UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 5, 2025**

bioAffinity Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41463**	**46-5211056**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

3300 Nacogdoches Road, Suite 216
San Antonio, Texas 78217
(Address of principal executive offices, including zip code)

(210) 698-5334
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e- 4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value $0.007 per share	BIAF	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

bioAffinity Technologies, Inc., a Delaware corporation, (the "Company") has prepared presentation materials (the "Presentation Materials") that management intends to use from time to time in presentations about the Company's operations and performance, including at the H.C. Wainwright 27th Annual Global Investment Conference being held September 8, 2025 through September 10, 2025. The Presentation Materials are furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K are furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Presentation Materials – September 2025
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 5, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: */s/ Maria Zannes*
Name: Maria Zannes
Title: President and Chief Executive Officer

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this presentation and statements by management or other persons acting by or on behalf of bioAffinity Technologies made in connection with this presentation constitute "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Because forward-looking statements relate to the future, they are inherently subject to significant known and unknown risks, uncertainties and other factors that are difficult to predict and are beyond the control of bioAffinity Technologies. The actual results, level of activity, performance or achievements of bioAffinity Technologies may be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "future," "outlook," and similar expressions that predict or indicate future events or trends. All statements that are not statements of historical matters are forward-looking statements.

The forward-looking statements made in this presentation are based on bioAffinity Technologies' current assumptions and judgments regarding future events and results. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of bioAffinity Technologies. Some important factors that could cause actual results to differ materially from those in any forward-looking statements could include changes in domestic and foreign business, market, financial, political and legal conditions. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied upon as, a guarantee, an assurance, a prediction or a definitive statement of fact, probability or outcome and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in bioAffinity Technologies' most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and Current Reports on Form 8-K filed with the Securities and Exchange Commission. Except as required by law, bioAffinity Technologies undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

bioAffinity TECHNOLOGIES

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

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[5]

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

bioAffinity TECHNOLOGIES

bioAffinity Technologies' Diagnostic Platform Starts with CyPath® Lung

We Tackled the Most Difficult Problem First : Lung Cancer

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[1] **87% Specificity[1]** **99% Negative Predictive Value[1]** **88% Accuracy[1]**

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

Proprietary Automated Data Analysis of Flow Cytometry Data

- Automated data analysis of flow cytometric data uses machine learning resulting in high accuracy
- 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

bioAffinity TECHNOLOGIES

Urgent Need for Early Detection of Lung Cancer

Only **28%** of patients with lung cancer survive 5 years[1]

- 63% of patients with Stages I-II lung cancer survive 5 years[1]
- Most patients are diagnosed with late-stage (Stages III-IV) lung cancer when survival is much lower[1]

92% of Stage I patients survive 10 years if treated within one month of diagnosis[2]

Accurate, early cancer detection can

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

1. American Lung Association, State of Lung Cancer 2024, https://www.lung.org/research/state-of-lung-cancer.
2. 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

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Real Patients, True Stories, Remarkable Outcomes

Patient Case Studies Reveal CyPath® Lung Finds Cancer at Curative Stage 1A

- Detected Stage 1A adenocarcinoma in 67-year-old woman when risk models suggested a low probability of cancer and other diagnostics were contraindicated. CyPath® Lung **led to biopsy and curative treatment**.
- Stage 1A mucinous adenocarcinoma was detected by CyPath® Lung in a 62-year-old woman after insurance denied coverage for a 2nd PET scan and our **competitor's test resulted in an "indeterminant" finding.**
- Detected Stage 1A rare neuroendocrine tumor in an 80-year-old woman **after** other diagnostic tools – bronchoscopy, our competitor's test and radiological risk model score **– failed to identify** the malignancy.
- **Patient previously treated for lung cancer** had a small nodule in the opposing lung. **CyPath® Lung was positive**. A biopsy confirmed a second primary lung cancer for which the patient is being treated.
- CyPath® Lung identified a hidden recurrence of breast cancer after a routine CT detected a small pulmonary nodule. Other diagnostic approaches like a PET scan or serum markers could not be used.
- Imaging revealed nodules in an 85-year-old man, but invasive biopsy was averted when **CyPath® Lung was negative**, and three months later a new CT showed the nodules had disappeared.

