

August 14, 2024



bioAffinity Technologies Reports \$2.4 Million Revenue for Q2 Driven by Growing CyPath® Lung Sales

Q2 CyPath® Lung test sales up 217% over Q1 2024

Expanded CyPath® Lung test sales to physicians in California and Ohio; now receiving orders from physicians in eight states outside of Texas

Raised full-year CyPath® Lung sales forecast for test marketing program by 85% during the second quarter

SAN ANTONIO, Texas--(BUSINESS WIRE)-- [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 June 30, 2024.

Key Highlights

- Generated quarterly revenue of \$2.4 million in the second quarter of 2024.
- Limited market launch in Texas has realized more than 963% annualized growth rate for [CyPath® Lung](#) orders in first six months of 2024 over full-year 2023, with second quarter 2024 sales up 217% over first quarter 2024 sales.
- Forecasting upwards of \$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 85% from the original forecast reported in the 2023 Annual Report, which would result in a 2,429% year-over-year full-year growth.
- Number of physician offices ordering CyPath® Lung is up 144% since Jan. 1, 2024.
- Referrals and word-of-mouth from physicians, including key opinion leaders (KOLs), continue to drive strong uptake of CyPath® Lung in states beyond Texas; now receiving CyPath® Lung orders from physicians in eight states, up from six in the first quarter of 2024. In addition to previously reported orders from Pennsylvania, New Jersey, North Carolina, Arizona, and Michigan, physicians in California and Ohio have also begun ordering CyPath® Lung tests.
- 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.
- Successfully closed a \$1.75 million registered direct offering and concurrent private

placement to fund continued growth.

Management Commentary

“We are encouraged by the momentum we've achieved in the second quarter, with CyPath[®] Lung sales growing 217% over the previous quarter and exceeding our initial forecasts,” bioAffinity President and Chief Executive Officer Maria Zannes said. “This growth underscores the increasing recognition of the role CyPath[®] Lung can play in the early detection of lung cancer, a disease where early diagnosis can significantly improve patient outcomes. As we expand our reach beyond Texas, the positive reception from physicians across multiple states reinforces our belief that CyPath[®] Lung will have a significant impact in lung cancer diagnostics, a U.S. market projected to reach \$4.7 billion by 2030.”

“Our strategic focus remains on scaling our operations and solidifying our position in this market, supported by a strong foundation of word-of-mouth referrals and physician enthusiasm,” Zannes continued. “With our experienced sales and support teams in place, we are well-prepared to meet the growing demand and continue market expansion. As we look ahead, we believe our efforts will not only drive further growth but also bring us closer to our mission of improving patient lives.”

Second Quarter Financial Results

Revenue for the second quarter of 2024 was \$2.4 million, compared with \$20,000 revenue for the prior-year period. The majority of the year-over-year increase is through the acquisition of 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 \$402,000 for the second quarter of 2024, compared with \$335,000 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 \$51,000 for the second quarter of 2024, compared with \$35,000 for the second quarter of 2023. The increase was primarily attributable to an increase in compensation costs and benefits from the addition of new clinical development personnel.

Selling, general and administrative expenses were \$2.5 million for the second quarter of 2024, compared with \$1.4 million for the comparable period in 2023. The increase was primarily attributed 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 second quarter of 2024 was \$2.1 million, or \$0.19 per share, compared with a net loss of \$1.7 million, or \$0.20 per share, for the comparable period in 2023.

Cash and cash equivalents as of June 30, 2024, were \$0.8 million, compared with \$2.8 million as of December 31, 2023. bioAffinity Technologies raised aggregate gross proceeds of \$1.75 million in a registered direct offering, concurrent private placement, and warrant inducement transaction that closed on Aug. 5, 2024.

