

**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): October 10, 2023

BIOAFFINITY TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41463
(Commission
File Number)

46-5211056
(I.R.S. Employer
Identification Number)

**22211 W Interstate 10
Suite 1206
San Antonio, Texas 78257
(210) 698-5334**

(Address of principal executive offices and Registrant's telephone number, including area code)

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).

Emerging growth company

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

If an emerging growth company, indicate by check mark 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”), will be making several presentations to investors over the next several weeks. In connection with the presentations, the Company intends to discuss the investor presentation, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, in the investor presentation furnished as Exhibit 99.1 and in the press release furnished as Exhibit 99.2 to this Current Report on Form 8-K shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The Company’s investor presentation furnished as Exhibit 99.1 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are “forward-looking” rather than historical.

On October 10, 2023, the Company issued a press release regarding the investor presentation and an upcoming conference at which the Company intends to present such presentation. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

The following exhibits are furnished with this Current Report on Form 8-K:

Exhibit Number	Exhibit Description
99.1	Investor Presentation of bioAffinity Technologies, Inc. dated October 2023
99.2	Press release dated October 10, 2023
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within in the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOAFFINITY TECHNOLOGIES, INC.

By: */s/ Maria Zannes*

Maria Zannes

President and Chief Executive Officer

Dated: October 10, 2023



NASDAQ: BIAF / BIAFW

8th Annual Dawson James Small Cap Growth Conference

October 12, 2023

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.

Investment Highlights

CyPathLung is an accurate, non-invasive test for **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%

Sensitivity¹

87%

Specificity¹

99%

Negative Predictive Value

High specificity and sensitivity, similar to more invasive, expensive diagnostic 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

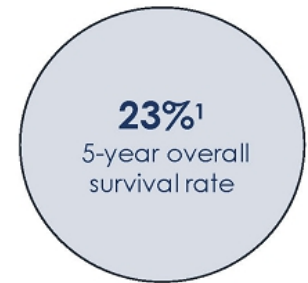


¹In individuals with nodules 20mm or less, CyPath[®] Lung performed with 92% sensitivity and 87% specificity

Market Opportunity: The Need for Early Lung Cancer Detection

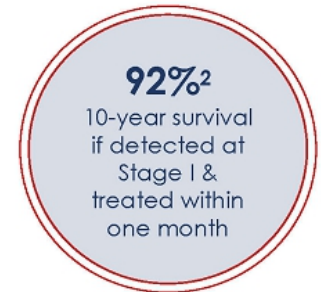


Most patients currently are diagnosed with late-stage (Stages III-IV) lung cancer when the survival rate is low



Accurate, early cancer detection can

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



¹ CancerNet, American Society of Clinical Oncology (ASCO), <https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics>

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>

Physician-Focused, Patient-Friendly Market Opportunity

More Accurate Diagnosis / Fewer Unnecessary, Invasive Procedures



Physician orders
CyPath® Lung test

Patients complete a
3-day sputum
sample 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

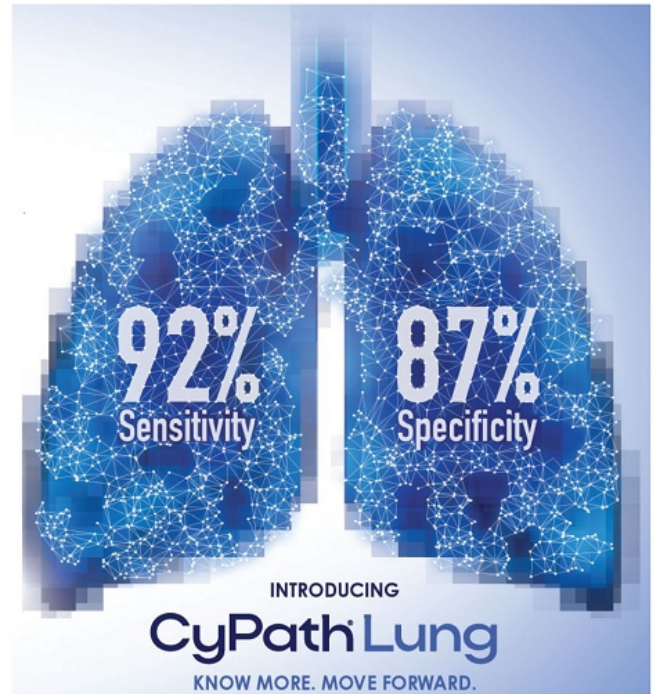
Impactful Branding

Well-tested Brand Strategy being rolled out:

