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): March 31, 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
(210) 698-5334
(Address of principal executive offices and Registrant's telephone number, including area code)

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).

Emerging growth company ☒

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

If an emerging growth company, indicate by check mark 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 2.02. Results of Operation and Financial Condition.

On March 31, 2025, bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), issued a press release that included financial information for its year ended December 31, 2024. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and in the press release attached 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. The information contained in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished with this Current Report on Form 8-K:

Exhibit	**Description**
99.1	Press Release issued by bioAffinity Technologies, Inc. dated March 31, 2025
104	Cover Page Interactive Data File (embedded within the Inline 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: March 31, 2025

BIOAFFINITY TECHNOLOGIES, INC. (Registrant)

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

Exhibit 99.1

News Release

bioAffinity Technologies Reports Record $9.4 Million Revenue for 2024

Increased Demand, Expanded Insurance Coverage Drive Record Growth

SAN ANTONIO, Texas (March 31, 2025) – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company focused on the need for noninvasive, accurate tests for the detection of early-stage lung cancer and other lung diseases, today reported financial results for the year ended December 31, 2024.

2024 Highlights

- **Record Revenue:** Revenue grew approximately 270% to $9.4 million in 2024, a significant increase from $2.5 million in 2023.
- **Increased Demand:** CyPath® Lung orders grew by approximately 1,400% over full-year 2023, reflecting increasing physician adoption.
- **CyPath® Lung Reimbursed by Medicare and Private Insurance:** The unique CPT code for CyPath® Lung was added to the Centers for Medicare and Medicaid Services (CMS) 2024 clinical laboratory schedule effective January 1, leading to reimbursement of the test by both Medicare and private insurers.
- **Expanded Physician Network:** Number of physician offices signed increased by over 300% in 2024, positioning the Company for continued growth in 2025.
- **Federal Supply Schedule (FSS) Listing:** In October 2024, CyPath® Lung was added to the U.S. Federal Supply Schedule, granting Veterans Health Administration and Military Health System facilities streamlined access to the test. Through 1,380 government healthcare facilities, Veterans at high risk for developing lung cancer can now benefit from CyPath® Lung.
- **Economic Validation:** A study published in the *Journal of Health Economics and Outcomes Research* concluded that adding CyPath® Lung to the standard of care for Medicare patients with a positive lung cancer screening could have saved an average of $2,773 per patient, amounting to $379 million in total cost savings in 2022. The savings for private insurance patients would have been even greater, an average of $6,460 per patient, an estimated total savings of $895 million if all individuals screened in 2022 were covered by private insurance.

- **Leadership Appointments:** Appointed J. Michael Edwards, CPA, MBA, as Chief Financial Officer. He previously served bioAffinity Technologies as consulting Chief Financial Officer until 2023 and rejoined the management team to help oversee the long-term financial and strategic direction of the Company, including the ongoing commercialization of CyPath® Lung. Appointed William Bauta, PhD, as Chief Science Officer. Bauta joined bioAffinity Technologies as Senior Vice President in 2016. He previously served as Associate Director of Science at Genzyme.
- **Innovation Pipeline Progress:** Company scientists are developing diagnostic tests for Chronic Obstructive Pulmonary Disease (COPD) and asthma that build on our expertise in using sputum as a sample for flow cytometric analysis, including research to detect the presence of specific therapeutic targets to identify patients who can benefit from specific treatments.
- **International Patent Recognition:** Received a Certificate of Grant of Patent from the Japan Patent Office for the Company's unique method using flow cytometry to predict the likelihood of lung disease, including CyPath® Lung's application for early-stage lung cancer detection.

2025 Financial Outlook

The Company anticipates generating between $6 million to $8 million in total revenue in 2025, including $1 to $2 million from sales of CyPath lung tests. The reduction in revenue for the 2025 financial outlook as compared to 2024 is a result of discontinuing certain unprofitable pathology services, which will be more than offset by corresponding cost reductions from lower labor and overhead costs at our subsidiary laboratory.

Recent Events

- **Case Studies:** Released a series of patient case studies in collaboration with Gordon Downie, MD, PhD, Director of the Pulmonary Nodule Clinic at Titus Regional Medical Center in Texas. The studies illustrate the benefit of CyPath® Lung to both patients and clinicians, including earlier diagnosis of recurrent cancer and new primary lung cancer and avoiding unnecessary invasive procedures that carry risks for elderly patients with comorbidities.
- **FDA Pivotal Study:** Submitted protocol for a pivotal clinical trial to the Sterling Institutional Review Board (IRB). Academic, private, military, and VA medical centers have been qualified as collection sites for an estimated 3,500-patient clinical trial expected to open in the second quarter of 2025.

Management Commentary

"We are proud of the tremendous strides bioAffinity Technologies made in 2024, achieving record revenue and laying the groundwork for continued growth," bioAffinity President and Chief Executive Officer Maria Zannes said. "The full-year integration of our pathology lab, Precision Pathology, and the growing adoption of CyPath® Lung reflect the success of our strategy to build a scalable, high-impact business focused on early lung cancer detection.

"Our inclusion on the U.S. Federal Supply Schedule marks a major milestone, ensuring Veterans and military personnel across the country have easy access to CyPath® Lung," Zannes continued. "Physician adoption is accelerating, driven by the clinical value and noninvasive nature of our test. Referrals and word-of-mouth continue to fuel our expansion beyond Texas, positioning us for sustained growth."

"As we look to 2025, our focus remains on expanding commercial adoption of CyPath® Lung, strengthening our relationships with key opinion leaders, starting our FDA

pivotal study, and advancing our pipeline of diagnostics powered by artificial intelligence and flow cytometry," Zannes added. "With the recent streamlining of operations that will increase profitability at our laboratory, we are building a company with the science, strategy and leadership to shape the future of lung cancer diagnostics — and with every test ordered, we're unlocking value for both patients and shareholders."