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 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 raising full-year CyPath® Lung sales forecast for test marketing program by 85% during the second quarter which would result in a 2,429% year-over-year full-year growth, forecasting upwards of \$9.6 million in 2024 revenues for Precision Pathology Laboratory Services, up 23% over 2023, referrals and word-of-mouth from physicians, including KOLs, continuing to drive strong uptake of CyPath® Lung in states beyond Texas, advancing new product development initiatives in collaboration with 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 companion test with bronchoscopy, the increasing recognition of CyPath® Lung's critical role in the early detection of lung cancer, CyPath® Lung setting a new standard in lung cancer diagnostics, scaling the Company's operations and solidifying its position in the lung cancer diagnostics market, being well-prepared with the Company's enhanced sales and support teams in place to meet the growing demand and continue its national expansion, and the Company's efforts to drive further growth and bring it closer to its mission of improving patient lives through innovative, noninvasive cancer diagnostics. 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 accelerate the commercialization of CyPath® Lung and capitalize on the lung

cancer diagnostics market; the ability of CyPath® Lung to provide the anticipated benefits to patients and physicians; 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.

bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 801,311	\$ 2,821,570
Accounts and other receivables, net	1,595,626	811,674
Inventory	29,768	18,484
Prepaid expenses and other current assets	253,726	321,017
Total current assets	<u>2,680,431</u>	<u>3,972,745</u>
Non-current assets:		
Property and equipment, net	449,250	458,633
Operating lease right-of-use asset, net	324,942	370,312
Finance lease right-of-use asset, net	973,358	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	804,306	833,472
Other assets	19,675	16,060
Total assets	<u>\$ 6,656,448</u>	<u>\$ 8,221,552</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 848,102	\$ 604,789
Accrued expenses	969,093	1,149,811
Unearned revenue	26,135	33,058
Operating lease liability, current portion	98,593	94,708
Finance lease liability, current portion	380,259	365,463
Notes payable, current portion	4,106	—
Total current liabilities	<u>2,326,288</u>	<u>2,247,829</u>
Non-current liabilities:		
Finance lease liability, net of current portion	641,566	835,467
Operating lease liability, net of current portion	232,714	283,001
Notes payable, net of current portion	22,766	—
Total liabilities	<u>3,223,334</u>	<u>3,366,297</u>
Commitments and contingencies		
Stockholders' equity:		

Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at June 30, 2024, and December 31, 2023

Common stock, par value \$0.007 per share; 100,000,000 shares authorized; 11,487,046 and 9,394,610 issued and outstanding at June 30, 2024, and December 31, 2023, respectively	79,407	65,762
Additional paid-in capital	52,030,280	49,393,972
Accumulated deficit	(48,676,573)	(44,604,479)
Total stockholders' equity	3,433,114	4,855,255
Total liabilities and stockholders' equity	\$ 6,656,448	\$ 8,221,552

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net Revenue	\$ 2,397,652	\$ 19,738	\$ 4,804,043	\$ 20,659
Operating expenses:				
Direct costs and expenses	1,407,710	1,234	2,981,151	1,322
Research and development	402,433	335,125	796,072	704,741
Clinical development	51,462	35,260	100,422	54,888
Selling, general, and administrative	2,472,775	1,404,917	4,658,719	2,552,792
Depreciation and amortization	151,070	21,552	300,707	43,236
Total operating expenses	4,485,450	1,798,088	8,837,071	3,356,979
Loss from operations	(2,087,798)	(1,778,350)	(4,033,028)	(3,336,320)
Other income (expense):				
Interest income	5,186	44,124	11,313	82,778
Interest expense	(22,249)	(1,360)	(45,799)	(3,015)
Other expense	1	—	4,511	—
Total other income (expense)	(17,062)	42,764	(29,975)	79,763
Net loss before provision for income tax expense	(2,104,860)	(1,735,586)	(4,063,003)	(3,256,557)
Income tax expense	5,419	4,587	9,091	16,406
Net loss	\$ (2,110,279)	\$ (1,740,173)	\$ (4,072,094)	\$ (3,272,963)
Net loss per common share, basic and diluted	\$ (0.19)	\$ (0.20)	\$ (0.38)	\$ (0.38)
Weighted average common shares outstanding	11,389,308	8,520,714	10,655,483	8,477,656

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bioAffinity Technologies
Julie Anne Overton
Director of Communications

jao@bioaffinitytech.com

Investor Relations

Dave Gentry

RedChip Companies Inc.

1-800-RED-CHIP (733-2447)

Or 407-491-4498

BIAF@redchip.com

Source: bioAffinity Technologies, Inc.