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 9, 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 8.01. Other Events.

On September 9, 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 identified cancer in a patient with an incidental finding of ground glass nodules.

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 September 9, 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 9, 2025

BIOAFFINITY TECHNOLOGIES, INC.

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

News Release

Case Study: CyPath® Lung Identifies Lung Cancer in Patient with Difficult-to-Diagnose Ground-Glass Pulmonary Nodules

bioAffinity Technologies' noninvasive diagnostic shifted the course of care from watchful waiting for up to 5 years to confirmed malignancy and immediate treatment

SAN ANTONIO, TX – September 9, 2025 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today released another compelling case study in which its flagship product, CyPath® Lung, identified cancer in a patient with an incidental finding of ground-glass lung nodules.

Ground-glass nodules appear in imaging as hazy gray areas distinct from solid nodules. Clinicians often find them challenging to assess because they can remain stable for many years, often mimic benign lesions caused by inflammation or fibrosis, and typically do not light up on PET scans.

"Society guidelines for ground-glass nodules recommend two to five years of watchful waiting with serial CT scans. Obviously, this can put both patients and their doctors in an uncomfortable position of balancing uncertainty against the risks of delayed diagnosis," said Gordon Downie, MD, PhD, bioAffinity Technologies' Chief Medical Officer. "Adding CyPath® Lung to the traditional standard of care can provide actionable results that move beyond watchful waiting to timely, potentially life-saving treatment."

The patient, a 66-year-old former smoker, underwent a CT scan for abdominal pain, suspecting kidney stones. The scan incidentally captured a ground-glass nodule in her lung, and a subsequent CT scan of the chest found multiple ground-glass nodules, the largest 13 mm in length. Because of her smoking history, she was referred to a lung clinic for evaluation and risk stratification. Her physician ordered the CyPath® Lung test, which returned a "likely malignant" result. Based on the positive CyPath® Lung test, the care team proceeded with robotic bronchoscopy. Pathology confirmed lung cancer, and the patient was referred for surgical treatment.

"This case provides another real-world example of CyPath® Lung's value in the evaluation of both solid and sub-solid lung nodules by providing actionable information in real time that can help direct next steps in care, reduce uncertainty and improve patient outcomes," bioAffinity Technologies President and CEO Maria Zannes said. "CyPath® Lung has the potential to significantly reduce the mystery of sub-solid, or ground-glass, nodules when they show up on imaging, and both patient and physician are reluctant to delay diagnosis."

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 identify lung cancer in difficult to diagnose patients, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, CyPath® Lung providing clarity when imaging and risk models are inconclusive, and the value of CyPath® Lung in the evaluation of both solid and sub-solid lung nodules. 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 identify lung cancer in difficult to diagnose patients, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, CyPath® Lung providing clarity when imaging and risk models are inconclusive, the value of CyPath® Lung in the evaluation of both solid and sub-solid lung nodules, 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.

Contact

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