

NASDAQ: BIAF / BIAFW

# INVESTOR PRESENTATION DECEMBER 2023

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# **Investment Highlights**

CyPath Lung

is a **non-invasive** test to improve **early detection of lung cancer** 



#### **Patient-friendly**

At-home collection (no needles, no blood) with results to physician 3 days after sample arrives at the lab



**92**%

Sensitivity<sup>1</sup>

Specificity<sup>1</sup> Negative Predictive Value<sup>1</sup> Accuracy<sup>1</sup>

High specificity and sensitivity with small nodules, similar to more invasive, expensive procedures



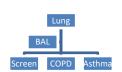
#### **Proprietary Automated Data Analysis**

Powerful automated data analysis utilizing artificial intelligence (AI) differentiates patients with lung cancer from those who are cancer-free



#### Flow Cytometry Data Collection

Profiles the lung microenvironment by identifying cancer and cancer-related cell populations and other characteristics indicative of lung cancer with high accuracy



#### **Growing Platform Technology and Therapeutics Potential**

Developing noninvasive diagnostic tests for additional lung diseases, starting with COPD; OncoSelect® Therapeutics research subsidiary developing a pipeline of preclinical therapeutics candidates



# Market Opportunity: The Need for Early Lung Cancer Detection



Most patients currently are diagnosed with late-stage (Stages III-IV) lung cancer when the survival rate is low

23%1
5-year overall survival rate

# 92%2 10-year survival if detected at Stage I & treated within one month

## Accurate, early cancer detection can

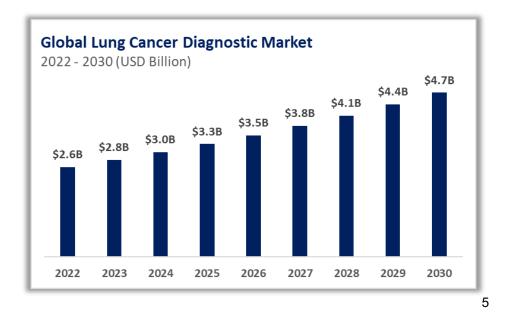
- ✓ Increase long-term survival
- ✓ Reduce unnecessary invasive procedures
- ✓ Improve the positive predictive value of screening

# Market Size: The Need for Early Lung Cancer Detection

Lung cancer is the leading cause of cancer-related death worldwide, claiming nearly 1.8 million lives annually.

- An estimated <u>19.3 million</u> Americans should have annual screening for lung cancer, according to American Cancer Society recommendations.
- Lung cancer is the leading cause of cancer death in the European Union.3
- China has an estimated 300 million smokers.

The market worldwide for lung cancer diagnostic tests was estimated at \$2.6 billion in 2022 and is projected to reach \$4.7 billion by 2030, with a CAGR of 7.8% over 2022-2030.



<sup>5</sup> ReportLinker, Global Lung Cancer Diagnostics Industry, Jan. 2023. https://www.reportlinker.com/p05834219/Global-Lung-Cancer-Diagnostics-Industry.html



<sup>1</sup> The Cancer Atlas, Third Edition, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <a href="https://canceratlas.cancer.org/the-burden/lung-cancer/">https://canceratlas.cancer.org/the-burden/lung-cancer/</a>

<sup>2</sup> NBC News. "Lung cancer screening guidelines: Quit smoking, annual test." NBC News Health. Accessed Nov. 2023. <a href="https://www.nbcnews.com/health/cancer/lung-cancer-screening-guidelines-quit-smoking-annual-test-rcna122602">https://www.nbcnews.com/health/cancer/lung-cancer-screening-guidelines-quit-smoking-annual-test-rcna122602</a>

<sup>3</sup> Lung Cancer Burden in EU. European Union Joint Research Centre. Jan. 2021. <a href="https://visitors-centre.jrc.ec.europa.eu/en/media/infographics/lung-cancer-burden-eu-27#:~:text=Lung%20cancer%20is%20the%20fourth,EU%2D27%20countries%20in%202020.">https://visitors-centre.jrc.ec.europa.eu/en/media/infographics/lung-cancer-burden-eu-27#:~:text=Lung%20cancer%20is%20the%20fourth,EU%2D27%20countries%20in%202020.</a>

