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, 2023

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 November 14, 2023, bioAffinity Technologies, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended September 30, 2023. 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, 2023
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 15, 2023

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 Third Quarter 2023 Financial Results and Provides Business Update

SAN ANTONIO (Nov. 14, 2023) – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer and other diseases of the lung, today reported financial results for the three and nine months ended Sept. 30, 2023, and provided a business update.

Highlights from the third quarter of 2023 and subsequent weeks included:

Corporate and Commercial Highlights

- The Company's wholly owned Precision Pathology Laboratory Services (PPLS) subsidiary acquired the non-medical assets of Village Oaks Pathology Services on Sept. 18, 2023. The clinical laboratory, certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and accredited by the College of American Pathologists (CAP), is now owned and operated by PPLS.

- The Centers for Medicare and Medicaid Services (CMS) released a preliminary payment decision in September 2023 for the Current Procedural Terminology (CPT) code for CyPath® Lung, our noninvasive test for lung cancer, issued by the American Medical Association (AMA) in June 2023. CMS is expected to finalize the 2024 payment for CyPath® Lung in November 2023 with an effective date of Jan. 1, 2024. CMS' final payment determination is expected to favorably impact PPLS' established fee schedule for CyPath® Lung, determining reimbursement by private insurance carriers.

- The U.S. Department of Defense (DOD) purchased CyPath® Lung tests for use in an observational study on active military personnel at high risk for developing lung cancer (NCT05870592) and for research on the use of bronchoalveolar lavage fluid to assess cardiopulmonary function and exercise performance in military personnel post-COVID-19 infection.

- Dallas J. Coleman joined the Company as National Director of Sales responsible for leading the CyPath® Lung sales team, sourcing new business opportunities and expanding the pilot market launch across Texas in preparation for the national rollout. Previously, Mr. Coleman was an Executive Account Manager for the respiratory portfolio of Olympus America's therapeutic solutions division.

Management Commentary

"The transformative strategic acquisition of PPLS in September gives us a strong revenue base as we move forward with the rollout of our game-changing CyPath® Lung test. PPLS is forecast to contribute $8.7 million in net revenue over the next 12 months, with additional upside as we work to expand sales of CyPath® Lung regionally and nationally," bioAffinity President and Chief Executive Officer Maria Zannes said.

"We achieved another significant milestone in September when we received a preliminary payment decision from CMS for CyPath® Lung that is in line with the July 2023 payment recommendation from the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests. The CMS payment determination is a crucial step forward in our commercial rollout of our noninvasive test to improve detection of early-stage lung cancer," Ms. Zannes said. " As we begin our pilot marketing program for CyPath® Lung in Texas, we look forward to applying what we learned in our beta market testing and informing and accelerating our regional and national rollout plans. As we plan to expand the geographic reach, add prescribing physicians, and partner with larger medical systems, we anticipate substantial revenue growth for CyPath® Lung."

Third Quarter Financial Results

Revenue for the third quarter of 2023 increased to $298,484, up from $1,150 in the prior-year period. Prior to the Sept. 18, 2023, acquisition of PPLS, bioAffinity Technologies' revenue was generated from royalties from sales of CyPath® Lung as a laboratory developed test (LDT), clinical flow cytometry services related to CyPath® Lung, and CyPath® Lung tests purchased by the DOD. Post-acquisition of PPLS, beginning Sept. 19, 2023, the income from royalties and clinical flow cytometry services was classified as related party income and eliminated from consolidated net revenues, while additional revenue streams from PPLS were consolidated. PPLS generates three sources of revenue: patient service fees, histology service fees and medical director fees. Sales to the DOD were $4,500 for the third quarter of 2023.

Research and development expenses were $330,376 for the third quarter of 2023, compared with $319,744 for the comparable period in 2022. The increase was primarily due to higher compensation costs from adding research personnel and higher costs for lab supplies and reagents.

