
**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): **August 14, 2025**

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
(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).

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

Emerging growth company ☒

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 August 14, 2025, bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), issued a press release that included financial information for its quarter ended June 30, 2025. 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 August 14, 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: August 14, 2025

BIOAFFINITY TECHNOLOGIES, INC.
(Registrant)

By: /s/ Maria Zannes

Name: Maria Zannes

Title: President and Chief Executive Officer



News Release

bioAffinity Technologies Reports Second Quarter 2025 Results

CyPath® Lung revenues up 62% year-over-year in first six months of 2025

SAN ANTONIO, Texas (August 14, 2025) – **bioAffinity Technologies, Inc.** (Nasdaq: **BIAF**; **BIAFW**), a biotechnology company focused on providing noninvasive, accurate detection of early-stage lung cancer and other lung diseases, today reported financial results for the three months ended June 30, 2025.

Key Highlights

- Increased CyPath® Lung revenues 62% year-over-year for the six-month period ended June 30, 2025.
- Completed CyPath® Lung tests in July represented a 72% increase over the previous monthly average for the first six months of 2025, including back-to-back record monthly sales in June and July.
- Released real-world case studies demonstrating the diagnostic utility of CyPath® Lung, including successful detection of Stage 1A lung cancers for multiple patients who had previous tests and imaging that incorrectly deemed the risk of cancer as low.
- Increased the list price of CyPath® Lung to \$2,900, aligning with private payer reimbursement strategies and enhancing per-test profitability.
- Expanded logistics capabilities through partnership with Cardinal Health™ OptiFreight® Logistics, improving sample tracking, cost efficiency, and national delivery reliability in support of CyPath® Lung's commercial growth.
- Completed a \$3.25 million public offering in May 2025 providing working capital.
- Appointed Dr. Gordon Downie, MD, PhD, as Chief Medical Officer, bringing more than 30 years of clinical leadership in pulmonology and interventional lung care to support bioAffinity's diagnostic and clinical strategy.
- Announced patent grants in the U.S., China, Canada, and Australia, expanding the Company's global intellectual property portfolio for both diagnostics and therapeutics, including a newly issued U.S. patent for a broad-spectrum cancer therapy targeting CD320 and LRP2 receptors.
- Presented novel siRNA-based cancer therapy research at the 2025 RNA Therapeutics Conference, showcasing the potential of a new therapeutic approach to selectively kill cancer cells without harming healthy tissue.
- bioAffinity President and CEO Maria Zannes appointed to the American Lung Association in Texas Leadership Board, reinforcing the Company's advocacy and leadership in lung health and early cancer detection.

Management Commentary

“Our second quarter results reflect the continued acceleration of our CyPath® Lung commercialization strategy, with testing revenue up 62% for the first half of the year,” Maria Zannes, President and Chief Executive Officer of bioAffinity Technologies said. “This growth is driven by increasing clinical adoption of our noninvasive lung cancer diagnostic and supported by physician-authored case studies showing that CyPath® Lung has identified early-stage cancers that other tests missed. These real-world results are validating our test’s unique value in guiding clinical decisions and improving patient outcomes.

“The success of our pilot marketing program in Texas, which has approximately 6% of the total number of U.S. pulmonologists, has demonstrated that our approach to the medical community is sound and effective. We are prepared to meet increased demand as we implement our strategy to enter additional key markets, including our expansion in the Mid-Atlantic region and the Veterans Administration healthcare system.

“During the quarter, we took important steps to strengthen our financial foundation, including a successful \$3.25 million public offering and a strategic price adjustment for CyPath® Lung to better reflect its value and align with reimbursement from private payers. At the same time, our partnership with Cardinal Health OptiFreight® Logistics has enhanced our national sample delivery capabilities to meet growing demand.

“We are also proud to have expanded our leadership team with the appointment of Dr. Gordon Downie as Chief Medical Officer. His expertise in pulmonary medicine and lung cancer screening is already shaping our clinical direction, including advancement toward pivotal trials.

“Our intellectual property portfolio continues to grow with newly granted patents in the U.S., China, Canada, and Australia—strengthening both our diagnostic and therapeutic platforms on a global scale. We also presented breakthrough research at the 2025 RNA Therapeutics Conference, showcasing our siRNA-based approach to selectively kill cancer cells while sparing healthy tissue, a strategy with broad potential across multiple tumor types.

“Looking ahead, we remain focused on expanding access to CyPath® Lung, delivering operational efficiency, and advancing the next generation of diagnostics and therapeutics,” Zannes added. “Every test we deliver is a step toward earlier cancer detection, better patient care, and stronger value for our shareholders.”

Second Quarter 2025 Financial Results

Revenue for the quarter ended June 30, 2025, was \$1.3 million, compared with \$2.4 million for the second quarter of 2024. The decrease was primarily attributable to the Company’s strategic decision to discontinue unprofitable pathology services and reallocate resources toward the commercialization of CyPath® Lung. CyPath® Lung testing revenue for the six months ended June 30, 2025, increased approximately 62% year-over-year to \$323,000, reflecting growth in physician adoption and an increase in total test results delivered.

Operating expenses for the second quarter of 2025 were \$3.8 million, down 16% from \$4.5 million in the second quarter of 2024. The decrease was primarily due to lower direct costs related to laboratory operations and reduced research and development expenses, partially offset by increased clinical development spending in support of the Company's pivotal trial strategy.

