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): **November 14, 2024**

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 November 14, 2024, bioAffinity Technologies, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended September 30, 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 November 14, 2024
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: November 14, 2024

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 $2.4 Million Revenue for Q3 2024

Expanded CyPath® Lung test sales to physicians in Illinois, Alabama, and Louisiana; now receiving orders from physicians in 11 states

Number of physician offices signed increased 75% over Q2 2024

Reaffirmed $9.6 million 2024 revenue forecast for wholly owned Precision Pathology subsidiary

SAN ANTONIO, Texas (November 14, 2024) – 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 three months ended September 30, 2024.

Key Highlights

- Generated quarterly revenue of $2.4 million in the third quarter of 2024.
- More than 1,300% growth rate for CyPath® Lung orders in first nine months of 2024 over full-year 2023.
- Number of physician offices signed increased by 75% compared to the second quarter of 2024, setting the stage for acceleration of CyPath® Lung sales in the quarters ahead.
- In October 2024, CyPath® Lung was added to the U.S. Federal Supply Schedule (FSS), a procurement system that provides the Veterans Health Administration and the Military Health System streamlined access to state-of-the-art healthcare products and services. Under the FSS contract, Veterans at high risk for lung cancer will have easy access to CyPath® Lung through 1,380 government health care facilities. Approximately 8,000 Veterans are treated for lung cancer annually, according to the VA.
- Referrals and word-of-mouth from physicians, including key opinion leaders (KOLs), continues to be a key driver for expanding CyPath® Lung in states beyond Texas; now receiving CyPath® Lung orders from physicians in 11 states, up from eight in the second quarter of 2024. In addition to previously reported orders from Pennsylvania, New Jersey, North Carolina, Arizona, Michigan, California, and Ohio, physicians in Alabama, Louisiana and Illinois have also begun ordering CyPath® Lung tests.
- Added new sales representative to target increasing opportunities in Texas.

- Continued to advance new product development initiatives in collaboration with Brooke Army Medical Center, the U.S Department of Defense's largest military health organization, focusing on tests that use the Company's artificial intelligence and flow cytometry platform for diagnosing COPD and a companion test with bronchoscopy.
- Economic study published in Journal of Health Economics and Outcomes Research, a peer-reviewed journal, concludes 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 for total cost savings of $379 million in 2022.
- Awarded 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 the CyPath® Lung diagnostic test for early-stage lung cancer.
- Appointed William Bauta, Ph.D., as Chief Science Officer following the retirement of Vivienne I. Rebel, M.D., Ph.D. Dr. Bauta joined bioAffinity in 2016 as Senior Vice President. Previously, he was Associate Director of science at Genzyme.
- Successfully closed a $2.7 million registered direct offering and concurrent private placement to fund continued growth.

Management Commentary

"We are pleased with the continued progress we achieved in the third quarter, highlighted by a 75% growth in the number of physician offices signing on to offer CyPath® Lung. This significant expansion not only reflects the increasing recognition of our test's value in early lung cancer detection but also lays a strong foundation for accelerating sales growth in the coming quarters," bioAffinity President and Chief Executive Officer Maria Zannes said. "With CyPath® Lung now being used in 11 states and its recent addition to the U.S. Federal Supply Schedule, we are making meaningful strides in broadening access to this innovative diagnostic tool.

"Our focus remains on expanding our operations and strengthening our foothold in this rapidly growing market," Zannes continued. "Our strategic approach in Texas has resulted in a robust sales and support infrastructure that has us well-equipped to meet rising demand and accelerate our nationwide growth. As we look toward the future, we are confident that these efforts will not only fuel our success but also advance our mission to enhance patient outcomes through groundbreaking, noninvasive cancer diagnostics."

Third Quarter Financial Results

Revenue for the third quarter of 2024 was $2.4 million, compared with $298,000 revenue for the prior-year period. The majority of the year-over-year increase is through the acquisition of Precision Pathology Laboratory Services, LLC (PPLS). Revenue is primarily generated from patient service fees, including billing for CyPath® Lung tests, with additional revenues generated from histology service fees and medical director fees.

Research and development expenses were $274,000 for the third quarter of 2024, compared with $330,000 for the comparable period in 2023. The decrease was primarily due to higher R&D laboratory supply and equipment costs following the acquisition of PPLS in the prior year period.

Clinical development expenses were $94,000 for the third quarter of 2024, compared with $106,000 for the third quarter of 2023. The decrease was primarily attributable to higher professional fees in the prior year period related to evaluating the clinical strategy for the Company's Food and Drug Administration (FDA) pivotal CyPath® Lung clinical trial.

