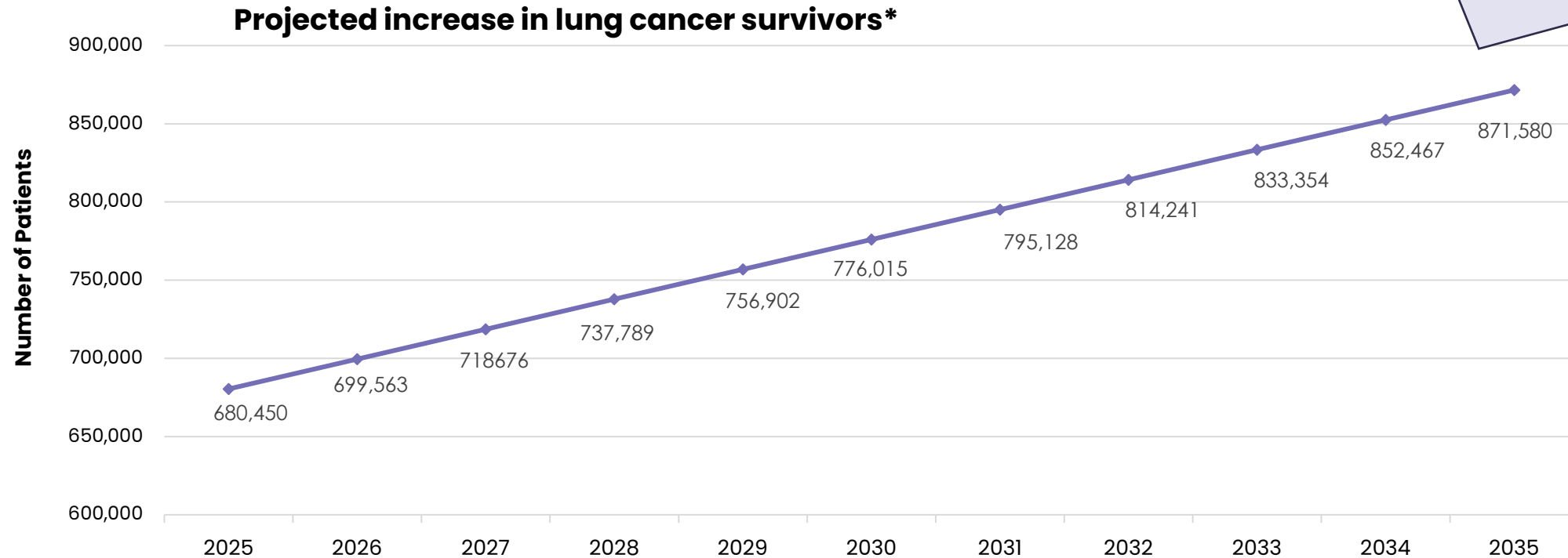
\*Projection assumes 10% compound annual growth for the 2024-2030 period based on 1) utilization of LCS increasing from 18.1% in 2023 to close to 50% by 2030 due to growing adoption and awareness with improved access, and 2) improved ability to detect IPN in CT and x-ray through greater adherence to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



# CyPath<sup>®</sup>Lung Market Opportunity

## CyPath<sup>®</sup> Lung Use for Surveillance of Lung Cancer Recurrence

10% 2035  
Market Share  
= \$87.16 MM



- 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.](#)

# 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 US<sup>1</sup> and 27 million people in the European Union<sup>2</sup> have been diagnosed with **asthma** and an estimated 14.2 million US adults have chronic obstructive pulmonary disease (**COPD**)<sup>3</sup>
- The global market for asthma and COPD therapeutics is estimated at \$26 billion<sup>4</sup>

1. Asthma and Allergy Foundation of America; accessed 2.17.2025; <http://bit.ly/3X7edil>  
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)<sup>CM</sup>**  
Chief Operating Officer

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

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Medical Director, The Lung Center and Interventional Pulmonology at Penn Highlands Healthcare



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**Robert Anderson, Director**

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**Maria Zannes, JD, Director, CEO**

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





NASDAQ: BIAF / BIAFW

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**President & CEO**

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