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): **August 7, 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously reported in a Current Report on Form 8-K filed by bioAffinity Technologies, Inc. (the "Company"), on February 7, 2025, the Company received written notice from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the preceding 30 consecutive business days (December 23, 2024 through February 6, 2025), the Company's common stock did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per share as required by Nasdaq Listing Rule 5550(a)(2). Therefore, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or util August 6, 2025, to regain compliance with the rule.

As previously reported in a Current Report on Form 8-K filed by the Company, on May 27, 2025 the Company received written notice from the Staff stating that the Company was not in compliance with Nasdaq Listing Rule 5550(b)(1) (the "Continued Listing Equity Requirement") because the stockholders' equity of the Company of $1,439,404 as of March 31, 2025, as reported in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2025, was below the minimum requirement of $2,500,000. Pursuant to Nasdaq's Listing Rules, the Company had 45 calendar days to submit a plan (a "Compliance Plan") to regain compliance with the Continued Listing Equity Requirement. On July 14, 2025, the Company submitted its plan to regain compliance with the Continued Listing Equity Requirement.

On August 7, 2025, the Company received written notice from the Listing Qualifications Staff of Nasdaq that the Company has not regained compliance with the Minimum Bid Price Requirement by August 6, 2025 and is not eligible for a second 180 day compliance period as the Company does not comply with the minimum stockholders' equity requirement for initial listing on the Nasdaq Capital Market. As a result, unless the Company requests an appeal to a hearings panel (the "Panel") by August 14, 2025, the Company's securities will be scheduled for delisting from The Nasdaq Capital Market and will be suspended at the opening of business on August 18, 2025.

In addition, as of the date hereof, the Company has not regained compliance with the Continued Listing Equity Requirement. As a result and pursuant to Listing Rule 5810(d)(2), this deficiency now serves as an additional basis for delisting of the Company's securities.

The Company intends to submit an appeal to Nasdaq on August 14, 2025, which will stay the delisting and suspension of the Company's securities pending the decision of the Panel. Hearings are typically scheduled to occur approximately 30-45 days after the date of the hearing request. At the hearing, the Company intends to present its views and its plans to regain compliance with the Minimum Bid Price Requirement and the Continued Listing Equity Requirement to the Panel. There can be no assurance that the Company will be able to evidence compliance with the Minimum Bid Price Rule, the Continued Listing Equity Requirement or any other applicable requirements for continued listing on The Nasdaq Capital Market prior to the hearing. It is the Company's understanding that the Panel typically issues its decision within 30 days after the hearing.

There can be no assurance that the Panel will grant the Company any extension period within which to regain compliance with the Minimum Bid Price Requirement and the Continued Listing Equity Requirement, or if any such extension period is granted, that the Company will regain compliance with the Minimum Bid Price Requirement and the Continued Listing Equity Requirement within such extension period, or that the Company will be successful in otherwise maintaining the listing of its common stock on The Nasdaq Capital Market.

This report contains forward-looking statements, including, but not limited to, the timing of the hearing and the timing of the decision of the Panel. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied by such forward-looking statements. In particular, the hearing may be scheduled, and the Panel may issue a decision, more quickly than expected based on the typical time periods in published Nasdaq guidance, which shorter timeline(s) may be unfavorable for the Company and the continued listing of the Company's common stock on The Nasdaq Capital Market. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. The Company undertakes no obligation to update any forward-looking statement in this report, except as required by law.

Item 8.01. Other Events.

On August 13, 2025, the Company issued a press release announcing an increase in commercial sales of its flagship product, CyPath® Lung, a noninvasive diagnostic for early-stage 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 August 13, 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: August 13, 2025

BIOAFFINITY TECHNOLOGIES, INC.

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

Exhibit 99.1

News Release

bioAffinity Technologies Reports Accelerating Growth in CyPath® Lung Test Sales
July Test Volume Surges 72% Over Prior Monthly Average

SAN ANTONIO, TX – August 13, 2025 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company focused on noninvasive diagnostics and early cancer detection, today announced a significant surge in commercial sales of its flagship product, **CyPath® Lung**, a noninvasive diagnostic for early-stage lung cancer.

Following a record-setting second quarter, the Company's third quarter started strong. Completed tests in July represent a 72% increase over the previous monthly average for the first six months of 2025. The upward trend reflects back-to-back record monthly sales in June and July. The Company reaffirmed its forecast of 3X year-over-year revenues for CyPath® Lung.

"CyPath® Lung's ability to detect lung cancer at its earliest stage, as evidenced by recent case studies, has fueled the growing adoption of CyPath® Lung across a growing base of clinicians, which is driving momentum in the marketplace," said Maria Zannes, President and CEO of bioAffinity Technologies. "This early Q3 surge is especially encouraging because it reflects increasing awareness and trust in our technology's ability to support earlier, more accurate diagnosis of lung cancer, especially for high-risk patients with indeterminate lung nodules."

"Physician demand, payer coverage, and patient access continue to build a strong foundation for long-term revenue growth," said J. Michael Edwards, bioAffinity Technologies' Chief Financial Officer. "The success of our pilot marketing program in Texas, which has approximately 6% of the total number of U.S. pulmonologists, has demonstrated that our approach to the medical community is sound and effective. We are prepared to meet increased demand as we implement our strategy to enter additional key markets, including our expansion in the Mid-Atlantic region and the Veterans Administration healthcare system."

The Company recently released three patient case studies in which CyPath® Lung detected Stage 1A cancer after standard imaging, risk calculator models and serum marker tests indicated the nodules were likely benign. The patients' final pathology reports confirmed Stage 1A for adenocarcinoma, a neuroendocrine tumor and mucinous adenocarcinoma, respectively. The latter two cancers are often difficult to detect with imaging and bronchoscopy alone.

“The key to improving survival rates for lung cancer is early detection. When lung cancer is found at Stage 1A, there are many curative options,” said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. “Physicians are finding that a CyPath® Lung test result – whether it is positive or negative for cancer – can better inform shared decision making between doctor and patient and ease anxiety about appropriate next steps.”

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 increase in the number of physician offices signed, positioning the Company for continued growth in 2025; the Company having the science, strategy and leadership to shape the future of lung cancer diagnostics; 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 increase in the number of physician offices signed, positioning the Company for continued growth in 2025; the Company having the science, strategy and leadership to shape the future of lung cancer diagnostics; 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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