Clinical development expenses were $106,422 for the third quarter of 2023, compared with $60,941 for the third quarter of 2022. The increase was primarily due to higher professional fees related to clinical strategy evaluation for the pivotal clinical trial of CyPath® Lung.

Selling, general and administrative expenses were $2.0 million for the third quarter of 2023, compared with $595,702 for the comparable period in 2022. The increase was primarily attributed to higher accounting, legal and professional fees related to the acquisition of PPLS and being a publicly traded company, higher board compensation, employee and stock-based compensation, and sales and marketing costs for commercialization of CyPath® Lung.

Net loss for the third quarter of 2023 was $2.3 million, or $0.26 per share, compared with a net loss of $4.9 million, or $1.17 per share, for the comparable period in 2022.

Cash and cash equivalents were $4.5 million as of Sept. 30, 2023, compared with $11.4 million as of December 31, 2022. Management will assess opportunities to raise additional capital when the markets are favorable.

2023 Financial Outlook and Next Twelve Months

The Company expects to generate between $2.1 and $2.3 million in net revenues for 2023. This is up from $4,800 in 2022. Over the next 12 months (fourth quarter 2023 to third quarter 2024), the Company expects to generate between $8.4 and $9.0 million in net revenues.

CyPath® Lung sales are expected to trend up as the Company expands its sales force and marketing efforts. Through Sept. 30, 2023, the pilot marketing program for CyPath® Lung had 20 physicians enrolled, 15 physicians who had ordered tests for their patients and 44 CyPath® Lung diagnostic tests conducted. Over the next 12 months (fourth quarter 2023 to third quarter 2024), the Company expects to grow the number of physicians enrolled to 82, the number of physicians that have ordered to 61, and the number of CyPath® Lung diagnostic tests conducted to 284, which will contribute gross revenues of $457,166. To achieve this growth, the Company plans to expand its sale force from two to five in strategic metropolitan areas of Texas, promote CyPath® Lung through branding and marketing assets, and benefit from broader reimbursement from private payers and public health insurance programs, including Medicare and Medicaid, based on CMS' final payment determination.

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 treatment. The Company's first product, CyPath® Lung, is a noninvasive test that has shown high sensitivity and specificity 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. Research and optimization of the Company's platform technologies are conducted in its laboratories at PPLS and The University of Texas at San Antonio. For more information, visit www.bioaffinitytech.com and follow us on LinkedIn, Facebook and X.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are identified by the use of the words "could," "believe," "anticipate," "intend," "estimate," ""expect," "may," "continue," "predict," "potential," "project" and similar expressions that are intended to identify forward-looking statements and include statements regarding CMS finalizing the 2024 payment for CyPath® Lung in November 2023 with an effective date of Jan. 1, 2024, CMS' final payment determination favorably impacting PPLS' established fee schedule for CyPath® Lung, determining reimbursement by private insurance carriers, moving forward with the rollout of the Company's CyPath® Lung test, PPLS contributing $8.7 million in net revenue over the next 12 months, additional upside as the Company expands sales of CyPath® Lung regionally and nationally, informing and accelerating the Company's regional and national rollout plans by applying what it learned in its beta market testing, anticipating substantial revenue growth for CyPath® Lung as the Company expands the geographic reach, adds prescribing physicians, and partners with larger medical systems, assessing opportunities to raise additional capital when the markets are favorable, generating between $2.1 and $2.3 million in net revenues for 2023, generating between $8.4 and $9.0 million in net revenues over the next 12 months, CyPath® Lung sales trending up as the Company expands its sales force and marketing efforts, over the next 12 months growing the number of physicians enrolled in the Company's pilot program to 82, the number of physicians that have ordered tests to 61, and the number of CyPath® Lung diagnostic tests conducted to 284, contributing gross revenues of $457,166, expanding the Company's sale force from two to five in strategic metropolitan areas of Texas, promoting CyPath® Lung through new branding and marketing assets, and benefiting from broader reimbursement from private payers and public health insurance programs, including Medicare and Medicaid, based on CMS' final payment determination. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of 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 roll out its CyPath® Lung test as planned, the Company's ability to generate substantial revenue for CyPath® Lung by expanding its geographic reach, adding prescribing physicians and partnering with larger medical systems, the Company's ability to raise additional capital when the markets are favorable, the Company's ability to expand its sales force and marketing efforts, the Company's ability to grow the number of physicians enrolled in the Company's pilot program, the number of physicians that have ordered tests, and the number of CyPath® Lung diagnostic tests conducted, the Company's ability to promote CyPath® Lung through new branding and marketing assets and benefit from broader reimbursement from private payers and public health insurance programs and the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company's Quarterly Reports on Form 10-Q, the Company's Current Reports on Form 8-K and subsequent filings filed with the Securities and Exchange Commission. The information in this release is provided only as of the date of this release, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events, except as required by law.