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Savings to Individual and Overall Healthcare With CyPath® Lung

2024 study[1] authored by pulmonologists practicing at Audie L. Murphy Memorial VA Hospital and Brooke Army Medical Center evaluated CyPath® Lung's 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 total annual savings of **~$370 million** to the healthcare system

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

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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Physician-Focused, Patient-Friendly CyPath® Lung

More Accurate Diagnosis With Fewer Unnecessary Invasive Procedures

@ Clinic	@ Home	@ Laboratory	@ Clinic

Physician orders **CyPath® 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.

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Established CAP/CLIA Laboratory - Precision Pathology Laboratory Services

Precision Pathology Laboratory Services – a wholly owned subsidiary of bioAffinity Technologies – offers CyPath Lung as a Laboratory Developed Test

- Current capacity for nationwide expansion of CyPath® Lung sales through 2030
- Established anatomical pathology laboratory with ability to market and service nationwide
- Strong client base and diagnostic test menu

How the CyPath® Lung Test Works

Flow cytometry interrogates sputum cells after sample processing

- Test uses antibodies, reagents, labeling agents and TCPP, a synthetic porphyrin that labels cancer and cancer-related cells
- Sputum samples are processed into a single-cell suspension and labelled before data acquisition

Proprietary automated software ensures only cells of interest are interrogated

- Automated analysis identifies sputum cells of interest and eliminates debris, dead cells, and cell aggregates

Quality control assures the sample is from the lungs

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

Automated analysis takes only minutes to identify lung cancer in samples

- Analysis developed by machine learning detects cell populations indicative of lung cancer
    - Includes cancer and cancer-related cells, immune cells, and dying cells

TCPP=tetra (4-carboxylphenyl) porphyrin.

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CyPath® Lung Comparison vs Standard-of-Care Follow-Up

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

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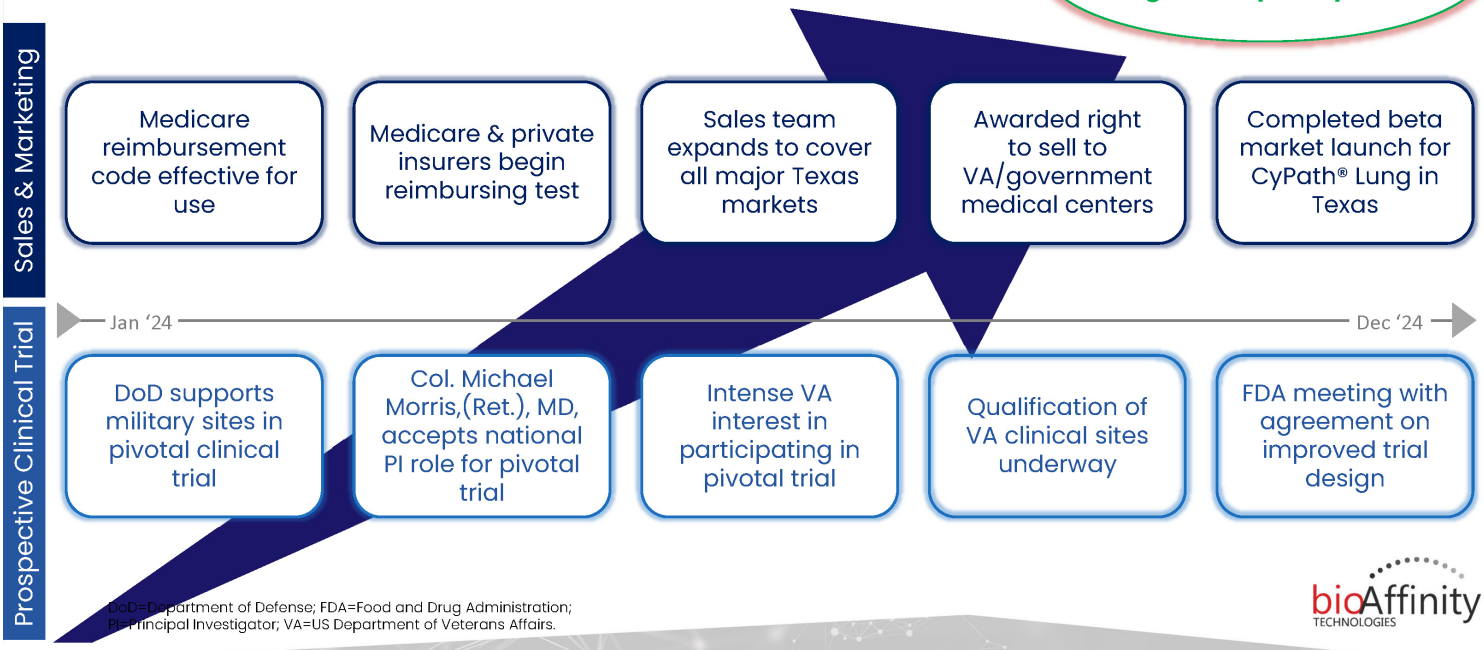
Milestones Accomplished in 2024

