
**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): **July 29, 2025**

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)

**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 8.01. Other Events.

On July 29, 2025, bioAffinity Technologies, Inc., a Delaware corporation, (the “Company”) issued a press release announcing the release of a new case study in which CyPath® Lung detected Stage 1A pulmonary mucinous adenocarcinoma in a high-risk individual whose previous tests and follow-up scans had suggested a low probability of cancer.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by bioAffinity Technologies, Inc., dated July 29, 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: July 31, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: /s/ Maria Zannes

Name: Maria Zannes

Title: President and Chief Executive Officer



News Release

Case Study: CyPath® Lung Detects Stage 1A Lung Cancer in High-Risk Patient with Inconclusive Imaging and Low-Risk Serum Test Results

bioAffinity Technologies' noninvasive sputum test catches rare cancer in time for curative surgery

SAN ANTONIO, TX – July 29, 2025 – **bioAffinity Technologies, Inc.** (Nasdaq: BIAF; BIAFW), a biotechnology company focused on noninvasive diagnostics and early cancer detection, today shared another compelling patient case study in which its flagship test, **CyPath® Lung**, detected pulmonary mucinous adenocarcinoma in a high-risk individual whose previous tests and follow-up scans had suggested a low probability of cancer that could have led to diagnosis at a later, less treatable stage.

“CyPath® Lung gave us the diagnostic clarity we needed to intervene before this cancer progressed further,” said Gordon Downie, MD, PhD, bioAffinity Technologies’ Chief Medical Officer. “This patient had low PET uptake, low serum marker risk, and gaps in imaging. CyPath Lung helped identify a relatively rare cancer that may have otherwise gone untreated.”

“Once again, CyPath® Lung has demonstrated that it can detect lung cancer at Stage 1A when traditional diagnostic tests indicated a low probability of cancer. For high-risk patients with inconclusive imaging or limited diagnostic options, we believe that our noninvasive test can offer a vital path forward. Every early diagnosis is a life potentially saved, and that’s the promise CyPath® Lung seeks to deliver on every day,” said Maria Zannes, President and CEO of bioAffinity Technologies.

The female patient, now 62 years old with a history of heavy smoking and COPD, initially presented in 2022 with a suspicious left upper lobe ground-glass opacity (GGO), a hazy gray area on the CT scan that indicates increased density in the airways. The initial PET scan in 2022 showed low uptake of the radioactive tracer, which is consistent with a benign outcome, and a blood-based risk test reported a reduced malignancy risk of 11%. Serial LDCTs appeared stable through 2023, but a July 2024 scan revealed a transition to a more solid nodule, raising clinical concern.

When the patient opted against surveillance CT scans and a follow-up PET scan, her physician ordered the CyPath® Lung test in March 2025. The test result of 0.56 – classified as “likely malignancy” – prompted her care team to recommend surgical consultation. The patient subsequently underwent wedge resection of the upper left lung in June 2025.

Final pathology confirmed Stage 1A invasive mucinous adenocarcinoma, a lung cancer subtype that is frequently missed by standard imaging and often presents with subtle radiographic changes. The patient successfully quit smoking in March 2025.

About CyPath® Lung

CyPath® Lung uses proprietary advanced flow cytometry and artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. Automated data analysis helps determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated that CyPath® Lung had 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small lung nodules less than 20 millimeters. Diagnosing and treating early-stage lung cancer can improve outcomes and increase patient survival. For more information, visit www.cypathlung.com.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and other diseases of the lung and broad-spectrum cancer treatments. The Company's first product, **CyPath® Lung**, is a noninvasive test that has shown high sensitivity, specificity and accuracy for the detection of early-stage lung cancer. CyPath® Lung is marketed as a Laboratory Developed Test (LDT) by Precision Pathology Laboratory Services, a subsidiary of bioAffinity Technologies. For more information, visit www.bioaffinitytech.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. These forward-looking statements are based upon current estimates and assumptions and include statements regarding the ability of CyPath® Lung to indicate a high probability of lung cancer, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, and CyPath® Lung providing clarity when imaging and risk models are inconclusive and when other adjuvant diagnostics are contraindicated. These forward-looking statements are subject to various 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 ability of CyPath® Lung to indicate a high probability of lung cancer, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, and CyPath® Lung providing clarity when imaging and risk models are inconclusive and when other adjuvant diagnostics are contraindicated, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, and its subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. While the Company believes these forward-looking statements are reasonable, readers of this press release are cautioned not to place undue reliance on any forward-looking statements. The information in this release is provided only as of the date of this release, and the Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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