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 28, 2025**

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 October 28, 2025, bioAffinity Technologies, Inc., a Delaware corporation, issued a press release announcing that the Australian Patent office has accepted its patent application AU 2019253111 titled "*System and Method for Determining Lung Health,*" which covers methods that use flow cytometry combined with fluorescent probes, molecular tags that attach to specific cell types, to detect cellular and molecular signatures of multiple lung diseases.

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 October 28, 2025
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 28, 2025

BIOAFFINITY TECHNOLOGIES, INC.

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

Exhibit 99.1

News Release

bioAffinity Technologies Announces Acceptance of Australian Patent Application for Platform to Detect and Characterize Multiple Lung Diseases

Australian patent strengthens global patent portfolio

SAN ANTONIO, TX — October 28, 2025 — bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company advancing early-stage diagnostics including CyPath® Lung, the Company's noninvasive test for lung cancer, today announced that the Australian Patent Office (IP Australia) has accepted a patent application for the Company's proprietary platform technology for assessing lung health and predicting the likelihood of multiple lung diseases in patients.

"This accepted patent application underscores the broad potential of our technology to improve the diagnosis and management of lung disease," said Maria Zannes, President and CEO of bioAffinity Technologies. "The invention behind this patent uses our flow cytometry platform to reveal disease-related changes across multiple cell types in a sputum sample. We believe this innovation can lead to a new generation of diagnostic tools for personalized lung health."

Australia patent application AU 2019253111, titled "*System and Method for Determining Lung Health*," covers methods that use flow cytometry combined with fluorescent probes, molecular "tags" that attach to specific cell types, to detect cellular and molecular signatures of multiple lung diseases.

bioAffinity's flagship product, CyPath® Lung, remains the centerpiece of the Company's commercial efforts, providing physicians with a noninvasive tool to assess lung nodules detected by low-dose CT scans and incidental imaging.

The Australian patent complements bioAffinity's existing intellectual property protection in the United States and other international jurisdictions. Together, these patents safeguard the core technology that powers the CyPath® Lung test and other diagnostics in the Company's pipeline.

The Australia patent will be automatically issued three months after the acceptance date unless a third party files an opposition and proves to IP Australia why the patent should not be issued. Until then, bioAffinity's expanding global patent estate includes 18 awarded and 33 pending patents. The Company holds patents in the U.S., Australia, Canada, China, France, Germany, Hong Kong, Italy, Japan, Mexico, Spain, Sweden and the United Kingdom.

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.

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 benefits to be derived from the patent if issued, the Company's ability to safeguard its intellectual property, the invention's ability of CyPath® Lung to identify multiple diseases of the lung, 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.

Contacts

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