# 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): **May 12, 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 May 12, 2026, bioAffinity Technologies, Inc., a Delaware corporation, issued a press release announcing that unit sales for its CyPath® Lung diagnostic test achieved a record high in a single month and increased nearly 300% in April 2026 compared to the same period in 2025, based on preliminary unaudited data.

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 May 12, 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: May 12, 2026

**BIOAFFINITY TECHNOLOGIES, INC.**

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

**Exhibit 99.1**

News Release

**bioAffinity Technologies Reports Record Monthly CyPath® Lung Unit Sales and Significant Year-Over-Year Growth in April 2026**

***CyPath® Lung unit sales in April increased nearly 300% compared to April 2025***

***Increasing unit sales for CyPath® Lung continues first quarter 2026 trend of accelerating adoption and clinical use***

***Noninvasive test has potential to transform lung cancer risk assessment and nodule management***

**SAN ANTONIO, TX – May 12, 2026 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)**, a biotechnology company focused on noninvasive diagnostics and early cancer detection, today announced that unit sales for its CyPath® Lung diagnostic test achieved a record high in a single month and increased nearly 300% in April 2026 compared to the same period in 2025, based on preliminary unaudited data. The strong CyPath® Lung unit sales growth so far this year continues to exceed the Company's internal projections and reflects accelerating physician adoption and expanding clinical use by physicians using the Company's noninvasive test to aid in diagnosing lung cancer.

"The growth in CyPath® Lung usage continues to accelerate at a rapid pace as the value of our novel lung cancer diagnostic is increasingly being recognized," said Maria Zannes, President and CEO of bioAffinity Technologies. "CyPath® Lung addresses a significant gap in the diagnostic pathway by supporting lung cancer risk stratification and pulmonary nodule management as physicians seek more accurate, noninvasive tools to assess cancer risk and detect disease at its earliest, most treatable stage. We are very pleased with the unit growth that we delivered in April, and we remain focused on expanding adoption of CyPath® Lung to aid physicians in the early detection of lung cancer and pulmonary nodule management."

**Addressing a Large and Growing Clinical Need**

The number of patients identified with indeterminate pulmonary nodules continues to rise, driven in part by increases in incidental findings and screening by low-dose CT for high-risk patients. This expanding patient population poses a diagnostic challenge for physicians who have to weigh the benefits and risks of "watchful waiting" versus invasive procedures like biopsy.

CyPath® Lung's flow cytometry+AI technology provides actionable information to support clinical decision-making by the ordering physician. The test result is intended to be used in conjunction with other clinical information and is not a standalone diagnostic. Real-world patient cases have demonstrated the test's ability to:

- Help detect lung cancer at Stage 1A, when it is most treatable
- Help avoid unnecessary invasive, risky, and costly procedures when the test result is negative

**Executing a Focused Commercial Strategy**

bioAffinity Technologies has prioritized CyPath® Lung as its core commercial focus, aligning resources to accelerate adoption and scale. Growth has been driven by:

- Expansion of ordering physician sites
- Increased peer-to-peer education among pulmonologists
- Integration of CyPath® Lung into clinical workflows for lung cancer risk assessment and nodule management

**Positioned for Continued Expansion**

The company is advancing multiple initiatives to further expand the clinical impact of its proprietary technology platform, including:

- A large-scale longitudinal clinical study designed to generate additional validation data for CyPath® Lung
- Broader use of CyPath® Lung to monitor lung cancer survivors after treatment
- An R&D pipeline that includes diagnostic tests for asthma and COPD that will help guide personalized treatment with targeted therapies.

**About CyPath® Lung**

CyPath® Lung by bioAffinity Technologies is a noninvasive 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. In a clinical trial of high-risk patients, CyPath® Lung demonstrated 92% sensitivity, 87% specificity, 88% accuracy and 99% negative predictive value (NPV) in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters. The high NPV gives physicians greater confidence that a negative result is truly negative, potentially sparing patients from unnecessary invasive and costly procedures. CyPath® Lung is marketed as a Laboratory Developed Test (LDT) and is not intended for use as a sole diagnostic tool and should be considered alongside other clinical findings.

**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. LDTs are overseen under the Clinical Laboratory Improvement Amendments (CLIA), administered by the Centers for Medicare & Medicaid Services. 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 maintain and grow CyPath® Lung unit volume, the Company's ability to achieve or maintain profitability, the Company's dependence on a single commercial product, risks related to the regulatory environment for laboratory developed tests, the Company's ability to obtain adequate reimbursement coverage for CyPath® Lung, the Company's ability to successfully execute its commercial strategy and expand its customer base, the outcome of ongoing and future clinical studies, and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, 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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