2024 Financial Results

Revenue for the year ended December 31, 2024, was $9.4 million, compared with $2.5 million for the prior year. The increase was primarily driven by a full year of consolidated operations of Precision Pathology Laboratory Services, LLC (PPLS), which was acquired in September 2023. Revenue was primarily generated from patient service fees, including CyPath® Lung tests, and histology fees.

Operating expenses for 2024 totaled $18.3 million, compared with $10.5 million in 2023. The increase reflects the full-year impact of PPLS operations, higher sales and marketing activities, and increased general and administrative expenses associated with scaling commercial operations.

Direct costs and expenses were $6.0 million for 2024, up from $1.7 million in 2023, due to the inclusion of a full year of pathology and lab operations for PPLS. Research and development expenses remained level at approximately $1.5 million in both years, reflecting consistent investment in lab operations and preclinical development. Clinical development expenses also remained level at $0.3 million in both years. The Company expects to see an increase in clinical development expense in 2025, as enrollment begins for the FDA study.

Selling, general and administrative expenses were $9.9 million, compared with $6.8 million in 2023. The increase was mainly attributed to the expanded operations and personnel costs related to the commercialization of CyPath® Lung and a full year of operating PPLS.

Net loss for the year ended December 31, 2024, was $9.0 million, or $0.75 per share, compared with a net loss of $7.9 million, or $0.91 per share, for the prior year.

Cash and cash equivalents as of December 31, 2024, were $1.1 million, compared with $2.8 million as of December 31, 2023. Subsequent to the end of 2024, bioAffinity Technologies raised aggregate gross proceeds of $1.4 million through warrant exercises in February 2025.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. 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® 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 increase in the number of physician offices signed positioning the Company for continued growth in 2025; healthcare cost savings from adding CyPath® Lung to the standard of care for Medicare and private insurance patients with a positive lung cancer screening; generating between $6 million to $8 million in total revenue in 2025, including $1 to $2 million from sales of CyPath lung tests; the reduction in revenue for the 2025 financial outlook as compared to 2024 being a result of discontinuing certain unprofitable pathology services, which will be more than offset by corresponding cost reductions from lower labor and overhead costs at our subsidiary laboratory; profitability at the laboratory increasing with the recent streamlining of operations; the Company having the science, strategy and leadership to shape the future of lung cancer diagnostics; and an expected increase in clinical development expense in 2025, as enrollment begins for the FDA study. 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 the Company to continue its growth in 2025; the ability to save costs by use of CyPath® Lung; the ability to generate between $6 million and $8 million in total revenue in 2025 and to offset a reduction in revenue for 2025 with cost savings; the ability to increase profitability at the laboratory; the ability to commence enrollment in the Company's FDA study and the other factors discussed in the Company's recent Annual Report on Form 10-K, 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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bioAffinity Technologies, Inc.
Consolidated Balance Sheets

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		

Cash and cash equivalents	$ 1,105,291	$ 2,821,570
Accounts and other receivables, net	1,139,204	811,674
Inventory	27,608	18,484
Prepaid expenses and other current assets	422,995	321,017
Total current assets	2,695,098	3,972,745
Non-current assets:		
Property and equipment, net	375,385	458,633
Operating lease right-of-use asset, net	463,011	370,312
Finance lease right-of-use asset, net	780,872	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	775,139	833,472
Other assets	19,676	16,060
Total assets	$ 6,513,667	$ 8,221,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 987,311	$ 604,789
Accrued expenses	1,398,722	1,149,811
Unearned revenue	24,404	33,058
Operating lease liability, current portion	127,498	94,708
Finance lease liability, current portion	395,301	365,463
Notes payable, current portion	171,669	—
Total current liabilities	3,104,905	2,247,829
Non-current liabilities		
Operating lease liability, net of current portion	342,098	283,001
Finance lease liability, net of current portion	444,448	835,467
Notes payable, net of current portion	20,180	—
Total liabilities	3,911,631	3,366,297
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no shares issued or outstanding at December 31, 2024 and 2023, respectively	—	—
Common stock, par value $0.007 per share; 100,000,000 shares authorized; 15,576,674 and 9,394,610 shares issued and outstanding as of December 31, 2024 and 2023, respectively	106,593	65,762
Additional paid-in capital	56,139,753	49,393,972
Accumulated deficit	(53,644,310)	(44,604,479)
Total stockholders' equity	2,602,036	4,855,255
Total liabilities, and stockholders' equity	$ 6,513,667	$ 8,221,552

bioAffinity Technologies, Inc.
Consolidated Statements of Operations

	2024	2023
Net Revenue	$ 9,362,022	$ 2,532,499
Operating expenses:		
Direct costs and expenses	5,983,475	1,740,884
Research and development	1,461,227	1,467,936
Clinical development	321,655	256,661
Selling, general and administrative	9,943,473	6,790,654
Depreciation and amortization	605,637	249,592
Total operating expenses	18,315,467	10,505,727
Loss from operations	(8,953,445)	(7,973,228)
Other income (expense):		
Interest income	17,610	122,131
Interest expense	(92,475)	(37,125)
Other income	10,323	3,325
Other expense	(10,194)	(31,121)
Loss before income taxes	(9,028,181)	(7,916,018)
Income tax expense	(11,650)	(20,993)
Net loss	$ (9,039,831)	$ (7,937,011)

Net loss per common share, basic and diluted	$	(0.75)	$	(0.91)
Weighted average common shares outstanding		12,125,029		8,747,509