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

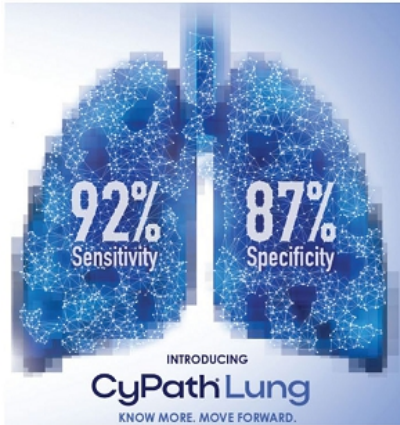
CyPath Lung

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



Market Testing: Lessons Learned

CyPath[®]Lung



- Reimbursement is Essential
 - Publications are Powerful
 - Brand Awareness is Key
 - Sales Driven by Reps + Multi-Media
-

Market Testing: Lessons Addressed

❑ Reimbursement is Essential

- ✓ Specific CPT code for CyPath® Lung effective October 1, 2023
- ✓ CMS decision November 2023 on allowable Medicare reimbursement with effective date January 1, 2024
- ✓ Precision fee schedule = \$1900 test reimbursement

❑ Publications are Powerful

- ✓ Clinical trial 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 are excited by our **noninvasive, accurate** 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



CyPathLung

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

<u>Lung Cancer Diagnostic Procedure or Test</u>	<u>Sensitivity</u>	<u>Specificity</u>
CyPathLung (individuals at high risk with nodules <20mm)	92%	87%
FDG PET imaging (individuals with suspicious lung nodules)	89%	75%
Bronchoscopy (individuals with suspicious lung nodules)	88%	47%
Fine Needle Biopsy (individuals with suspicious lung nodules)	90%	75%
Core Needle Biopsy (individuals with suspicious lung nodules)	89%	89%

CyPathLung

Revealing the Lung Microenvironment with AI-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

AI-driven analysis detects cell populations indicative of lung cancer including populations of cancer and cancer-related 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

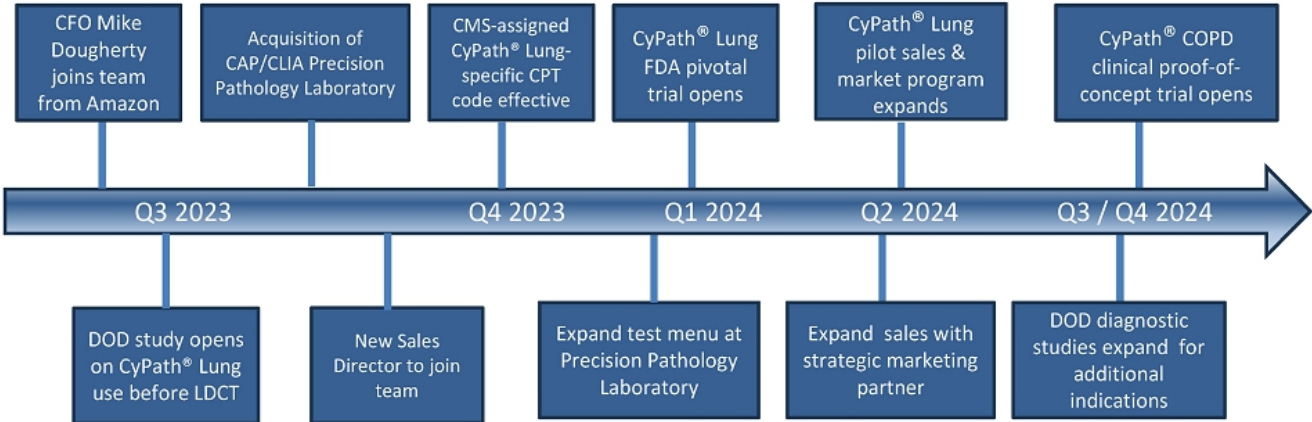
- ✓ Adds capacity for nationwide expansion under one structure
- ✓ Expands client base to 155 customer sites including seven Central Texas hospitals and nearly 600 practicing physicians



\$6.9M

Precision's 2022 net revenue; **12.5% growth** first half 2023 vs. first half 2022

bioAffinity Technologies Recent and Anticipated Milestones



Management

Innovative, Experienced, Dedicated



Maria Zannes, JD
Founder, President & CEO

30+ years as C-suite 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 & CFO

20+ years 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 Dana-Farber Cancer Institute; received UT Health SA Cancer Therapy and Research Center's Discovery of the Year Award



Xavier Reveles
Chief Operating Officer

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

Science & Medical Advisory Board



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)



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.



