

**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 3, 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 September 3, 2025, bioAffinity Technologies, Inc., a Delaware corporation, (the “Company”) issued a press release announcing that U.S. Medicine Magazine has featured CyPath® Lung in its pulmonary issue, highlighting the test’s potential to improve lung cancer detection while lowering costs for the Department of Veterans Affairs (VA).

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 3, 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 3, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: /s/ Maria Zannes

Name: Maria Zannes

Title: President and Chief Executive Officer



News Release

U.S. Medicine Magazine Spotlights CyPath® Lung as Promising Tool to Improve Lung Cancer Detection in Veterans, Lower Costs to the VA

Noninvasive diagnostic can help federal medical system address veterans at higher risk for developing lung cancer

SAN ANTONIO, TX – September 3, 2025 – *U.S. Medicine*, a leading publication for federal healthcare professionals, has featured bioAffinity Technologies' CyPath® Lung in its pulmonary issue, highlighting the test's potential to improve lung cancer detection while lowering costs for the Department of Veterans Affairs (VA).

"We are honored that *U.S. Medicine* recognized both the economic and clinical benefits of CyPath® Lung in veterans' healthcare," said Maria Zannes, President and CEO of bioAffinity Technologies. "Adding CyPath® Lung to the standard of care reduces costs to the federal medical system and provides physicians who care for our veterans with a powerful tool to clarify uncertainty and improve patient outcomes."

In its most recent issue, *U.S. Medicine* reported on research published in the peer-reviewed *Journal of Health Economics and Outcomes Research* (JHEOR) that analyzed the economic impact of adding CyPath® Lung to the standard of care for patients at high risk for lung cancer. Economic modeling showed savings of nearly \$895 million for private payers and \$379 million for Medicare assuming CyPath Lung had been part of the standard of care in 2022 for diagnosing lung cancer in patients with small pulmonary nodules. The authors emphasized that these savings were primarily due to reductions in follow-up diagnostic assessments and procedures, reducing unnecessary interventions and their risks.

An earlier clinical study of people at high risk for lung cancer who had small pulmonary nodules concluded that CyPath® Lung delivers high diagnostic performance with 92% sensitivity and 87% specificity and overall 88% accuracy in nodules 20 mm or smaller. Recent case studies of patients using CyPath® Lung reported that the test detected lung cancer at the curative Stage 1A when other diagnostic tools including PET/CT, serum markers and risk models used with imaging failed to indicate a higher chance of cancer.

Michael J. Morris, M.D., Brooke Army Medical Center (BAMC) pulmonology and critical care physician and Assistant Dean of Research at San Antonio Uniformed Services Health Education Consortium (SAUSHEC), and Sheila A. Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital were first and second authors on the JHEOR study.

As more at-risk veterans are screened, the number of small pulmonary nodules discovered by imaging is on the rise, posing challenges to practitioners who often have to choose between watchful waiting and invasive diagnostic procedures that may not be necessary. The study authors concluded that integrating companion tests to work in conjunction with the standard of care has the potential to improve outcomes by more efficiently triaging patients along the care pathway, resulting in positive reductions in delay of diagnosis, more favorable prognosis, and better patient outcomes.

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. (Nasdaq: BIAF; BIAFW)

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 improve lung cancer detection; the ability of CyPath® Lung to help federal medical systems address veterans at higher risk for developing lung cancer; potential cost savings resulting from the use of CyPath® Lung; and the benefits of adding CyPath® Lung to the standard of care. 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 improve lung cancer detection; the ability of CyPath® Lung to help federal medical systems address veterans at higher risk for developing lung cancer; potential cost savings resulting from the use of CyPath® Lung; and the benefits of adding CyPath® Lung to the standard of care, 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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