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): **December 3, 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 December 3, 2025, bioAffinity Technologies, Inc., a Delaware corporation, issued a press release announcing that it will present a poster entitled *"CyPath® Lung in Practice: From Uncertainty to Clarity and Confidence"* (the "Poster") at the American Cancer Society National Lung Cancer Roundtable on December 8, 2025. The Poster showcases three cases in which CyPath® Lung, a noninvasive sputum-based flow cytometry test, successfully identified Stage 1A lung cancer in patients with atypical and diagnostically challenging presentations.

Copies of the press release and Poster are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively and are 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 December 3, 2025
99.2	Poster entitled "*CyPath® Lung in Practice: From Uncertainty to Clarity and Confidence*"
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: December 3, 2025

BIOAFFINITY TECHNOLOGIES, INC.

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

Exhibit 99.1

News Release

bioAffinity Technologies' Noninvasive CyPath® Lung Test to Be Highlighted at American Cancer Society National Lung Cancer Roundtable

SAN ANTONIO, Texas – December 3, 2025 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today announced that Chief Medical Officer Gordon Downie, MD, PhD, will present a poster at the American Cancer Society National Lung Cancer Roundtable (NLCRT) showcasing three cases in which CyPath® Lung, a noninvasive sputum-based flow cytometry test, successfully identified Stage 1A lung cancer in patients with atypical and diagnostically challenging presentations.

"Indeterminate pulmonary nodules pose a significant and growing clinical burden, especially when clinicians are confronted with conflicting or inconclusive diagnostic data," Dr. Downie said. "Risk calculators, imaging, genetic testing, and biomarker tools can at times point in opposing directions, leaving clinicians and patients uncertain about next steps. This challenge is amplified in patients with unusual risk profiles, discordant imaging and advanced age."

Dr. Downie's poster, *"CyPath® Lung in Practice: From Uncertainty to Clarity and Confidence,"* details three complex cases from his tenure as Director of the Titus Regional Hospital Lung Nodule Clinic and Interventional Pulmonology. CyPath® Lung was used alongside other diagnostic tools, including standard low-dose CT (LDCT), PET imaging, risk calculators, bronchoscopy and blood serum marker tests. In each case, CyPath® Lung provided clarity and actionable results which led to confirmed diagnoses at the earliest and most treatable stage.

"These three cases illustrate scenarios that are increasingly common in real-world lung nodule practice," Dr. Downie said. "Incorporating CyPath® Lung into the diagnostic pathway can accelerate diagnosis, guide difficult conversations with anxious patients, and prevent unnecessary invasive procedures that carry their own risks."

The NLCRT is a coalition of 194 medical, public health, advocacy, government, and corporate organizations that work together to fight lung cancer by working collectively and collaboratively to reduce lung cancer mortality. This year's annual meeting is December 8-9, 2025, at the Grand Hyatt Atlanta in Buckhead, Atlanta, Georgia.

Dr. Downie's poster session is scheduled for Monday, December 8, 2025, from 2:35-3:15 p.m. ET. The poster can be viewed on the bioAffinity website.

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 ability of CyPath® Lung to identify lung cancer 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

bioAffinity Technologies
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CyPath® Lung in Practice: From Uncertainty to Clarity and Confidence

Gordon Downie, MD, PhD
Former Director, Titus Regional Hospital Lung Nodule Clinic and Interventional Pulmonology
Chief Medical Officer, bioAffinity Technologies, Inc.

bioAffinity TECHNOLOGIES

CyPath Lung

Case Study Gloria: CyPath® Lung detects rare pulmonary mucinous adenocarcinoma at Stage 1A

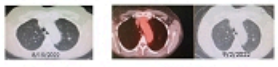
Patient Information and Initial Workup

- **Age:** 62 years old
- **Sex:** Female
- **Smoking status:** 100+ pack-year history
- **Medical history:** Stage 1 COPD (FEV1 109%)
- **Status:** High risk due to heavy smoking history and COPD
- **Presentation:** Chest X-ray with abnormal hyperinflation
- **Scans:** LDCT in August 2022, May 2023 and July 2024; PET in September 2022
- **Surveillance:** Patient missed recommended follow-up appointments

NOTE: Actual patient case, but name has been changed to ensure privacy.

