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, 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 August 14, 2023, bioAffinity Technologies, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended June 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 August 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: August 14, 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 Second Quarter 2023 Financial Results and Provides Business Update

SAN ANTONIO (Aug. 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 six months ended June 30, 2023, and provided a business update.

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

Corporate and Commercial Highlights

- The American Medical Association (AMA) issued a Current Procedural Terminology (CPT) code for use with CyPath® Lung with an effective date of Oct. 1, 2023. CPT codes provide a uniform system to identify medical services and procedures and seek reimbursement from private payers and public health insurance programs, including Medicare and Medicaid.
- The 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.
- Michael Dougherty joined the management team as Chief Financial Officer. Previously, he served as CFO of Amazon's Alexa commercial domains with responsibility for financial strategy over Alexa's multibillion-dollar investments in AI-generated customer experiences.
- The Company launched a pilot marketing and sales program in select cities in Texas to provide insights and strategies for the successful product rollout for CyPath® Lung.

Research and Development Highlights

- Presented advancements in CyPath® Lung at the Cleveland Clinic's invitation-only fourth annual "*Advances in Early Lung Cancer Detection*" symposium, which focuses on accelerating the development and implementation of new technologies and methods for the early detection of lung cancer.
- Presented a poster titled "Development of porphyrin-stained polystyrene compensation beads for use on an automated analysis platform" at CYTO 2023, the annual Congress for the International Society for the Advancement of Cytometry, that demonstrated the suitability of the Company's proprietary compensation beads for commercial use with flow cytometry, including with CyPath® Lung.

- Presented a poster titled "Vitamin B12 deprivation does not phenocopy selective cytotoxicity of CD320 and LRP2 silencing" at the University of Massachusetts T.H. Chan Medical School's fifth annual RNA Therapeutics Symposium demonstrating that deprivation of vitamin B12 does not play a role in the selective cytotoxicity of cancer cells observed after silencing the expression of CD320 and LRP2; this research follows the Company's discovery that using small interfering RNA (siRNA) to knock down CD320 and LRP2 killed cancer cells *in vitro* without harming healthy cells.

Management Commentary

“Our sales team is implementing a test market pilot program of CyPath® Lung across various target markets in Texas, and we are encouraged with their progress. The pilot program is a tactical program to test various marketing and selling approaches to accelerate the development of a successful regional and then national roll out of the CyPath® Lung test. Issuance of a CPT code by the AMA specifically for CyPath® Lung is another important milestone that we believe signals the value our diagnostic adds to the clinical care of patients at high risk for developing lung cancer,” bioAffinity President and Chief Executive Officer Maria Zannes said.

“We are building brand awareness and market positioning at the same time we are showcasing our innovation at prestigious medical and scientific conferences. The result is increased recognition and adoption of CyPath® Lung, including interest by the DOD. We expect revenues from CyPath® Lung to grow as we expand our geographic reach, add prescribing physicians and focus on larger medical systems,” Ms. Zannes added.

Second Quarter Financial Results

Revenue for the second quarter of 2023 was $20,000, compared with $1,000 for the prior-year period. Revenue is generated from royalties from the Company’s licensee, Precision Pathology Services, from sales of CyPath® Lung as a laboratory developed test, from clinical flow cytometry services provided to Precision Pathology Services related to CyPath® Lung and from CyPath® Lung tests purchased by the DOD. Sales to the DOD were $10,000 for the second quarter of 2023.

Research and development expenses were $335,000 for the second quarter of 2023, compared with $248,000 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 $35,000 for the second quarter of 2023, compared with $28,000 for the second quarter of 2022. The increase was primarily due to higher professional fees related to clinical strategy evaluation as the Company prepares to launch the CyPath® Lung pivotal trial.

Selling, general and administrative expenses were $1.4 million for the second quarter of 2023, compared with $409,000 for the comparable period in 2022. The increase was primarily attributed to higher consulting, legal and professional fees related to being a publicly traded company, higher board compensation, and sales and marketing costs for commercialization of CyPath® Lung.