2024 sales nearly 14X higher vs prior years



DoD=Department of Defense; FDA=Food and Drug Administration; PI=Principal Investigator; VA=US Department of Veterans Affairs.

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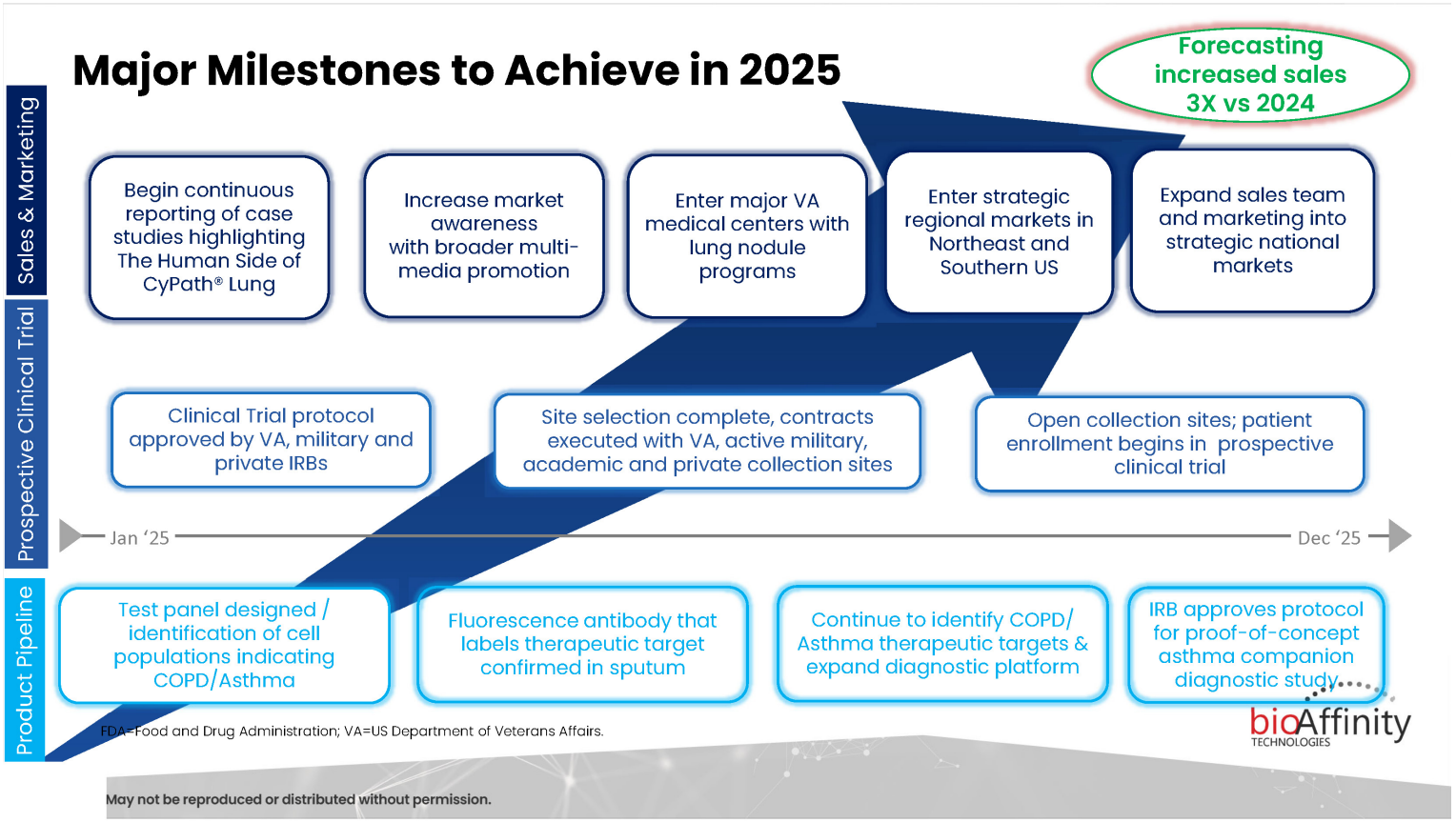

