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): May 15, 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)

22211 W Interstate 10
Suite 1206
San Antonio, Texas 78257
(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 May 15, 2024, bioAffinity Technologies, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended March 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 May 15, 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: May 15, 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 Record Q1 Revenue Driven by Accelerating Growth of CyPath® Lung Sales and Increased Laboratory Volumes

Expanded, experienced sales team more than doubles number of physician practices ordering CyPath® Lung test year-to-date

More than 547% annualized growth rate for CyPath® Lung orders in first four months of 2024 over full-year 2023, leading to 35% increase in original 2024 forecast

KOL referrals and word-of-mouth expanding adoption of CyPath® Lung outside of the beta market launch in Texas

SAN ANTONIO, Texas (May 15, 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 March 31, 2024.

Key Highlights

- Generated record quarterly revenue of $2.4 million in the first quarter of 2024.
- Forecasting between $9.2 and $9.6 million in 2024 revenues for wholly owned subsidiary Precision Pathology Laboratory Services (PPLS), up 23% over 2023.
- Increased 2024 CyPath® Lung sales forecast 35% from the original forecast reported in the 2023 Annual Report.
- Number of physician offices ordering CyPath® Lung is up 112%, more than double, since January 1, 2024.
- Medicare reimbursement for CyPath® Lung became effective on January 1, 2024.
- More than 547% annualized growth rate for CyPath® Lung orders in first four months of 2024 over full-year 2023 with April sales showing a robust increase of 21% over the previous month.
- Referrals and word-of-mouth from physicians, including key opinion leaders (KOLs), resulting in significant uptake of CyPath® Lung by physicians in states beyond Texas.
- Physicians in Pennsylvania, New Jersey, North Carolina, Arizona, and Michigan are ordering CyPath® Lung after hearing about it from patients and colleagues.
- Medical Director of Lung Innovations Network and The Lung Center at Penn Highlands Healthcare, Dr. Sandeep Bansal, joined our Medical and Scientific Advisory Board and incorporated CyPath® Lung into his medical practice that offers comprehensive lung care to over 10,000 patients in central and western Pennsylvania.
- Continued to advance new product development initiatives in collaboration with the U.S Department of Defense's largest military health organization, focusing on tests that use our artificial intelligence and flow cytometry platform for diagnosing COPD and companion test with bronchoscopy.
- OncoSelect Therapeutics, a subsidiary of bioAffinity, was awarded a therapeutic patent in India for a novel cancer treatment method using chemotherapeutic agents conjugated to porphyrins.
- Successfully closed a $2.5 million registered direct offering and concurrent private placement to fund continued growth.

Management Commentary

"We are entering a period of accelerating growth with orders for CyPath® Lung up 547% on an annualized basis in the first four months of the year compared to all of 2023," bioAffinity President and Chief Executive Officer Maria Zannes said. "As we continue to advance our commercial strategy, moving beyond the initial test market in Texas, the unique and compelling attributes of CyPath® Lung, including its AI-enhanced data analysis and non-invasive sample collection, have proven to be key differentiators in the market and are resonating with physicians and patients alike. This growing interest is leading to increased adoption by prominent medical practices and double-digit month-over-month growth in test orders."

"CyPath® Lung is positioned to set a new standard in the early detection of lung cancer – a market projected to reach $4.7 billion by 2030," Zannes continued. "As we continue to scale our operations and enhance our offerings, our focus remains steadfast on improving patient outcomes and delivering shareholder value. With Medicare and major private insurers now providing coverage, the pathway for increased adoption and accelerated growth in usage is clear, setting the stage for substantial market penetration and revenue generation in the upcoming quarters."

First Quarter Financial Results

Revenue for the first quarter of 2024 was $2.4 million, compared with $921 revenue for the prior-year period. The majority of the year-over-year increase is through the acquisition of Precision Pathology Laboratory Services. 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 $394,000 for the first quarter of 2024, compared with $370,000 for the comparable period in 2023. The increase was primarily due to higher compensation costs for additional research personnel and higher R&D laboratory supply costs.