<sup>&</sup>lt;sup>4</sup> WHO. Tobacco. World Health Organization, China. Accessed Nov. 2023. <a href="https://www.who.int/china/health-topics/tobacco">https://www.who.int/china/health-topics/tobacco</a>

# Physician-Focused, Patient-Friendly Market Opportunity More Accurate Diagnosis / Fewer Unnecessary, Invasive Procedures



Physician orders
CyPathLung test



Patients complete a 3day sputum sample collection at home



Al-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



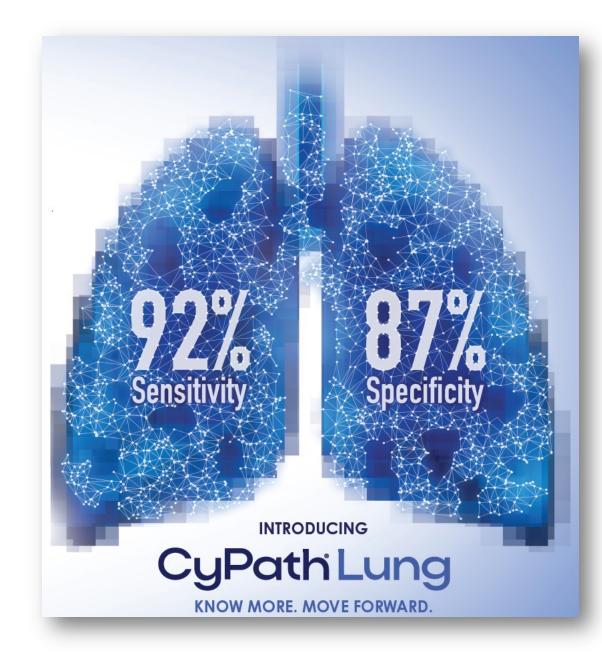
# **Impactful Branding**

#### Well-tested Brand Strategy being rolled out:

- ✓ Articulates a clear, simple message
- ✓ Acknowledges the clinical need
- ✓ Highlights competitive advantages

# **CyPath Lung**

THE NODULE WAS INDETERMINATE.
BUT YOU CAN'T TREAT INDETERMINATE.





# **Results of Market Testing**

#### □ Reimbursement is Essential

- ✓ Specific CPT code for CyPath® Lung effective October 1, 2023
- ✓ CMS decision November 2023 on allowable Medicare payment with effective date January 1, 2024
- ✓ Precision fee schedule = \$1,900 per test

#### □ Publications are Powerful

- ✓ Clinical trial results published in peer-reviewed Respiratory Research journal (1/23/2023)
- ✓ CyPath® Lung technology's ability to diagnose lung diseases published in peer-reviewed PLOS One (8/17/2022)
- ✓ Publications build upon numerous peer-reviewed journal articles about CyPath ® Lung

#### □ Brand Awareness is Key

- ✓ Market research reveals physicians see the need for our noninvasive test providing actionable results.
- ✓ Branding complete; multi-media/multi-channel implementation underway

#### □ Sales Driven by Reps + Multi-Media

- ✓ Approach to market = multi-media and personal selling
- ✓ Physician testimonials highly effective
- ✓ Physician follow-up and feedback inform and improve operational efficiencies



# **CyPath Lung**

# Comparison to Current Standard of Care for Follow-up after Positive LDCT

Lung Cancer Diagnostic Procedure or Test	<u>Sensitivity</u>	<b>Specificity</b>	100%
CyPath Lung (marriagues at high risk with nodules <20mm)	<b>92</b> %	<b>87</b> %	80%
FDG PET imaging (individuals with suspicious lung nodules)	89%	75%	70%
Bronchoscopy (individuals with suspicious lung nodules)	88%	47%	50%
Fine Needle Biopsy (individuals with suspicious lung nodules)	90%	75%	CJP ORTH LIND Bronchoscopy Bronchoscopy Bronchoscopy
Core Needle Biopsy (individuals with suspicious lung nodules)	89%	89%	Sensitivity Specificity



