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

March 31, 2023
Date of Report (Date of earliest event reported)

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 Operations and Financial Condition.

On March 31, 2023, the Company issued a press release regarding its financial results for the three and 12 months ended December 31, 2022. The press release is attached as Exhibit 99.1 to this Form 8-K.

The information contained in this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release of bioAffinity Technologies, Inc., dated March 31, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOAFFINITY TECHNOLOGIES, INC.

By: */s/ Maria Zannes*
Maria Zannes
President and Chief Executive Officer

Dated: April 3, 2023

Exhibit 99.1

News Release

bioAffinity Technologies Reports Fourth Quarter and Full Year 2022 Financial Results

Conference Call Scheduled for April 3, 2023, at 9:00 a.m. Eastern Time

SAN ANTONIO, Texas (March 31, 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 12 months ended December 31, 2022.

Financial Highlights

- Raised net proceeds of approximately $6.0 million from an initial public offering (IPO) in September 2022
- Converted nearly $16 million in debt, related accrued interest and fair value adjustments into shares of common stock in connection with the IPO
- Raised an additional $7.8 million from the exercise of warrants and stock options

Corporate and Operational Highlights

- Announced publication in Respiratory Research of an article titled "Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning" detailing results of bioAffinity Technologies' clinical validation trial, which showed CyPath® Lung had 92% sensitivity and 87% specificity in high-risk patients with nodules smaller than 20 millimeters or no nodules in the lung, with an area under the ROC curve of 94%
- Selected a contract research organization to manage the pivotal trial intending to seek U.S. Food and Drug Administration clearance of CyPath® Lung as a Class II IVD medical device for the detection of lung cancer; the pivotal trial is expected to recruit 1,800 patients beginning in 2023, with participants followed for at least one year to determine the presence of lung cancer
- Research continues aimed at the expansion of the Company's flow cytometric platform technology for use in detecting additional lung diseases, including Chronic Obstructive Pulmonary Disease (COPD)
- Announced publication in the Journal of Visualized Experiments of an article titled "Porphyrin-Modified Beads for Use as Compensation Controls in Flow Cytometry" describing the beads engineered by the Company for use with its CyPath® Lung test

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- Received Notice of Allowance for a U.S. patent protecting the targeted delivery of novel cancer treatments using porphyrin compounds for bioAffinity Technologies' wholly owned subsidiary, OncoSelect® Therapeutics
- Awarded therapeutic patents in China, Mexico and Australia for compounds comprised of porphyrins conjugated to chemotherapeutic agents that can provide selective treatment for cancer; the Company's global patent portfolio now includes the U.S., Australia, Canada, China, France, Germany, Hong Kong, Italy, Mexico, Spain, Sweden and the United Kingdom
- Expanded the Company's Scientific and Medical Advisory Board with the appointments of Sheila Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at South Texas Veterans Health Care, and David Hill, M.D., National Board Member of the American Lung Association and assistant clinical professor of medicine at Yale University School of Medicine
- Strengthened the diagnostics division with the appointment of Rossella Titone, Ph.D., and Alvaro Souto Padron de Figueiredo, Ph.D., who bring significant technical expertise in flow cytometry and clinical research across various cancers
- Appointed Julie Anne Overton, a veteran of print and broadcast journalism, corporate communications and federal public affairs, as Director of Communications
- Scheduled to ring the Nasdaq closing bell on April 5 to commemorate the Company's 2022 IPO

Management Commentary

"Through the capital raised during and following our IPO, 2022 was a landmark year for bioAffinity Technologies as we executed on our goal to become a leader in non-invasive early-stage cancer diagnosis by bringing our first flow cytometry-based diagnostic, CyPath® Lung, to market. With key research and leadership appointments, we are engaging clinicians and patients on the value of early lung cancer screening, lowering healthcare costs and raising the survival rate for one of the deadliest cancers," said Maria Zannes, President and Chief Executive Officer of bioAffinity Technologies.

Low-dose computed tomography (LDCT) is the standard of care for screening patients at high risk for lung cancer and can significantly increase survival by finding early-stage cancer. But screening's low positive predictive rate of 3.8% means that only four people out of 100 who get a positive screening result will actually have lung cancer. CyPath® Lung assists clinical decision-making for patients whose screening results are not clear. Physicians can order bioAffinity's patient-friendly CyPath® Lung test to confirm or rule out cancer, reducing the need for biopsy and other costly invasive procedures, and providing greater clarity to determine next steps in patient care.

"Our ongoing pilot launch of CyPath® Lung in Texas continues to provide value by helping us to refine positioning, gather valuable insights from labs and healthcare providers, and optimize logistics throughout the care pathway, from ordering the test to reporting results. By building upon real-world feedback from this test market, we are enhancing the value proposition of CyPath® Lung and can achieve more impactful adoption as we prepare for commercial expansion," Ms. Zannes said.

Fourth Quarter Financial Results

Revenue for the fourth quarter of 2022 was approximately $2,500, compared with no revenue for the prior-year period. Revenue was derived from the sale of CyPath® Lung as a Laboratory Developed Test (LDT).

