# 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): **March 13, 2026**

# 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) |

**3300 Nacogdoches Road, Suite 216**
**San Antonio, Texas 78217**
**(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 March 13, 2026, bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), issued a press release that included financial information for its year ended December 31, 2025. 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 March 13, 2026 |
| 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: March 13, 2026

**BIOAFFINITY TECHNOLOGIES, INC.**
(Registrant)

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

**Exhibit 99.1**


News Release

**bioAffinity Technologies Announces Record 2025 Revenue and Unit Sales for Flagship Lung Cancer Diagnostic CyPath® Lung**

***Laboratory business streamlined in 2025 to focus on profitable diagnostic testing services including the Company's high-value CyPath® Lung test***

***Number of CyPath® Lung tests performed in 2025 increased by 99% compared to 2024***

***Orders for CyPath® Lung by physicians and clinics rose 67% YoY due to peer-to-peer marketing, positive real-world experiences and growing test awareness***

**SAN ANTONIO, Texas – March 13, 2026 – bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW),** a biotechnology company focused on the need for noninvasive, accurate tests for the detection of early-stage lung cancer and other lung diseases, today reported financial results for the year ended December 31, 2025.

**2025 Highlights**

- **Record CyPath® Lung Revenue and Unit Sales.** Revenue from our noninvasive diagnostic for lung cancer increased 87% over 2024 with the number of tests performed rising 99% year over year, reflecting growing clinical utilization and validating the first phase of our commercialization strategy. The Company's strategic decision to discontinue unprofitable pathology services and reallocate resources to the commercialization of CyPath® Lung led to a 34% decrease in total revenue and a 9% decrease in operating expenses compared to 2024, respectively.

- **Expanded Physician Network.** The number of physician offices and clinics ordering CyPath® Lung for their patients increased 67% over 2024. We expect the trend to accelerate in 2026 as we expand our sales force into new markets. Peer-to-peer physician engagement remains a key driver of growth. Compelling patient case studies and key opinion leaders (KOLs) who are sharing their clinical experience are building awareness and clinical adoption of CyPath® Lung.

- **Leadership Appointments.** Gordon Downie, MD, PhD, joined bioAffinity Technologies as Chief Medical Officer, bringing more than three decades of experience in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology to the role. Roberto Rios, CPA, and John J. Oppenheimer, MD, were appointed to the Board of Directors in 2025. Mr. Rios has more than four decades of executive leadership experience in corporate finance and governance across industries including biotechnology and medical devices. Dr. Oppenheimer is a recognized leader in the diagnosis and treatment of asthma and COPD and directs clinical research in lung health while also teaching at the University of Medicine and Dentistry of New Jersey-Rutgers.

- **Successful Financings.** The Company raised approximately $16.9 million in gross proceeds during 2025 from equity transactions to fund CyPath® Lung clinical development, commercialization, and operational expansion.

- **CyPath® Lung-Centered Performance.** Through targeted operational streamlining and the discontinuation of certain unprofitable pathology services at our laboratory, Precision Pathology Laboratory Services (PPLS), we positioned CyPath® Lung as the core driver of long-term shareholder value. While these actions contributed to lower consolidated revenue in the short term, they improved operating focus and cost structure and are intended to position our noninvasive lung cancer diagnostic for scalable growth and improved long-term margin potential.

- **Innovation Pipeline Progress.** Research and development continued on diagnostic tests for chronic obstructive pulmonary disease (COPD) and asthma that build on our expertise in using sputum as a sample for flow cytometric analysis. Research is focused on detecting specific receptors in sputum to guide personalized treatment and identify patients likely to benefit from emerging targeted therapies. Asthma and COPD impact approximately 650 million children and adults globally.[1] We expect to begin patient studies in 2026.

- **Expanded Global Intellectual Property Portfolio.** During 2025, we strengthened our intellectual property portfolio supporting CyPath® Lung and our broader flow cytometry platform through multiple patent allowances and acceptances. These included notification of allowance from the U.S. Patent and Trademark Office for our diagnostic algorithm and test method, patent allowances in Canada and China covering flow cytometry-based lung cancer detection methods, and acceptance of patent applications in Australia related to early-stage lung cancer detection and multi-disease lung health assessment. These developments further expand international protection of our diagnostic technology and support our long-term commercialization strategy.

