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 9, 2024**

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 7.01. Regulation FD Disclosure.

On October 9, 2024, bioAffinity Technologies, Inc. (the "Company") issued a press release announcing that CyPath® Lung, its noninvasive test to detect early-stage lung cancer, will be added to the U.S. Federal Supply Schedule, a procurement system that provides the Veterans Health Administration (VHA) and the Military Health System streamlined access to state-of-the-art healthcare products and services.

The information in this Item 7.01 and in the press release furnished 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 and 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. The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Item 8.01. Other Events.

On April 17, 2024, the Company issued a press release announcing that CyPath® Lung, its noninvasive test to detect early-stage lung cancer, will be added to the U.S. Federal Supply Schedule, a procurement system that provides the Veterans Health Administration (VHA) and the Military Health System streamlined access to state-of-the-art healthcare products and services.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by bioAffinity Technologies, Inc., dated October 9, 2024
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 9, 2024

BIOAFFINITY TECHNOLOGIES, INC.
(Registrant)

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

Exhibit 99.1

News Release

bioAffinity Technologies Awarded U.S. Federal Supply Schedule Contract for CyPath® Lung Test

Noninvasive diagnostic test for lung cancer available to U.S. Veterans, other federal health services patients

SAN ANTONIO, TX (Oct. 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 announced that CyPath® Lung, its noninvasive test to detect early-stage lung cancer, will be added to the U.S. Federal Supply Schedule, a procurement system that provides the Veterans Health Administration (VHA) and the Military Health System streamlined access to state-of-the-art healthcare products and services.

The VHA, part of the U.S. Department of Veterans Affairs (VA), serves 9.1 million Veterans each year and is the largest integrated health care system in the country, providing care at 1,380 health care facilities, including 170 medical centers and 1,193 outpatient sites of care of varying complexity (VHA outpatient clinics). Approximately 8,000 Veterans are diagnosed and treated for lung cancer annually, according to the VA.

"Lung cancer is the leading cause of cancer-related death in Veterans, despite being one of the most preventable cancers in the world. The University of California, Irvine School of Medicine reports that an estimated 15 Veterans die of lung cancer each day, and Veterans are 25% more likely to receive a lung cancer diagnosis compared to non-Veterans," bioAffinity President and CEO Maria Zannes said. "My father was one such Veteran who died from lung cancer at age 39. That is just one of many reasons I am immensely proud that VA and Department of Defense physicians will be able to order CyPath® Lung for their patients to help detect early-stage lung cancer with the goal of leading to better treatment and longer lives."

Retired Col. Roby Joyce, M.D., Medical Director of bioAffinity's subsidiary laboratory, Precision Pathology Laboratory Services, and a bioAffinity board member, served in the Army Medical Corps for 15 years. "Both as a Veteran who was honored to serve and as the Medical Director for the lab that developed CyPath ® Lung to detect this deadly cancer, I am proud to partner with the VA and the Military Health System to help improve health outcomes for the millions of Veterans and active-duty military who are at higher risk for lung cancer," Joyce said. "It's incredibly gratifying to see the VA acknowledge CyPath ® Lung as a valuable tool for the early diagnosis of lung cancer, which affects far too many past and present members of our military."

Veterans are at higher risk for lung cancer due to older age, smoking and environmental exposure during and after military service. Through programs like the Lung Precision Oncology Program (LPOP), the VA promotes annual lung cancer screening for high-risk individuals. CyPath® Lung is especially effective for patients who receive a positive screening result. When a low dose computed tomography (LDCT) scan reveals indeterminate pulmonary nodules, CyPath® Lung helps close the gap between a "wait and see" option and an invasive procedure, including biopsy, that may turn out to be unnecessary.

A recent economic impact study found that adding CyPath® Lung to the current standard of care could save hundreds of millions of dollars per year in healthcare costs by reducing follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications. Michael J. Morris, M.D., Brooke Army Medical Center (BAMC) pulmonology and critical care physician and Assistant Dean of Research at San Antonio Uniformed Services Health Education Consortium (SAUSHEC), and Sheila A. Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital and Assistant Professor at the University of Texas Health Science Center at San Antonio, were lead co-authors of the study.

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, meso-tetra (4-carboxyphenyl) 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 lung cancer can improve outcomes and increase patient survival. For more information, visit www.cypathlung.com.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. (Nasdaq: BIAF) 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. 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 CyPath® Lung for helping to detect early-stage lung cancer with the goal of leading to better treatment and longer lives, adding CyPath® Lung to the current standard of care saving hundreds of millions of dollars per year in healthcare costs by reducing follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications, and diagnosing and treating early-stage lung cancer improving outcomes and increasing patient survival. 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 aid in helping to detect early-stage lung cancer and tosave hundreds of millions of dollars per year in healthcare costs by reducing follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications 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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