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): **July 22, 2025**

bioAffinity Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41463**	**46-5211056**
(State or other jurisdiction	(Commission	(I.R.S. Employer
of incorporation)	File Number)	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 July 22, 2025, bioAffinity Technologies, Inc., a Delaware corporation, (the "Company") issued a press release announcing it has received notification of allowance from the Canadian Patent Office for a patent application related to methods of predicting the likelihood of lung cancer using flow cytometry.

The newly allowed Canadian patent titled "System and Method for Determining Lung Health" protects the use of defined antibodies and the porphyrin TCPP to label cell populations in sputum and the use of flow cytometry to determine the presence of lung cancer cells in the sputum.

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 July 22, 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: July 22, 2025

BIOAFFINITY TECHNOLOGIES, INC.

By: */s/ Maria Zannes*

Name: Maria Zannes

Title: President and Chief Executive Officer

Exhibit 99.1

Canada Awards New Patent to bioAffinity Technologies for CyPath® Lung, Company's Noninvasive Lung Cancer Diagnostic

New patent protects market expansion to the north where lung cancer is leading cause of cancer deaths

SAN ANTONIO, TX — July 22, 2025 —bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company advancing early-stage cancer diagnostics including CyPath® Lung, the Company's commercially available test for early-stage lung cancer, today announced its patent related to a method to detect lung disease through flow cytometry analysis of sputum has been allowed by the Canadian Patent Office. This patent strengthens the international protection of the Company's diagnostic platform that powers its flagship test, CyPath® Lung.

"As with the recent announcement of the award of our patent in China, this Canadian patent reflects our continued execution toward building long-term shareholder value through innovation, protection of our unique assets, and a clear focus on early cancer detection that can save lives," said Maria Zannes, President and CEO of bioAffinity Technologies.

Lung cancer is the leading cause of cancer death in Canada, according to theCanadian Cancer Society. In 2024, approximately 31,000 Canadians were diagnosed with lung cancer, and approximately 20,700 people died of the disease. More than 70% of the lung cancer deaths were linked to smoking.

"We believe that the award of this patent by the Canadian Patent Office further validates the diagnostic platform behind CyPath® Lung, expands the global footprint of our intellectual property portfolio and highlights the strength of our science," Ms. Zannes said. "Recent case studies highlight CyPath Lung's ability to detect lung cancer at its earliest stages, making our test all the more valuable in Canada where 50% of all lung cancer cases are diagnosed late at Stage IV with the five-year survival rate overall of about 19% in Canada, according to government statistics."

The Canadian patent (Patent No. 3,136,245) – titled "System and Method for Determining Lung Health" – protects the use of defined antibodies and the porphyrin TCPP to label cell populations in sputum and the use of flow cytometry to determine the presence of lung cancer cells in the sputum.

CyPath® Lung is the Company's first commercial product, with clinical study results demonstrating 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.

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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 based upon current estimates and assumptions and include statements regarding the benefits to be derived from the patent, the Company's ability to safeguard its intellectual property, and the ability to market CyPath® Lung in Canada. 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, the Company's ability to safeguard its intellectual property, and the ability to market CyPath® Lung in Canada, and 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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