Selling, general and administrative expenses were $2.4 million for the third quarter of 2024, compared with $2.0 million for the comparable period in 2023. The increase was primarily attributed to an increase in sales personnel and services to support the launch of CyPath® Lung, together with acquired general and administrative costs from PPLS.

Net loss for the third quarter of 2024 was $2.0 million, or $0.16 per share, a $0.3 million improvement from a net loss of $2.3 million, or $0.26 per share, for the comparable period in 2023.

Cash and cash equivalents as of September 30, 2024, were $0.8 million, compared with $2.8 million as of December 31, 2023. Subsequent to the end of the third quarter of 2024, bioAffinity Technologies raised aggregate gross proceeds of $2.7 million in a registered direct offering and concurrent private placement closed on October 21, 2024.

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® Lung is marketed as a Laboratory Developed Test (LDT) by Precision Pathology Laboratory Services, a wholly owned 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 accelerating sales growth in the coming quarters; broadening access to CyPath® Lung; expanding the Company's operations and strengthening its foothold in the rapidly growing market; the Company's ability to meet rising demand and accelerate its nationwide growth; the Company's ability to advance its mission to enhance patient outcomes through groundbreaking, noninvasive cancer diagnostics; and the ability of the Company to address the need for noninvasive diagnosis of early-stage cancer and diseases of the lung and broad-spectrum cancer treatments. 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 accelerate sales growth and expand its operations; the Company's ability to meet rising demand and accelerate its nationwide growth; the Company's ability to advance its mission to enhance patient outcomes through groundbreaking, noninvasive cancer diagnostics; the ability of the Company to address the need for noninvasive diagnosis of early-stage cancer and diseases of the lung and broad-spectrum cancer treatments, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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.
Condensed Consolidated Balance Sheets

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 756,580	$ 2,821,570
Accounts and other receivables, net	1,327,168	811,674
Inventory	25,363	18,484
Prepaid expenses and other current assets	440,027	321,017
Total current assets	2,549,138	3,972,745
Non-current assets:		
Property and equipment, net	418,190	458,633
Operating lease right-of-use asset, net	493,687	370,312
Finance lease right-of-use asset, net	877,115	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	789,722	833,472
Other assets	19,676	16,060
Total assets	$ 6,552,014	$ 8,221,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 782,937	$ 604,789
Accrued expenses	904,252	1,149,811
Unearned revenue	24,404	33,058
Operating lease liability, current portion	124,710	94,708
Finance lease liability, current portion	387,780	365,463

Notes payable, current portion	267,081	—
Total current liabilities	2,491,164	2,247,829
Non-current liabilities:		
Finance lease liability, net of current portion	543,007	835,467
Operating lease liability, net of current portion	375,139	283,001
Notes payable, net of current portion	21,679	—
Total liabilities	3,430,989	3,366,297
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at September 30, 2024, and December 31, 2023	—	—
Common stock, par value $0.007 per share; 100,000,000 shares authorized; 13,424,648 and 9,394,610 issued and outstanding at September 30, 2024, and December 31, 2023, respectively	90,064	65,762
Additional paid-in capital	53,708,374	49,393,972
Accumulated deficit	(50,677,413)	(44,604,479)
Total stockholders' equity	3,121,025	4,855,255
Total liabilities and stockholders' equity	$ 6,552,014	$ 8,221,552

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net Revenue	$ 2,350,386	$ 298,484	$ 7,154,429	$ 319,143
Operating expenses:				
Direct costs and expenses	1,440,158	74,704	4,421,309	76,025
Research and development	274,497	330,376	1,070,569	1,035,118
Clinical development	93,705	106,422	194,127	161,310
Selling, general and administrative	2,364,592	2,023,917	7,023,311	4,576,708
Depreciation and amortization	151,298	57,569	452,005	100,805
Total operating expenses	4,324,250	2,592,988	13,161,321	5,949,966
Loss from operations	(1,973,864)	(2,294,504)	(6,006,892)	(5,630,823)
Other income (expense):				
Interest income	2,228	27,193	13,541	109,971
Interest expense	(21,631)	(8,785)	(67,430)	(11,801)
Other income	9,683	4,606	9,683	4,606
Other expense	(14,697)	(17,100)	(10,186)	(17,100)
Total other income (expense)	(24,417)	5,914	(54,392)	85,676
Net loss before provision for income tax expense	(1,998,281)	(2,288,590)	(6,061,284)	(5,545,147)
Income tax expense	2,559	2,294	11,650	18,700
Net loss	$ (2,000,840)	$ (2,290,884)	$ (6,072,934)	$ (5,563,847)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.26)	$ (0.54)	$ (0.65)
Weighted average common shares outstanding	12,391,867	8,696,554	11,237,324	8,551,154

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