# CyPath Lung

# Revealing the Lung Microenvironment with Al-driven Flow Cytometry

#### Advanced flow cytometry interrogates millions of cells in minutes

Reveals cell populations residing in the lung micro-environment (sputum) by labelling cancer and cancer-related cells with TCPP, our specific porphyrin that is taken up by cancer cells

#### Proprietary automated software ensures only cells of interest are interrogated

The automated analysis identifies sputum cells of interest and eliminates debris, dead cells and cell aggregates

#### Quality control assures the sample comes from the lung

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

#### Automated analysis takes minutes to identify lung cancer in patient samples

Al-driven analysis detects cell populations indicative of lung cancer including populations of cancer and cancerrelated cells, immune cells and dying cells. Proprietary algorithm uses flow cytometric data and patient age to determine patient risk of lung cancer

### **Automated Analysis = Standardized Results**



# Benefits of Precision Pathology Laboratory Acquisition

**September 18, 2023** 

#### **Increases Revenues**

- √ Captures CyPath® Lung full revenues
- ✓ Adds Precision revenues to consolidated financials
- ✓ Accretive in 2023; 100% return on cash investment expected in 24 months

#### **Adds Resources**

- ✓ Integrates operations and captures efficiencies
- ✓ Adds 54 experienced laboratory professionals to team
- ✓ Roby Joyce, MD, continues as laboratory and medical director;
  joins BIAF Board of Directors

## **Expands Reach**

- ✓ Adds capacity for nationwide expansion under one structure
- ✓ Expands client base to 155 customer sites including seven Central Texas hospitals and nearly 600 practicing physicians



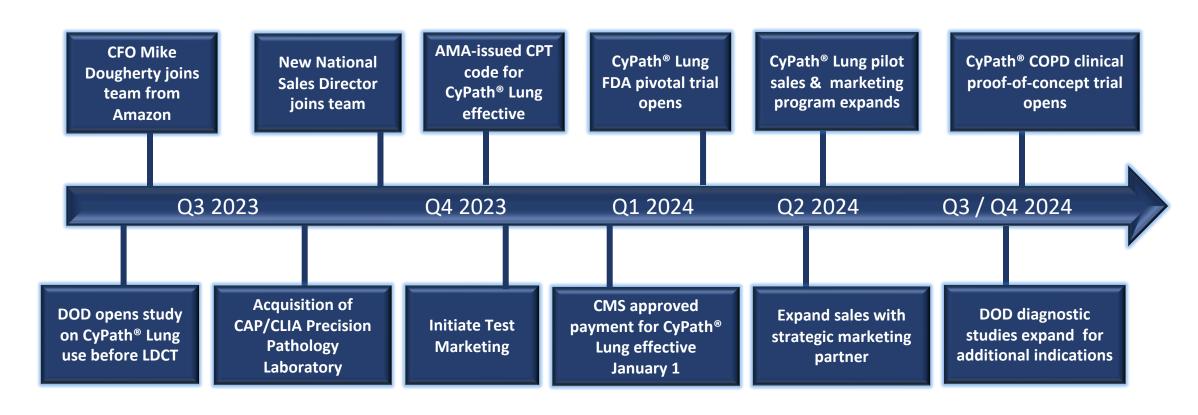


\$6.9M Precision's 2022 net revenue; 12.5% growth

H1 2023 vs. H1 2022



# bioAffinity Technologies Recent and Anticipated Milestones





# Management

## Innovative, Experienced, Dedicated



Maria Zannes,
JD
Founder,
BOesixbans &s CEswite
executive in the
medical, environmental
and engineering fields;
focused on building
high performing
corporate teams who
meet ambitious business
goals