Imaging Results

LDCT on 08/15/22 revealed 12mm LUL mixed solid nodule with GGO features, lung cancer probability of 16%. PET scan SUV was 1.19, lung cancer probability 3.5% under Herder model.



12 mm GGO LUL — PET SUV 1.19

Missed 2 follow-up appointments; next LDCT scans were 5/25/23 and 10/18/2023 without significant changes. But 7/18/24 LDCT showed growth and less GGO characteristics. By 3/18/25 LDCT nodule had grown to 14mm with cystic changes.

No significant change — More solid, less GGO — Enlarged to 14mm, solid with cystic changes

Additional Findings/Next Steps

- **Brock model risk:** 16%/3.5% (Herder model with PET)
- **Nodify:** first blood serum marker test returned "reduced risk" result; second Nodify test came back as "indeterminate" with no circulating antibodies
- Patient refused invasive bronchoscopic biopsy
- **Follow-up PET:** denied by insurance in July 2024

Outcome with CyPath® Lung

- **CyPath® Lung:** 3/1/25 test result: 0.56, likely malignancy
- **Wedge resection:** Successful surgery on 6/11/25 with good margins, negative nodes
- **Diagnosis:** Stage 1A lung mucinous adenocarcinoma
- Patient quit smoking March 2025 and has returned to baseline pulmonary function
- **CyPath® Lung:** detected pulmonary mucinous adenocarcinoma in a high-risk individual whose previous tests and follow-up scans suggested a low probability of cancer

COPD=chronic obstructive pulmonary disease; LDCT=low-dose computed tomography; PET=positron emission tomography; LUL=left lower lobe; GGO=ground-glass opacity.

Case Study Paula: Complex low-metabolic nodule detected at Stage 1A in low-risk patient

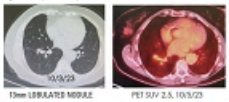
Patient Information and Initial Workup

- **Age:** 80 years old
- **Sex:** Female
- **Smoking status:** Quit in 1999
- **Medical history:** Hypertension, stroke, COVID-19 infection in 2021
- **Status:** Low risk
- **Presentation:** Asthma symptoms post-COVID, including cough, dyspnea, wheezing. Patient placed on Augmentin, asthma inhalers
- **Chest x-ray** showed lobulated opacity in RLL
- **Surveillance:** 6-month follow-up LDCT recommended

NOTE: Actual patient case, but name has been changed to ensure privacy.

Imaging Results

LDCT on 10/3/23 revealed 13mm lobulated nodule in RLL. 10/5/23 PET scan SUV was 2.5, lung cancer probability 15.8%



13mm LOBULATED NODULE — PET SUV 2.5, 10/5/23

LDCT scans on 1/10/2024 and 7/9/2024 no significant changes in the RLL nodule. LDCT on 5/14/2025 revealed a change in the distal component of the lobulated RLL process, with growth and a more nodular appearance.

Additional Findings/Next Steps

- **Brock model risk:** 15.8%/16.5% (Herder model with PET)
- **Nodify** blood serum marker test returned "reduced risk" result
- **Bronchoscopy** on 10/9/23 negative for suspicious cells but found S. Viridans consistent with active infection
- **Second bronchoscopy** on 3/17/25 again revealed inflammatory markers but no suspicious cells

Outcome with CyPath® Lung

- **CyPath® Lung:** 3/4/25 test result: 0.72, likely malignancy
- **Shared decision-making:** CyPath® Lung result convinced patient to undergo surgery despite conflicting information from other indicators
- **Robotic wedge resection:** Patient referred for surgery in June 2025
- **Diagnosis:** Stage 1A neuroendocrine tumor
- **CyPath® Lung:** Detected lung cancer in low-risk patient when PET, bronchoscopy and serum marker test suggested it was benign inflammation

LDCT=low-dose computed tomography; PET=positron emission tomography; RLL=right lower lobe.

