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): **March 10, 2026**

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 March 10, 2026, bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), issued a press release announcing the initiation of its planned large-scale, longitudinal clinical study for CyPath® Lung, its noninvasive diagnostic test for the detection of early-stage lung 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 March 10, 2026
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: March 10, 2026

BIOAFFINITY TECHNOLOGIES, INC.

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

Exhibit 99.1

News Release

bioAffinity Technologies Announces Initiation of Large-Scale Longitudinal Clinical Study for Its Noninvasive CyPath® Lung Cancer Diagnostic

Study to evaluate clinical performance of CyPath® Lung for the early detection of lung cancer in high-risk patients

Murtha Cancer Center Research Program at Uniformed Services University of the Health Sciences provides support for longitudinal study

SAN ANTONIO, TX – March 10, 2026 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company focused on non-invasive diagnostics and early cancer detection, today announced initiation of the Company's planned large-scale, longitudinal clinical study for CyPath® Lung, its noninvasive diagnostic test for the detection of early-stage lung cancer.

The 2,000-patient longitudinal study is designed to evaluate the clinical performance of the CyPath® Lung flow cytometry test as a noninvasive diagnostic that uses sputum samples to detect the presence of lung cancer in high-risk individuals with existing lung nodules six millimeters (mm) to less than 30 mm in diameter identified by lung cancer screening. In an earlier clinical trial, CyPath® Lung showed 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients with small pulmonary nodules less than 20mm. Several recent patient case studies demonstrate the test's ability to detect lung cancer at its curative Stage 1A.

bioAffinity Technologies expects up to 20 clinical study sites, including a dozen Department of Veterans Affairs (VA) medical centers and two of the nation's largest military hospitals, will participate in the study. Michael J. Morris, MD, pulmonology and critical care physician at Brooke Army Medical Center, is the national Principal Investigator for the study (NCT07168993). The John P. Murtha Cancer Center Research Program (MCCRP), a research program within the Department of Surgery at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, is providing support and funding associated with the trial at several federal facilities.

Physicians currently order CyPath® Lung, a laboratory developed test (LDT) offered by bioAffinity Technologies' subsidiary Precision Pathology Laboratory Services, for their patients with indeterminate lung nodules to determine next steps in patient care.

The longitudinal clinical trial announced today will evaluate FlowPath Lung, a research-use test that uses the same technology and follows the same procedures as CyPath® Lung. The different name is simply used to distinguish the investigational assay from the commercially available test.

“As more indeterminate pulmonary nodules are found either incidentally or by routine lung cancer screening, CyPath® Lung can fill the diagnostic gap between ‘watchful waiting’ and invasive procedures that carry risk,” said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. “As a result, we see growing adoption and use of CyPath® Lung by physicians and expect this longitudinal trial to provide additional evidence to support inclusion of our noninvasive test as part of the standard of care for lung cancer screening and diagnosis.”

“Initiating this study represents an important milestone for CyPath® Lung,” said Maria Zannes, President and CEO of bioAffinity Technologies. “By following patients longitudinally across multiple sites, we expect to acquire robust, real-world data that reflects how CyPath® Lung may be used to support risk assessment and clinical decision-making aligned with our objective to establish CyPath® Lung as a standard of care for evaluating patients at high-risk for early-stage lung cancer.”

The study includes participation from several federal facilities to examine the test’s performance in diverse patient populations, including military service members and veterans. Patient enrollment is expected to take up to 18 months with patients followed for up to 24 months or until a definitive diagnosis of cancer or no cancer is determined.

About CyPath® Lung

CyPath® Lung is a non-invasive test designed to improve the early detection of lung cancer in patients at high risk for the disease. CyPath® Lung uses advanced flow cytometry and proprietary artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for non-invasive 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 non-invasive 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 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 ability to initiate and conduct the study as planned; challenges in patient identification, enrollment, retention, and protocol adherence; site performance and operational execution; variability in study data and outcomes; the possibility that study results do not demonstrate the anticipated performance or clinical utility; changes in standards of care, competitive developments, or technological advances; delays or difficulties in obtaining, maintaining, or expanding regulatory approvals or clearances; manufacturing, quality, supply chain, and scaling challenges; reimbursement and coverage uncertainties; the ability to obtain clinician and patient adoption; 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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