- Direct costs and expenses were \$1.0 million, a 28% decrease from the prior-year period, driven by cost-saving initiatives implemented in March 2025.
- Research and development expenses decreased 23% year-over-year to \$311,000, reflecting lower compensation and lab supply costs.
- Clinical development expenses increased to \$129,000, up from \$51,000 in Q2 2024, due to higher professional fees.
- Selling, general and administrative expenses decreased 10% to \$2.2 million, largely reflecting efficiencies following the integration of PPLS and adjustments to staffing and support functions.
- Depreciation and amortization expense declined 25% year-over-year to \$113,000.

Net loss for the quarter ended June 30, 2025, was \$4.1 million, or \$0.17 per share, compared with a net loss of \$2.1 million, or \$0.19 per share, for the second quarter of 2024. The increase in net loss was primarily driven by a \$1.5 million increase in non-cash expenses related to warrant remeasurement and offering costs associated with the Company's May 2025 public offering.

Cash and cash equivalents as of June 30, 2025, were \$0.8 million, compared with \$1.1 million as of December 31, 2024. bioAffinity Technologies raised aggregate gross proceeds of \$3.25 million through a public offering in May 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[®] 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 strategic actions reducing costs while expanding sales focus on high-margin diagnostics like CyPath[®] Lung; international patents expanding CyPath[®] Lung’s global commercialization potential; the targeted actions accelerating the commercial growth of CyPath[®] Lung; patient case studies continuing to underscore the diagnostic power of CyPath[®] Lung in real-world settings; expanding access to CyPath[®] Lung for patients at risk of lung cancer; and advancing new diagnostics for diseases like COPD and asthma. 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, strategic actions reducing costs while expanding sales focus on high-margin diagnostics like CyPath[®] Lung; international patents expanding CyPath[®] Lung’s global commercialization potential; the targeted actions accelerating the commercial growth of CyPath[®] Lung; patient case studies continuing to underscore the diagnostic power of CyPath[®] Lung in real-world settings; expanding access to CyPath[®] Lung for patients at risk of lung cancer; advancing new diagnostics for diseases like COPD and asthma; 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

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bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 802,835	\$ 1,105,291
Accounts and other receivables, net	421,869	1,139,204
Inventory	43,971	27,608
Prepaid expenses and other current assets	400,151	422,995
Total current assets	<u>1,668,826</u>	<u>2,695,098</u>
Non-current assets:		
Property and equipment, net	351,368	375,385
Operating lease right-of-use asset, net	399,879	463,011
Finance lease right-of-use asset, net	167,730	780,872
Goodwill	1,404,486	1,404,486
Intangible assets, net	745,972	775,139
Other assets	12,814	19,676
Total assets	<u>\$ 4,751,075</u>	<u>\$ 6,513,667</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 1,169,837	\$ 987,311
Accrued expenses	1,048,034	1,398,722
Unearned revenue	24,404	24,404
Operating lease liability, current portion	133,239	127,498
Finance lease liability, current portion	179,844	395,301
Notes payable, current portion	32,946	171,669
Total current liabilities	<u>2,588,304</u>	<u>3,104,905</u>
Non-current liabilities:		
Operating lease liability, net of current portion	274,074	342,098
Finance lease liability, net of current portion	3,942	444,448
Notes payable, net of current portion	45,952	20,180
Warrant liability	3,974,911	—
Total liabilities	<u>6,887,183</u>	<u>3,911,631</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at June 30, 2025, and December 31, 2024	—	—
Common stock, par value \$0.007 per share; 100,000,000 shares authorized; 28,459,541 and 15,576,674 issued and outstanding at June 30, 2025, and December 31, 2024, respectively	197,236	106,593
Additional paid-in capital	58,032,170	56,139,753
Accumulated deficit	(60,365,514)	(53,644,310)
Total stockholders' equity (deficit)	<u>(2,136,108)</u>	<u>2,602,036</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 4,751,075</u>	<u>\$ 6,513,667</u>

bioAffinity Technologies, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net revenue	\$ 1,269,483	\$ 2,397,652	\$ 3,123,080	\$ 4,804,043
Operating expenses:				
Direct costs and expenses	1,016,602	1,407,710	2,384,462	2,981,151
Research and development	311,372	402,433	678,758	796,072
Clinical development	129,279	51,462	267,632	100,422
Selling, general and administrative	2,214,561	2,472,775	4,667,110	4,658,719
Depreciation and amortization	113,229	151,070	267,817	300,707
Total operating expenses	3,785,043	4,485,450	8,265,779	8,837,071
Loss from operations	(2,515,560)	(2,087,798)	(5,142,699)	(4,033,028)
Other income (expense):				
Interest income	2,025	5,186	2,567	11,313
Interest expense	(10,460)	(22,249)	(25,945)	(45,799)
Other income	38,053	1	38,055	4,511
Other expense	(483,043)	—	(492,685)	—
Change in fair value of warrants issued	(1,062,818)	—	(1,062,818)	—
Total other income (expense), net	(1,516,243)	(17,062)	(1,540,826)	(29,975)
Net loss before provision for income tax expense	(4,031,803)	(2,104,860)	(6,683,525)	(4,063,003)
Income tax expense	28,984	5,419	37,679	9,091
Net loss	\$ (4,060,787)	\$ (2,110,279)	\$ (6,721,204)	\$ (4,072,094)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.19)	\$ (0.20)	\$ (0.38)
Weighted average common shares outstanding	24,021,546	11,389,308	20,148,211	10,655,483