Background

The clinical burden of competent pulmonary nodule identification and definitive diagnosis is increasingly common. This is especially true in complex cases with conflicting results from diagnostic tests and procedures. Clinicians are tasked with in-depth difficult discussions with their patients when risk calculators, imaging, genetic and other adjuvant testing information points definitively either at benign or malignant process. Clinical presentations with unusual risk, imaging, age, functionality or newer adjuvant testing parameters make these discussions nearly impossible. I present three cases employing noninvasive sputum flow cytometry analysis in addition to standard LDCT, PET scans and blood proteomic testing to help address clinical decisions in three "atypical" presentations in our pulmonary nodule clinic. [1,2,3,4]

Case Study Mary: Stage 1A NSCLC Detected in Patient With Low-Risk PET Result and Risk Calculator Score

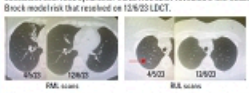
Patient Information and Initial Workup

- **Age:** 67 years old
- **Sex:** Female
- **Smoking status:** >50 pack-year history; currently smokes ½ PPD
- **Medical history:** Stage 3 COPD with frequent exacerbations; FEV1 = 45%
- **Family history:** Unremarkable
- **Status:** High risk because of smoking history and COPD
- **Presentation:** Symptoms of RML syndrome
- **LDCT scans:** 4/5/23 and 12/6/23
- **Surveillance:** 6-month follow-up recommended, but patient only agreed to 12-month LDCT

NOTE: Actual patient case, but name has been changed to ensure privacy.

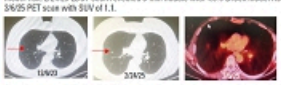
Imaging Results

RML and RUL scans: RML changes on 4/5/23 LDCT improved on 12/6/23 LDCT, consistent with RML syndrome. 4/5/23 RUL LDCT revealed 5-mm nodule with 1.8% Brock model risk that resolved on 12/6/23 LDCT.



RML scans — RUL scans

Minor fissure scans: 12/6/23 LDCT scan revealed 3-mm nodule with 0.2% Brock model risk. 3/24/25 LDCT scan revealed 8-mm nodule with 4.6% Brock model risk. 3/6/25 PET scan with SUV of 1.1.



Changing non-calcified nodule in the minor fissure in the context of waxing and waning images in other parts of the lungs.

Additional Findings/Next Steps

- **Brock model risk:** 4.6%
- Bronchoscopy high risk and poor yield without robotic augmentation in a low-risk situation
- Risk calculator and PET suggested inflammation and not cancer, consistent with waxing and waning images

Outcome with CyPath® Lung

- **CyPath® Lung:** 3/4/25 test result: 0.83, likely lung cancer (NOTE: CyPath® Lung was not available at the time of the 2023 scans.)
- **Robotic wedge resection:** R0 resection on 6/5/25, but with close margin
- **Diagnosis:** Stage 1A NSCLC, adenocarcinoma histology
- **Radiation oncology referral:** Opinion on close margin and possible need for radiation treatment
- **CyPath® Lung:** Detected lung cancer in high-risk patient with complex nodules when PET and risk models indicated low risk of malignancy

COPD=chronic obstructive pulmonary disease; LDCT=low-dose computed tomography; NSCLC=non-small cell lung cancer; PET=positron emission tomography; PPD=pack per day; RML=right middle lobe; RUL=right upper lobe.

Note: Actual patient cases but names have been changed to protect privacy.

Conclusions

Presented here are three clinical scenarios that have significant atypical features, but which are becoming more frequent in lung nodule practices. We have found that adding CyPath® Lung testing to our algorithm has accelerated diagnosis, helped guide difficult clinical discussions and prevented unnecessary invasive procedures.

References

1. Ludmila Gurskiik, et al., Journal of Nuclear Medicine April 2015, 56 (4) 518-522; DOI: https://doi.org/10.2967/jnumed.113.131656

2. Ambrosini V, et al., PET/CT imaging in different types of lung cancer: an overview. Eur J Radiol. 2012 May;81(5):988-1001. doi: 10.1016/j.ejrad.2011.03.020. Epub 2011 Mar 31. PMID: 21458981.

3. Kavidasan A, et al. (2018) Atypical Presentations of Lung Cancer: A Case Series. J Oncol Res Ther: JONT-143. DOI: 10.29011/2574- 7107. 000043

4. Gould MK, et al., Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2013 May;143(5 Suppl):e93S-e120S. doi: 10.1378/chest.12-2351. PMID: 23649456; PMCID: PMC3749714