
**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 7, 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 October 7, 2025, bioAffinity Technologies, Inc., a Delaware corporation, issued a press release announcing that sales of its CyPath® Lung diagnostic test for lung cancer reached a new high in the third quarter of 2025.

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 October 7, 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: October 7, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: /s/ Maria Zannes

Name: Maria Zannes

Title: President and Chief Executive Officer



News Release

bioAffinity Technologies Reports Record Growth in CyPath® Lung Test Volume for Third Quarter 2025

SAN ANTONIO, TX – October 7, 2025 – **bioAffinity Technologies, Inc.** (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today announced sales of its CyPath® Lung diagnostic test for lung cancer reached a new high in the third quarter of 2025, representing a 95% increase over the previous quarter. The increase reflects growing adoption by Veterans' hospitals and market expansion in the mid-Atlantic region. In the first nine months of 2025, sales of CyPath® Lung rose 97% over the same period in 2024.

"The continued acceleration in CyPath® Lung adoption underscores the growing physician confidence in our test to detect lung cancer at its earliest, most treatable stages," said Maria Zannes, President and CEO of bioAffinity Technologies. "Physicians are equally impressed by CyPath® Lung's ability to save patients from unnecessary invasive procedures when the nodule is benign.

"Our strong quarter-over-quarter growth demonstrates that CyPath® Lung is gaining traction in the marketplace, and we are encouraged by the test's increasing integration into clinical practice," Zannes said. "Performance metrics showed similar improvements in the third quarter, including a 77% increase in the number of new patients using CyPath® Lung and greater patient compliance for at-home sample collection and return."

Published patient case studies demonstrate the clinical impact of CyPath® Lung, including:

- **Detecting Stage 1A lung cancer** in patients after other diagnostics suggested a low probability of cancer.
- **Sparing patients from invasive procedures** when the CyPath® Lung result was negative.
- Detecting lung cancer earlier in **difficult-to-diagnose ground-glass nodules**.

"As we expand our marketing and sales efforts, we are immensely proud of the real-world impact CyPath® Lung is having on patients and their families," said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. "Every early cancer detected means a life that may be saved, and every unnecessary invasive procedure avoided means a patient spared from risk, anxiety and cost. This is why more physicians are adding CyPath® Lung as an essential tool in the diagnostic pathway."

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 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 Company's ability to continue sales growth in 2025 and beyond, 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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