# 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 30, 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 7.01 Regulation FD Disclosure.**

On November 30, 2023, bioAffinity Technologies, Inc. (the "Company") issued a press release announcing that the Centers for Medicare and Medicaid Services ("CMS") has made a final determination for payment for CyPath® Lung, the Company's noninvasive test for early-stage lung cancer, for the 2024 calendar year and that CyPath® Lung is now on CMS' 2024 clinical laboratory fee schedule.

Based on the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests recommendation, in September 2023 CMS had previously released a preliminary payment decision for the Current Procedural Terminology ("CPT") code specific to CyPath® Lung. For the calendar year 2024 Medicare Clinical Lab Fee Schedule, CMS has finalized the panel's recommendation for CyPath® Lung for purposes of payment by Medicare. This payment information also serves as a reference for private payers and other public health insurance programs.

On November 30, 2023, the Company issued a press release disclosing the foregoing. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.1 and incorporated by reference into this Item 7.01.The information in this Item 7.01 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 7.01 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.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

**Item 8.01. Other Events.**

On November 30, 2023, the "Company issued a press release announcing that CMS has made a final determination for payment for CyPath® Lung, the Company's noninvasive test for early-stage lung cancer, for the 2024 calendar year and that CyPath® Lung is now on CMS' 2024 clinical laboratory fee schedule.

In March 2023, the Company applied to the American Medical Association ("AMA") for a CPT code specific to CyPath® Lung. At that time, Precision Pathology Services, now Precision Pathology Laboratory Services ("PPLS"), a subsidiary of the Company, billed for reimbursement of CyPath® Lung utilizing a combination of CPT codes associated with flow cytometry, including codes 88184, 88185 and 88188. Reimbursement amounts totaled approximately $300 using a combination of the flow cytometry codes that were descriptive of the test. Based on the existing flow cytometry codes, PPLS' fee schedule set the price of the test at $905 based on Medicare reimbursement.

In June 2023, the AMA issued a CPT code for use in reimbursement of CyPath® Lung, effective October 1, 2023, for private payers and public health insurance programs, including Medicare and Medicaid. The CPT Proprietary Laboratory Analyses (PLA) code assigned to CyPath® Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer."

In July 2023, the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests recommended crosswalking, or using payment for a similar existing test, to determine the payment for the CPT code specific to CyPath® Lung. In September 2023, CMS released a preliminary payment decision in line with the Medicare Advisory Panel's recommendation. The Company then submitted comments during the 30-day comment period in support of the preliminary decision to crosswalk the payment for CyPath® Lung to CPT code 0021U, which was $760 for the fourth quarter of 2023. Based on that payment, PPLS is currently billing $1,900 for CyPath® Lung. The 2024 Medicare Clinical Lab Fee Schedule will establish the 2024 Medicare payment for CyPath® Lung and serve as a reference for private payers and other public health insurance programs. In November 2023, CMS finalized the 2024 payment determination for CPT 0406U, effective January 1, 2024.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued by bioAffinity Technologies, Inc. on November 30, 2022 |
| 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: November 30, 2023

**Exhibit 99.1**

News Release

**CMS Posts Final Payment Determination for bioAffinity Technologies' CyPath® Lung Effective January 2024**

**SAN ANTONIO, Texas (Nov. 30, 2023) – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW),** a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer and other lung diseases, today announced that the Centers for Medicare and Medicaid Services (CMS) has made a final determination for payment for CyPath® Lung, a noninvasive test for early-stage lung cancer, for the 2024 calendar year.

"CyPath® Lung, our noninvasive test for the detection of early-stage lung cancer, is now on CMS' 2024 clinical laboratory fee schedule, a major milestone that facilitates reimbursement by both Medicare and private payers, which in turn should make our test even more attractive to both physicians and their patients at high risk for lung cancer," bioAffinity Technologies President and CEO Maria Zannes said. "The CMS payment determination is an important achievement in our strategic plan to ramp up the commercialization of CyPath® Lung."

Based on the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests recommendation, CMS previously released a preliminary payment decision for the Current Procedural Terminology (CPT) code specific to CyPath® Lung. For the calendar year 2024 Medicare Clinical Lab Fee Schedule, CMS finalized the panel's recommendation for CyPath® Lung for purposes of payment by Medicare. This payment information also serves as a reference for private payers and other public health insurance programs.

In June 2023, the American Medical Association (AMA) issued the CPT Proprietary Laboratory Analyses (PLA) code 0406U for CyPath® Lung with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer." CMS released a preliminary payment decision in September 2023, agreeing with the Medicare Advisory Panel's recommendation. In November 2023, CMS finalized the 2024 payment determination for CPT 0406U, effective January 1, 2024.

Physicians can order CyPath® Lung from Precision Pathology Laboratory Services, a subsidiary of bioAffinity Technologies. CyPath® Lung, a laboratory developed test (LDT), uses flow cytometry to identify cell populations in patient sputum that indicate malignancy. Automated data analysis developed using proprietary artificial intelligence can help determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin, TCPP, that is preferentially taken up by cancer and cancer-related cells. In a clinical trial, CyPath® Lung showed 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. Half of all patients in the trial who had cancer were diagnosed in early Stages I or II.

The discovery of small pulmonary nodules as part of annual lung cancer screening using low dose computed tomography (LDCT) can be problematic to diagnose. Patients may be asked to "wait and see" if the next scan reveals the nodule has grown or proceed immediately with invasive procedures, including biopsy, that may turn out to be unnecessary. "Actionable results from CyPath® Lung may help doctors and their patients determine appropriate next steps for suspected cases of lung cancer," Ms. Zannes said.

---

**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® 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 Precision Pathology 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**

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 CMS' 2024 clinical laboratory fee schedule making the Company's test even more attractive to both physicians and their patients at high risk for lung cancer and CyPath® Lung helping doctors and their patients determine appropriate next steps for suspected cases of lung cancer. 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 ability of the Company to benefit from the 2024 payment determination for CPT 0406U, the ability of the Company's test to produce actionable results to help doctors and their patients determine appropriate next steps for suspected cases of lung cancer, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, 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.

**Contacts**

**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