Clinical development expenses were $49,000 for the first quarter of 2024, compared with $20,000 for the first quarter of 2023. The increase was primarily due to an increase in compensation costs and benefits from the addition of new clinical development personnel.

Selling, general and administrative expenses were $2.2 million for the first quarter of 2024, compared with $1.1 million for the comparable period in 2023. The increase was primarily due to acquired general and administrative costs from PPLS and an increase in personnel and services to support the launch of CyPath® Lung.

Net loss for the first quarter of 2024 was $2.1 million, or $0.21 per share, compared with a net loss of $1.5 million, or $0.18 per share, for the comparable period in 2023.

Cash and cash equivalents as of March 31, 2024, were $2.5 million, compared with $2.8 million as of December 31, 2023.

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 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 continuing to advance the Company's commercial strategy, moving beyond the initial test market in Texas, positioning CyPath ® Lung to set a new standard in the early detection of lung cancer – a market projected to reach $4.7 billion by 2030, increased adoption by prominent medical practices and double-digit month-over-month growth in test orders, revised forecast of between $9.2 million and $9.6 million in 2024 revenues for wholly owned subsidiary Precision Pathology Laboratory Services, up 23% over 2023, and the increased 2024 CyPath® Lung sales forecast of 35% from the original forecast reported in the 2023 Annual Report. 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 continue to advance the Company's commercial strategy, moving beyond the initial test market in Texas, the ability to generate revenue forecasted and to generate forecasted 2024 CyPath® Lung sales, 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.

Contacts

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bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,453,165	$ 2,821,570
Accounts and other receivables, net	1,123,609	811,674
Inventory	9,487	18,484
Prepaid expenses and other current assets	344,900	321,017
Total current assets	3,931,161	3,972,745
Non-current assets:		
Property and equipment, net	461,209	458,633
Operating lease right-of-use asset, net	347,860	370,312
Finance lease right-to-use, net	1,069,601	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	818,889	833,472
Other assets	16,060	16,060
Total assets	$ 8,049,266	$ 8,221,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 442,485	$ 604,789
Accrued expenses	923,810	1,149,811
Unearned revenue	30,174	33,058
Operating lease liability, current portion	96,631	94,708
Finance lease liability, current portion	372,787	365,463
Notes payable, current portion	4,686	—
Total current liabilities	1,870,573	2,247,829
Non-current liabilities:		
Finance lease liability, net of current portion	739,478	835,467

Operating lease liability, net of current portion	258,110	283,001
Notes payable, net of current portion	23,037	—
Total liabilities	2,891,198	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 March 31, 2024, and December 31, 2023	—	—
Common stock, par value $0.007 per share; 25,000,000 shares authorized; 11,214,502 and 9,394,610 issued and outstanding at March 31, 2024, and at December 31, 2023, respectively.	78,515	65,762
Additional paid-in capital	51,744,830	49,393,972
Accumulated deficit	(46,665,277)	(44,604,479)
Total stockholders' equity	5,158,068	4,855,255
Total liabilities and stockholders' equity	$ 8,049,266	$ 8,221,552

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2024	2023
	(unaudited)	
Net Revenue	$ 2,406,391	$ 921
Operating expenses:		
Direct costs and expenses	1,660,007	87
Research and development	393,639	369,617
Clinical development	48,960	19,628
Selling, general and administrative	2,196,361	1,147,875
Depreciation and amortization	149,637	21,684
Total operating expenses	4,448,604	1,558,891
Loss from operations	(2,044,213)	(1,557,970)
Other income (expense):		
Interest income	6,127	38,654
Interest expense	(23,550)	(1,655)
Other income	—	—
Other expense	4,510	—
Net loss before provision for income taxes	(2,057,126)	(4,919,158)
Income tax expense	(3,672)	(11,819)
Net loss	$ (2,060,798)	$ (1,532,790)
Net loss per common share, basic and diluted	$ (0.21)	$ (0.18)
Weighted average common shares outstanding, basic and diluted	9,915,426	8,433,689