

**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

January 24, 2023

Date of Report (Date of earliest event reported)

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)

**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 8.01. Other Events.

Recent Press Release

On January 24, 2023, the Company issued a press release announcing the publication of the results of a clinical trial. The press release is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of bioAffinity Technologies, Inc., dated January 24, 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: January 24, 2023



News Release

For Immediate Release

bioAffinity Technologies Announces Publication of Results of Clinical Trial in Peer-Reviewed Journal Respiratory Research***Noninvasive Test Developed Using Machine Learning Detects Early-Stage Lung Cancer with High Sensitivity and Specificity***

SAN ANTONIO, TX – Jan. 24, 2023 – bioAffinity Technologies, Inc. (NASDAQ: BIAF; BIAFW) today announced publication of “*Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning*” detailing results of the Company’s clinical trial for its non-invasive diagnostic CyPath® Lung in Respiratory Research, one of the leading peer-reviewed open access journals in the field of respiratory medicine.

CyPath® Lung showed 92% sensitivity and 87% specificity in high-risk patients who had nodules smaller than 20 millimeters or no nodules in the lung, with an area under the ROC curve of 94%. Overall, the test resulted in specificity of 88% and sensitivity of 82%, similar to far more invasive procedures currently used to diagnose lung cancer. More than half of those in the cancer cohort had early Stage I or II lung cancer. CyPath® Lung detected multiple forms of cancer including adenocarcinoma, squamous cell carcinoma and small cell lung cancer.

“The fact that CyPath® Lung can accurately predict lung cancer at an early stage in patients with small nodules is particularly important. Findings of lesions between six and 20 millimeters as a result of lung cancer screening can lead to unnecessary invasive procedures or a ‘watchful waiting’ period for patients,” said Vivienne Rebel, MD, PhD, bioAffinity Chief Medical and Science Officer and Executive Vice President. “Our test is intended for use with patients who display these indeterminate nodules to increase the accuracy of lung cancer screening and provide certainty for patients and their physicians.”

“CyPath® Lung uses an automated flow-based approach combined with machine learning that can be put into routine lab use without requiring expert evaluation of samples or being subject to operator bias,” said Madeleine Lemieux, PhD, who is first author and led development of the automated analysis used in CyPath® Lung. “The entire sample is rapidly analyzed which ensures maximal sensitivity. The automated, numerical analysis captures complex interactions between lung cancer and the micro-environment to reliably predict the presence of lung cancer that would not be possible for even expert individuals to do from visual flow data.”

Before working with bioAffinity Technologies, Dr. Lemieux was a computational biologist at the Dana Farber Institute and Harvard Medical School. She has contributed to more than 40 publications leveraging data from high-throughput platforms. Dr. Lemieux and Dr. Rebel began their successful collaboration during their doctoral studies.

CyPath® Lung uses flow cytometry, a method able to interrogate individual cells in a fraction of a second, and automated analysis to identify parameters in sputum that are indicative of cancer. Unlike genomic or other molecular markers used in liquid biopsies, bioAffinity’s CyPath® technology does not collect genetic material for evaluation. Instead, CyPath® Lung analyzes the lung micro-environment and identifies whole cell populations that indicate cancer is present in the lung.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. (NASDAQ: BIAF; BIAFW) addresses the need for noninvasive detection 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.

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.

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