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

July 9, 2024
Date of Report (Date of earliest event reported)

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)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

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 ☒

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 Operations and Financial Condition.

On July 9, 2024, bioAffinity Technologies, Inc. (the "Company") issued a press release that included financial information for its fiscal quarter ended June 30, 2024. 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 8.01. Other Events

On July 9, 2024, the Company issued a press release that included financial information for its fiscal quarter ended June 30, 2024, which included a reported 217% growth in second-quarter sales over first quarter 2024 and 53 CyPath® Lung tests ordered by physicians in the first quarter of 2024 compared to 168 CyPath® Lung tests ordered by physicians in the second quarter of 2024 .

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 July 9, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

bioAffinity Technologies, Inc.

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

Dated: July 9, 2024

Exhibit 99.1

News Release

bioAffinity Technologies Reports 217% Sales Growth in Second Quarter 2024 for CyPath® Lung

Sales of CyPath® Lung tests continue to accelerate as sales team expands customer base of pulmonology practices

SAN ANTONIO, TX (July 9, 2024) – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company focused on the need for noninvasive tests for the detection of early-stage cancer, today raised its full-year forecast for sales of CyPath® Lung in the Company's test marketing program by 85% and reported 217% growth in second-quarter sales over first quarter 2024, outpacing the forecast previously reported in May by 75%.

CyPath® Lung fulfills the need for a noninvasive test for the early detection of lung cancer and is especially useful for patients whose lung cancer screening or other scan reveals a pulmonary nodule. The lung cancer diagnostics market is projected to reach $4.7 billion by 2030, according to ReportLinker's industry analysis.

The accelerating growth of CyPath® Lung sales builds on the foundation laid in 2023 when bioAffinity launched a strategic beta marketing program in Texas after obtaining a CPT code and Medicare reimbursement for CyPath® Lung. This initiative included hiring seasoned sales executives to educate physicians on the benefits of CyPath® Lung for patients at risk for lung cancer. Additionally, private insurers have begun reimbursing for the test, which is billed at $1,900 by Precision Pathology Laboratory Services (PPLS), a wholly owned subsidiary of bioAffinity. PPLS is projected to generate between $9.2 and $9.6 million revenue in 2024, including sales of CyPath® Lung.

"We strategically focused our marketing efforts on our home state of Texas as we launched CyPath® Lung, a noninvasive test that has shown 92% sensitivity and 87% specificity in detecting cancer in the lung for people who have pulmonary nodules 20 millimeters or less," bioAffinity Technologies President and CEO Maria Zannes said. "The strategic decision to begin our commercial launch in Texas allows us to hone our message, improve operations and prepare for a broader market launch now scheduled for the fourth quarter of 2024."

In the second quarter of 2024, physicians ordered 168 CyPath® Lung tests. Based on the accelerating pace of test orders, the Company has raised its forecast for 2024 CyPath® Lung sales to exceed 880 tests. "In the fourth quarter of 2023, we processed 12 CyPath® Lung tests. That number increased to 53 tests in the first quarter of 2024 and now 168 tests in the second quarter," Ms. Zannes said.

Texas represents the third largest market of critical care pulmonologists in the nation, according to a November 2023 market insight report by IQVIA Holdings Inc., a global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. bioAffinity estimates Texas physicians currently using CyPath® Lung for their patients at high risk for lung cancer represent 10% of the Texas critical care pulmonology market, and the expanded sales team is onboarding new physicians weekly. Physicians in eight other states are ordering CyPath® Lung after referrals from their peers who have incorporated the test into their clinical practice, including pulmonologists in New Jersey, Ohio, Pennsylvania, Michigan, North Carolina, California, Florida and Arizona.

In addition to critical care pulmonologists who are considered opinion leaders in advancing innovative lung cancer diagnostics like CyPath® Lung, other physician specialties that may use the test for their high-risk patients include general pulmonologists and primary care physicians.

"Lung cancer screening and early diagnosis improve outcomes and extend lives for patients at high risk for lung cancer. But imaging is not always definitive, especially for pulmonary nodules smaller than 20 millimeters," Ms. Zannes said. "By combining the simplicity of sputum as a biological sample with advanced flow cytometry and automated analysis, CyPath® Lung gives physicians a valuable diagnostic tool with high sensitivity and specificity for high-risk patients, especially those with indeterminate nodules. And their patients appreciate the user-friendly, noninvasive design of the test."

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 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 raising the full-year forecast for sales of CyPath® Lung, PPLS generating between $9.2 and $9.6 million in revenue in 2024 including sales of CyPath® Lung, honing

the Company's message, improving operations and preparing for a broader CyPath® Lung market launch for the fourth quarter of 2024, 2024 CyPath® Lung sales exceeding 880 tests, Texas physicians currently using CyPath® Lung for their patients at high risk for lung cancer representing 10% of the Texas critical care pulmonology market, the sales team onboarding new physicians weekly, other physician specialties using the CyPath® Lung test for their high-risk patients and the lung cancer diagnostics market reaching $4.7 billion by 2030. 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 accelerate the commercialization of CyPath® Lung and capitalize on the lung cancer diagnostics market; the ability of CyPath® Lung to provide the anticipated benefits to patients and physicians; and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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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