Research and development expenses were $429,000 for the fourth quarter of 2022, compared with $318,000 for the comparable period in 2021. General and administrative expenses were $1.2 million for the fourth quarter of 2022, compared with $341,000 for the comparable period in 2021.

Net loss for the fourth quarter of 2022 was $1.7 million, compared with a net loss of $5.6 million for the comparable period in 2021.

Full Year Financial Results

Revenue for 2022 was approximately $5,000, compared with no revenue for 2021.

Research and development expenses were $1.1 million in 2022, compared with $1.0 million in 2021. The increase was primarily due to higher personnel, legal and research costs, partially offset by lower stock-based compensation expense.

General and administrative expenses were $2.7 million in 2022, compared with $1.1 million in 2021. The increase was primarily due to higher consulting, legal and professional fees related to the Company's IPO and compliance with public company reporting requirements. The increase was also attributed to higher stock-based compensation expense, as well as hiring-related expenses to support the commercial launch of CyPath® Lung.

Net loss for 2022 was $8.2 million, or $1.81 per share, compared with a net loss for 2021 of $6.3 million, or $2.36 per share.

Cash and cash equivalents as of December 31, 2022, were $11.4 million. On September 6, 2022, bioAffinity Technologies raised net proceeds of $6.0 million from an IPO of 1,282,600 units, with each unit consisting of one share of common stock, one tradeable warrant to purchase one share of common stock and one non-tradable warrant. An additional $7.8 million was raised from the exercise of warrants and options. bioAffinity Technologies believes that its available cash will be sufficient to fund planned operations for at least the next 12 months.

Conference Call and Webcast

Management will host a conference call on Monday, April 3, 2023, at 9:00 a.m. Eastern time to discuss those results and answer questions.

Date:	Monday, April 3, 2023
Time:	9:00 a.m. Eastern time
Toll Free:	877-270-2148
International:	412-902-6510
Webcast:	Webcast link

A replay of the event will be available for 90 days at the webcast link above, which can also be found in the Investor Relations section of bioAffinity Technologies' website at ir.bioaffinitytech.com.

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 forward-looking statements, including statements regarding the anticipated use of proceeds from the Company's offering of common shares. Forward-looking statements can be identified by words such as "believes," "expects," "estimates," "intends," "may," "plans," "will" and similar expressions, or the negative of these words. 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. Readers of this press release are cautioned not to place undue reliance on any forward-looking statements. 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.
Consolidated Balance Sheets

	December 31,	
	2022	**2021**

ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,413,759	$ 1,360,638
Accounts and other receivables, net	10,489	1,530
Inventory	5,540	—
Prepaid expenses and other current assets	531,899	76,065
Total current assets	11,961,687	1,438,233
Deferred offering costs	—	7,942
Property and equipment, net	214,438	4,633
Other assets	6,000	2,500
Total assets	$ 12,182,125	$ 1,453,308
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 345,042	$ 230,407
Accrued expenses	541,894	483,501
Accrued interest	—	1,121,392
Current portion of Paycheck Protection Program loan	—	52,074
Loan payable	251,746	—
Convertible notes payable at fair value	—	11,152,151
Total current liabilities	1,138,682	13,039,525
Paycheck Protection Program loan, less current portion	—	160,184
Total liabilities	1,138,682	13,199,709
Commitments and contingencies		
Convertible preferred stock, par value $0.001 per share; 20,000,000 shares authorized; 0 and 756,558 shares issued and outstanding, aggregate liquidation preference of $0 and $5,825,648 at December 31, 2022 and 2021, respectively	—	4,044,318
Stockholders' equity (deficit):		
Preferred stock, no shares issued or outstanding at December 31, 2022 and 2021, respectively	—	—
Common Stock, par value $0.007 per share; 14,285,714 shares authorized; 8,381,324 and 2,677,140 shares issued and outstanding as of December 31, 2022 and 2021, respectively	58,669	18,740
Additional paid-in capital	47,652,242	12,703,896
Accumulated deficit	(36,667,468)	(28,513,355)
Total stockholders' equity (deficit)	11,043,443	(15,790,719)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 12,182,125	$ 1,453,308

bioAffinity Technologies, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2022 and 2021

	2022	2021
Revenue	$ 4,803	$ —
Cost of sales	467	—
Gross profit	4,336	—
Operating expenses:		
Research and development	1,142,777	1,007,476
Clinical development	145,546	130,475
Selling, general and administrative	2,727,071	1,068,871
Total operating expenses	4,015,394	2,206,822
Loss from operations	(4,011,058)	(2,206,822)
Other income (expense):		
Interest income	46,708	424
Interest expense	(2,532,640)	(1,001,854)
Gain on extinguishment of debt	212,258	239,200
Fair value of warrants issued	—	(4,080,339)
Fair value adjustments on convertible notes payable	(1,866,922)	724,928
Loss before income taxes	(8,151,654)	(6,324,463)
Income tax expense	(2,459)	(1,950)

Net loss	$ (8,154,113)	$ (6,326,413)
Net loss per common share, basic and diluted	$ (1.81)	$ (2.36)
Weighted average common shares outstanding	4,498,964	2,675,270

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