Michael
Dougherty,
MBA, CPA
Vice President &
20 Dyears of experience
in financial management
and business strategy;
previously CFO of
Amazon's Alexa
commercial domains,
TINT, Filestack and
Amazon Pay



Vivienne Rebel,
MD, PhD
EVP, Chief Science &
Medical Officer
20+ years as a leader in
cancer research; 11
years at Harvard's DanaFarber Cancer Institute;
received UT Health SA
Cancer Therapy and
Research Center's
Discovery of the Year
Award



Officer

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

Clinical Pathology

**Xavier Reveles** 

Chief Operating

#### **Science & Medical Advisory**



Sheila Habib, MD
Director of Pulmonary Lung
Nodule Clinic and the Lung
Cancer Screening,
South Texas VA



Neil Alexis, PhD
Principal Investigator, UNC
School of Medicine;
Environmental Medicine, Asthma
& Lung Biology



Gerard Silvestri MD, FCCP
Professor of Medicine & Lung
Cancer Pulmonology, Medical
University of South Carolina



David Hill, MD
Director, American Lung
Association;
Assistant Professor,
Yale School of Medicine



Catherine Sears MD
Assistant Professor,
Indiana University School
of Medicine



## **Board of Directors**

# Decades of Successful Leadership from Start-Ups to Global Corporations



Steve Girgenti
Executive Chairman

Founded Healthworld, a leading global healthcare marketing firm with 36 offices in 26 offices worldwide; NASDAQ's "Entrepreneur of the Year" (1999)



Peter Knight
Director

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



Robert Anderson
Director

50+ years in healthcare holding executive positions at CIBA Pharmaceutical Co, Becton Dickinson, Pfizer, Parke-Davis Division of Warner-Lambert, and Schering Plough



Stuart Diamond
Director

Global CFO for GroupM, the world's leading media investment company responsible for more than \$50 billion in media investment



Roby Joyce, MD
Director

Precision Pathology founder and Medical Director; board-certified in pathology, neurology; former chief of staff at Methodist Healthcare System; Colonel, US Army, ret.



Jamie Platt, PhD
Director

20+ years in genomics and molecular diagnostics, bringing novel diagnostic technologies to global markets; led successful M&A exits for two companies; Managing Director, CEO of Pictor Ltd.; Founder, CEO of BRIDGenomics



Gary Rubin
Director

CPA, Co-founder and Managing Member of Masters Research Partners, an investment fund of hedge funds



Maria Zannes, JD

Director, CEO
BIAF founder and previously
held executive positions at
Biomoda, The Zannes Firm,
The Energy Recovery
Council, ECOS Corp.



# **Investment Recap**

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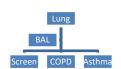
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#### **Publication Links**

3/24/2023: Porphyrin-Modified Beads for Use as Compensation Controls in Flow Cytometry

1/23/2023: Detection of Early-Stage Lung Cancer in Sputum Using Automated Flow Cytometry and Machine Learning

8/17/2022: Sputum Analysis by Flow Cytometry; an Effective Platform to Analyze the Lung Environment

8/9/2022: Quality-Controlled Sputum Analysis by Flow Cytometry

7/2/2021: Meso-tetra (4-carboMeso-tetra (4-carboxyphenyl) Porphyrin (TCPP) is taken up in Cancer Cells by the CD320 Receptor

6/25/2021: Selective Cancer Cell Killing by Dual siRNA Knockdown of CD320 and LRP2 Receptors

5/22/2021: Simultaneous Knockdown of CD320 and LRP2 Receptors is Selectively Toxic to Cancer Cells but not Normal Cells

2/25/2021: Identification of a Novel Mechanism for Meso-Tetra (4-Carboxyphenyl) Porphyrin (TCPP) Uptake in Cancer Cells

1/16/2021: Automated Flow Cytometry Test Distinguishes Cancer from Non-Cancer in Sputum with High Sensitivity and Specificity

Additional publications can be found on the Company website



## For More Information



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