Peter Knight
Director

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



Mohsin Meghji
Director

Managing Partner of M3 Partners, a New York-based merchant banking firm; nationally recognized leading U.S. turnaround professional; Chairman of the Board of Infrastructure & Energy Alternatives



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.



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For More Information

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jao@bioaffinitytech.com

Tirth Patel, LHA Investor Relations
tpatel@lhai.com





News Release

bioAffinity Technologies to Present at the 8th Annual Dawson James Small Cap Growth Conference

CEO Maria Zannes to hold one-on-one investor meetings and present a corporate update highlighting commercial strategy

SAN ANTONIO, Texas (Oct. 10, 2023) – **bioAffinity Technologies, Inc.** (Nasdaq: BIAF; BIAFW), a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer, today announced that Maria Zannes, President and CEO, will be participating in the 8th Annual Dawson James Small Cap Growth Conference being held on Thursday, Oct. 12, 2023, in Jupiter, Florida.

Ms. Zannes is scheduled to present a company overview at 9:30 a.m. ET in Track One-Preserve Ballroom C at the Wyndham Grand Jupiter at Harbourside Place. She will also be holding one-on-one meetings with prospective investors throughout the day.

On September 19, bioAffinity Technologies announced the acquisition of the clinical laboratory that helped develop and licensed CyPath[®] Lung, a noninvasive test for the early detection of lung cancer currently available as a laboratory developed test (LTD). The acquired laboratory assets are now known as Precision Pathology Laboratory Services, LLC.

“Our in-depth marketing research for CyPath[®] Lung has shown that physicians are enthusiastic about using our test. Our market research has equipped us with a well-documented commercial growth strategy that I look forward to sharing at the Dawson James conference,” Ms. Zannes said. “Our recent acquisition of Precision Pathology Laboratory Services strengthens our commercial potential with a large and growing base of physician customers. The acquisition also boosts our R&D capabilities for additional tests under development. We believe bioAffinity will be able to build on the success of CyPath[®] Lung to become a leader in diagnostics.”

Event: 8th Annual Dawson James Small Cap Growth Conference
Date: Thursday, October 12, 2023
Time: 9:30 a.m. Eastern Time
Location: Track One-Preserve Ballroom C, Wyndham Grand Jupiter at Harbourside Place
Webcast: <https://wsw.com/webcast/dawson8/biaf/1990152>

A webcast of the presentation will be live and archived on the [News & Events](#) section of the company website.

About Dawson James Securities, Inc.

Dawson James Securities specializes in capital raising for small and microcap public and private growth companies primarily in the Life Science/Health Care, Technology, Clean Tech and Consumer sectors. We are a full-service investment banking firm with research, institutional and retail sales, and execution trading and corporate services. By investing the time required to completely understand your business, we can provide an appropriate capital transaction structure and strategy including direct investment through our independent fund. Our team will assist in crafting your vision and shaping your message for the capital markets. Headquartered in Boca Raton, Florida, Dawson James is privately held with offices in New York, Maryland and New Jersey. www.dawsonjames.com

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer treatment. The Company's first product, [CyPath[®] Lung](#), is a noninvasive test that has shown high sensitivity and specificity for the detection of early-stage lung cancer. OncoSelect[®] Therapeutics, LLC, a subsidiary of bioAffinity Technologies, is advancing its discoveries shown in vitro to kill cancer cells without harm to normal cells. Research and optimization of the Company's platform technologies are conducted in its laboratories at The University of Texas at San Antonio. For more information, visit www.bioaffinitytech.com.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are identified by the use of the words "could," "believe," "anticipate," "intend," "estimate," "expect," "may," "continue," "predict," "potential," "project" and similar expressions that are intended to identify forward-looking statements and include statements regarding bioAffinity being able to build on the success of CyPath[®] Lung to become a leader in diagnostics. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict, that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the Company's ability to successfully integrate the pathology laboratory acquisition and increase revenue, the Company's ability to pursue the development and support the commercialization of its CyPath[®] Lung test, the Company's ability to build near and longer-term value for its Company's shareholders and the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company's Quarterly Reports on Form 10-Q, the Company's Current Reports on Form 8-K and subsequent filings filed with the Securities and Exchange Commission. The information in this release is provided only as of the date of this release, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events, except as required by law.

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