
**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): **September 17, 2026**

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)

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))

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 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 September 17, 2026, bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), issued a press release announcing that the Hong Kong Intellectual Property Department has granted a patent for the Company’s proprietary technology for predicting the likelihood of lung cancer using flow cytometry and fluorescent markers to characterize cell populations in 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 September 17, 2026
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: September 17, 2026

BIOAFFINITY TECHNOLOGIES, INC.

By: /s/ Maria Zannes

Name: Maria Zannes

Title: President and Chief Executive Officer



News-Release

bioAffinity Technologies Announces Grant of Hong Kong Patent for Company's CyPath® Lung Noninvasive Lung Cancer Diagnostic

Dual patent protection in Hong Kong and China strengthens CyPath Lung's positioning to enter Asian market

Asia accounts for nearly two-thirds of lung cancer cases worldwide

SAN ANTONIO, Texas – September 17, 2026 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company developing noninvasive healthcare solutions for the early detection and monitoring of lung disease, today announced that the Hong Kong Intellectual Property Department has granted a patent for the Company's proprietary platform technology for predicting the likelihood of lung cancer using flow cytometry and fluorescent markers to characterize cell populations in sputum.

"The grant of this patent in Hong Kong and the 2025 patent we received from China strengthen the intellectual property protection for our technology in Asia, a region with a substantial burden of lung cancer," said Maria Zannes, President and CEO of bioAffinity Technologies. "With an estimated 1.6 million new lung cancer cases diagnosed annually across Asia,¹ the region represents a significant potential market for noninvasive technologies like CyPath® Lung that support earlier detection and more informed clinical decision-making that can lead to better patient outcomes."

Hong Kong Patent No. HK40048460, titled "System and Method for Determining Lung Health," covers, as described in the patent claims, 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. The patented technology is the scientific foundation underlying CyPath Lung, which remains the centerpiece of the Company's commercial efforts, providing physicians with a noninvasive tool to assess the likelihood of malignancy in lung nodules detected by low-dose CT scans and incidental imaging.

The Hong Kong patent complements bioAffinity's expanding global patent estate, which now covers multiple patents and pending applications in the United States and other international jurisdictions, including Australia, Canada, China, the European Union, Japan, Mexico and Singapore. Together, these patents safeguard the core technology that powers the CyPath Lung test and other diagnostics in the Company's pipeline.

¹ **Source:** International Agency for Research on Cancer (IARC), World Health Organization, Global Cancer Observatory, *GLOBOCAN 2022: Lung Cancer Fact Sheet*.

About CyPath Lung

CyPath Lung by bioAffinity Technologies is a noninvasive test designed to improve the early detection of lung cancer in patients at high risk for the disease. CyPath Lung uses advanced flow cytometry and proprietary artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. CyPath Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. In a [published clinical trial](#) of high-risk patients, CyPath Lung demonstrated 92% sensitivity, 87% specificity, 88% accuracy and 99% negative predictive value (NPV) in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters. These clinical performance data relate to CyPath Lung's use in the detection setting and have not been separately validated for post-treatment surveillance. The high NPV may help inform physician decision-making when evaluating whether further invasive procedures are warranted. CyPath Lung is marketed as a Laboratory Developed Test (LDT) and is not intended for use as a sole diagnostic tool and should be considered alongside other clinical findings.

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. LDTs are overseen under the Clinical Laboratory Improvement Amendments (CLIA), which are administered by the Centers for Medicare & Medicaid Services. 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 Company's ability to successfully commercialize CyPath® Lung or other diagnostic products in the United States or internationally; the Company's ability to obtain and maintain patent protection and defend its intellectual property rights in the United States and foreign jurisdictions; uncertainties regarding the enforceability of patents in foreign jurisdictions, including Hong Kong and China; the Company's ability to obtain regulatory approvals or clearances required to market its products in international markets; the accuracy of third-party estimates of market size and lung cancer incidence; the Company's need for additional capital and its ability to obtain financing on acceptable terms; and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, 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.

Contact

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