Net loss for the second quarter of 2023 was $1.7 million, or $0.20 per share, compared with a net loss of $88,000, or $0.03 per share, for the comparable period in 2022.

Cash and cash equivalents were $8.3 million as of June 30, 2023, compared with $11.4 million as of December 31, 2022. bioAffinity Technologies believes that its available cash will be sufficient to fund planned operations for at least the next 12 months.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted 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 Services. OncoSelect® Therapeutics, LLC, a subsidiary of bioAffinity Technologies, is advancing its discoveries shown *in vitro* to kill cancer cells without harm to normal cells. Research and optimization of the Company's platform technologies are conducted in its laboratories at The University of Texas at San Antonio. For more information, visit www.bioaffinitytech.com.

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 implementing a test market pilot program of CyPath® Lung across various target markets in Texas, accelerating the development of a successful regional and then national roll out of the CyPath® Lung test, building brand awareness and market positioning while showcasing the Company at prestigious medical and scientific conferences, and growing revenues from CyPath® Lung as the Company expands its geographic reach, adds prescribing physicians and focuses on larger medical systems. 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 accelerate the development of a successful regional and then national roll out of the CyPath® Lung test, the Company's ability to build brand awareness and market positioning for the CyPath® Lung test, the Company's ability to grow revenues from CyPath® Lung by expanding its geographic reach, adding prescribing physicians and focusing on larger medical systems, 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

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,279,182	$ 11,413,759
Accounts and other receivables, net	90,233	10,489
Inventory	10,101	5,540
Prepaid and other current assets	279,687	531,899
Total current assets	8,659,203	11,961,687
Property and equipment, net	207,377	214,438
Other assets	6,920	6,000
Total assets	$ 8,873,499	$ 12,182,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 174,404	$ 345,042
Accrued expenses	515,663	541,894
Unearned revenue	42,750	—
Loan payable	42,334	251,746
Total current liabilities	775,151	1,138,682
Total liabilities	775,151	1,138,682
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at June 30, 2023, and December 31, 2022	—	—
Common stock, par value $0.007 per share; 25,000,000 shares authorized; 8,555,365 issued and outstanding at June 30, 2023; and 8,381,324 shares issued and outstanding at December 31, 2022	59,887	58,669
Additional paid-in capital	47,978,892	47,652,242
Accumulated deficit	(39,940,431)	(36,667,468)
Total stockholders' equity	8,098,348	11,043,443
Total liabilities and stockholders' equity	$ 8,873,499	$ 12,182,125

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue	$ 19,738	$ 1,306	$ 20,659	$ 1,306
Cost of sales	1,234	146	1,322	146
Gross profit	18,504	1,160	19,337	1,160
Operating expenses:				
Research and development	335,125	248,419	704,741	528,267
Clinical development	35,260	28,240	54,888	80,744
General and administrative	1,426,469	408,619	2,596,027	803,311
Total operating expenses	1,796,854	685,279	3,355,657	1,412,322
Loss from operations	(1,778,350)	(684,119)	(3,336,320)	(1,411,162)
Other income (expense):				
Interest income	44,124	276	82,778	847
Interest expense	(1,360)	(399,265)	(3,015)	(1,546,848)
Gain on extinguishment of debt	—	212,258	—	212,258
Fair value adjustments on convertible notes payable	—	782,798	—	1,186,992
Net loss before provision for income taxes	(1,735,586)	(88,052)	(3,256,557)	(1,557,913)
Income tax expense	4,587	—	16,406	2,159
Net loss	$ (1,740,173)	$ (88,052)	$ (3,272,963)	$ (1,560,072)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.03)	$ (0.38)	$ (0.58)
Weighted average common shares outstanding	8,520,714	2,693,511	8,477,656	2,687,431

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