Our Pipeline: Companion Diagnostics for $26 Billion Market

Asthma and COPD treatments work, but not for everyone . Our noninvasive tests aim to ensure patients receive the right treatment for their disease

Our pipeline of companion diagnostics targets a large global markets estimated at $26 billion for asthma and chronic obstructive pulmonary disease (COPD) therapeutics

Asthma

- An estimated **23 million adults** in the US[1] and **27 million people** in the European Union[2] have been diagnosed with asthma. China reported **45.7 million adults** had asthma in 2019[3]

COPD

- An estimated **14.2 million US adults** in the US have COPD[4]. An estimated **36.6 million people in Europe** have COPD, with more than 50 million expected by 2050[5]

COPD=chronic obstructive pulmonary disease.

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. Huang, et al. Prevalence, risk factors, and management of asthma in China: a national cross-sectional study, *The Lancet* (2019). 4. CDC Morbidity and Mortality Weekly Report (MMWR) 2023, 72(46), 1250-1256. 5. Benjafield, A. et al. An estimate of the European prevalence of COPD in 2050. *Eur. Resp. J.* 2021.

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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

Science & Medical Advisory Board

Sandeep Bansal, MD, FCCP
Medical Director,
The Lung Center and Interventional Pulmonology at Penn Highlands Healthcare

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

David Hill, MD
Chairman of the Board, American Lung Association; Assistant Professor, Yale School of Medicine

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

Catherine Sears, MD
Assistant Professor, Indiana University School of Medicine

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

bioAffinity TECHNOLOGIES

Board of Directors

Decades of Successful Leadership from Start-Ups to Global Corporations

Steve Girgenti, Executive Chairman
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

John Oppenheimer, MD, Director
Clinical Professor of Medicine and Director of Clinical Research. Leading authority on asthma and COPD, participated in 180+ clinical trials, authored 260+ publications, and contributed to numerous national clinical guidelines.

Jamie Platt, PhD , Director
20+ years of diagnostic expertise, led successful M&A exits for two diagnostic companies totalling $1 Billion; Managing Director, CEO of Pictor Ltd.; Founder, CEO of BRIDGenomics

Roberto (Bobby) Rios, CPA, Director
40+ years of senior financial leadership in biotechnology, medical devices, and large-scale construction. Former CFO and board member for ILEX Oncology, BioMedical Enterprises, and Bartlett Cocke General Contractors,

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.

Robert Anderson, Director
50+ years in healthcare executive positions at CIBA Pharmaceuticals, Becton Dickinson, Pfizer, Parke-Davis Division of Warner-Lambert, and Schering Plough

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

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Perspective

"Exact Sciences was founded in 1995, although it took about 15 years to get the fecal DNA test off the ground. . .The company eventually went public with an initial offering on the NASDAQ in 2001. In the early years, there was much speculation that the company would be acquired by a competitor or exit the market; during this time the company's share price fell to less than one dollar."

For more information see: https://www.gastroendonews.com/In-the-News/Article/07-20/A-Closer-Look-at-Exact-Sciences-The-Company-Behind-Cologuard/59002?sub=46E34BC468AA42105FBFEB39A554DC4977EE2D415596C5B71CFB24B34418180 and https://en.wikipedia.org/wiki/Exact_Sciences_Corp.

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NASDAQ: BIAF / BIAFW

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