

**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 5, 2024

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)

**22211 W Interstate 10
Suite 1206
San Antonio, Texas 78257
(210) 698-5334**

(Address of principal executive offices and Registrant's telephone number, including area code)

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).

Emerging growth company ☒

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

If an emerging growth company, indicate by check mark 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 2.02. Results of Operation and Financial Condition.

On March 5, 2024, bioAffinity Technologies, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its year ended December 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished with this Current Report on Form 8-K:

Exhibit	Description
99.1	Press Release issued by bioAffinity Technologies, Inc. dated March 5, 2024
104	Cover Page Interactive Data File (embedded within the Inline 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 5, 2024

BIOAFFINITY TECHNOLOGIES, INC.
(Registrant)

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



News Release

bioAffinity Technologies Reports Accelerating Sales Growth of CyPath® Lung

Increasing physician interest, newly approved reimbursement code driving growth

SAN ANTONIO (March 5, 2024) – **bioAffinity Technologies, Inc.** (Nasdaq: BIAF; BIAFW), a biotechnology company focused on the need for noninvasive tests for the detection of early-stage cancer and lung disease, today reported accelerating growth of 375% in CyPath® Lung tests ordered and processed over the past three months as compared to the previous three months. CyPath® Lung is a noninvasive test to detect early-stage lung cancer.

bioAffinity Technologies is on target to meet its sales forecast for the previously announced limited test market launch in Texas designed to refine future positioning and strategic insight for CyPath® Lung in preparation for expanding to the national market.

“The introduction of our reimbursement code, completion of our branding, and expansion of our sales force have markedly contributed to the growing physician interest and adoption of our innovative, noninvasive CyPath® Lung test. Increasing physician satisfaction and adoption have also been driven by the successful integration and efficient operation of our commercial laboratory, Precision Pathology Laboratory,” bioAffinity Technologies’ President and CEO Maria Zannes said. “Importantly, our sales growth has been in line with our expectations and bolsters our confidence in our ability to capitalize on the lung cancer diagnostics market projected to reach \$4.7 billion by 2030.”

Pulmonologists and other lung health specialists understand the critically important role of screening and early diagnosis in improving outcomes for those diagnosed with lung cancer and providing peace of mind for individuals at elevated risk of developing the disease. bioAffinity Technologies’ commitment to noninvasive cancer detection is poised to reshape the landscape of lung health management by increasing early detection and treatment.

bioAffinity Technologies will release financial results for the fourth quarter and full year ended December 31, 2023, on April 1, 2024.

About CyPath® Lung

CyPath® Lung uses 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, TCPP, 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 cancer can improve outcomes and increase patient survival.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and 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. Research and optimization of the Company’s platform technologies are conducted in its laboratories at Precision Pathology and The University of Texas at San Antonio. For more information, visit www.bioaffinitytech.com and follow us on [LinkedIn](#), [Facebook](#) and [X](#).

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 Company being on target to meet its sales forecast for the previously announced limited test market launch in Texas, the Company’s ability to capitalize on the lung cancer diagnostics market projected to reach \$4.7 billion by 2030 and the Company’s commitment to noninvasive cancer detection being poised to reshape the landscape of lung health management by increasing early detection and treatment. 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 to meet its forecast and capitalize on the lung cancer diagnostics market, and the other factors discussed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, 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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