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bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,509,236	$ 11,413,759
Accounts and other receivables, net	1,108,414	10,489
Inventory	9,908	5,540
Prepaid expenses and other current assets	382,651	531,899
Total current assets	6,010,209	11,961,687
Non-current assets:		
Property and equipment, net	512,152	214,438
Operating lease right-of-use asset, net	392,347	—
Finance lease right-to-use, net	1,262,087	—
Goodwill	1,148,553	—
Intangible assets, net	848,056	—
Other assets	16,060	6,000
Total assets	$ 10,189,464	$ 12,182,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 827,407	$ 345,042
Accrued expenses	643,786	541,894
Unearned revenue	38,250	—
Operating lease liability, current portion	484,211	—
Finance lease liability, current portion	364,934	—
Loan payable	—	251,746
Total current liabilities	1,958,588	1,138,682
Non-current liabilities:		
Finance lease liability, net of current portion	921,546	—
Operating lease liability, net of current portion	315,421	—
Total liabilities	3,195,555	1,138,682
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, 2023, and December 31, 2022	—	—
Common stock, par value $0.007 per share; 25,000,000 shares authorized (increase from 14,285,714 approved by shareholder vote on June 6, 2023); 9,216,883 issued and outstanding at September 30, 2023; and 8,381,324 shares issued and outstanding at December 31, 2022	64,535	58,669
Additional paid-in capital	49,160,689	47,652,242
Accumulated deficit	(42,231,315)	(36,667,468)
Total stockholders' equity	6,993,909	11,043,443
Total liabilities and stockholders' equity	$ 10,189,464	$ 12,182,125

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Net Revenue	$ 298,484	$ 1,150	$ 319,143	$ 2,457
Cost of sales	74,704	146	76,025	292
Gross profit	223,780	1,004	243,118	2,165
Operating expenses:				
Research and development	330,376	319,744	1,035,118	949,388
Clinical development	106,422	60,941	161,310	141,684
General and administrative	2,023,917	595,702	4,576,708	1,295,558
Depreciation and amortization	57,569	773	100,805	2,852
Total operating expenses	2,518,284	977,160	5,873,941	2,389,482
Loss from operations	(2,294,504)	(976,156)	(5,630,823)	(2,387,317)
Other income (expense):				
Interest income	27,193	7,414	109,971	8,261
Interest expense	(8,785)	(896,502)	(11,801)	(2,443,350)
Other income	4,606	—	4,606	—
Other expense	(17,100)	—	(17,100)	—
Gain on extinguishment of debt	—	—	—	212,258
Fair value adjustments on convertible notes payable	—	(3,053,914)	—	(1,866,922)
Net loss before provision for income taxes	(2,288,590)	(4,919,158)	(5,545,147)	(6,477,070)
Income tax expense	(2,294)	(300)	(18,700)	(2,460)
Net loss	$ (2,290,884)	$ (4,919,458)	$ (5,563,847)	$ (6,479,530)
Net loss per common share, basic and diluted	$ (0.26)	$ (1.17)	$ (0.65)	$ (2.03)
Weighted average common shares outstanding, basic and diluted	8,696,554	4,203,781	8,551,154	3,194,765