[1] https://academic.oup.com/ajrccm/article/212/2/297/8444672?login=false&utm

**Management Commentary**

“2025 was a transformational year for bioAffinity Technologies. We took deliberate actions to streamline operations at PPLS and align our resources behind the national expansion of CyPath® Lung,” said Maria Zannes, bioAffinity President and Chief Executive Officer. “While these actions contributed to a decrease in consolidated revenue, we believe that the Company is now better positioned to leverage revenue generated from the profitable testing services performed in our lab. Importantly, revenue for our core value driver, CyPath® Lung, increased 87% year over year, reflecting continued physician adoption and growing clinical utilization.

“The work we accomplished in 2025 was intentional and strategic. We strengthened our capital base, removed unprofitable legacy services from PPLS services and concentrated on high-value diagnostics. The launch of our longitudinal trial and our ongoing integration into the military healthcare system are both significant milestones that support our strategy of establishing CyPath® Lung as a standard of care for indeterminate pulmonary nodules and a tool for surveillance after cancer treatment.

“Every day, we hear from practitioners who confirm the need for noninvasive, accurate lung cancer diagnostics, particularly when imaging and risk models are inconclusive or turn out to be wrong. CyPath® Lung remains our first priority. It is a gamechanger that provides clinical confidence for physicians and better outcomes for patients. We believe our focus on improving care for patients at risk for lung cancer and other pulmonary diseases will create long-term value for our shareholders.”

**2026 Outlook**

- **Financial Outlook.** bioAffinity entered 2026 with strong momentum, building on a year of increased sales and revenue growth and positioning the Company for continued expansion in the lung cancer diagnostics market. Our forecast for unit sales of CyPath® Lung reflects an increase of greater than 100% over 2025, with a corresponding increase in revenues for our noninvasive lung cancer diagnostic. We will continue to expand our market both geographically and by the number of physicians and medical facilities adding CyPath® Lung to the diagnostic pathway for patients with indeterminate pulmonary nodules and to post-treatment care for surveillance of lung cancer survivors.

- **Market Opportunity.** Consistent with estimates from the US Preventive Services Task Force, the number of indeterminate pulmonary nodules detected in the U.S. through lung cancer screening and incidental imaging is projected to grow 62% from 2.9 million in 2025 to 4.7 million in 2030, representing an estimated market opportunity exceeding $4.7 billion for CyPath® Lung. The forecast assumes 10% compound annual growth from 2024–2030, driven by increased lung cancer screening adoption, improved adherence to screening guidelines, and enhanced detection through AI-enabled imaging tools. Another market opportunity opening up for CyPath® Lung is its potential to improve post-treatment surveillance for lung cancer survivors. The number of Americans living with lung cancer is projected to increase 28% from 680,450 in 2025 to 871,580 in 2035[2], representing an estimated $870 million market opportunity over the next decade.

[2] *Wagel, et al. *Cancer treatment and survivorship statistics, 2025* CA Cancer J Clin. 2025 Sep 13;75(6):683.

- **CyPath® Lung Longitudinal Trial.** In March 2026, we enrolled the first patient in our longitudinal study evaluating CyPath® Lung as a noninvasive diagnostic for high-risk patients with indeterminate pulmonary nodules. The trial plans to enroll up to 2,000 patients across 17 Veterans Administration (VA), military, academic, and private medical centers and will assess the sensitivity and specificity of the test over a follow-up period of up to two years. The John P. Murtha Cancer Center Research Program (MCCRP), a research program within the Department of Surgery at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, is providing support and funding associated with the trial at several federal facilities. This study is intended to provide additional clinical validation to support broader adoption in federal and commercial markets.

- **Military Research Collaboration to Expand Sample Collection Options for CyPath® Lung.** In February 2026, we announced a collaboration with Brooke Army Medical Center (BAMC) to evaluate the use of CyPath® Lung on sputum samples obtained via tracheal and bronchial suctioning during bronchoscopy. This study is designed to assess the clinical utility of CyPath® Lung for earlier detection of lung cancer in patients undergoing standard bronchoscopy procedures, potentially expanding the test's applicability to a larger patient population and increasing integration into pulmonology workflows.

- **Real-World Case Studies Validate CyPath® Lung.** The Company released 10 patient case studies in 2025 including multiple cases in which CyPath® Lung detected curative Stage 1A lung cancer. In February 2026, we released two new real-world clinical cases in which a negative CyPath® Lung test result supported the physician's decision to continue monitoring high-risk patients with indeterminate nodules through noninvasive surveillance. CyPath® Lung guided physician decision-making and reduced the burden on the patients by easing anxiety and helping them avoid additional invasive, costly and often risky procedures. The body of clinical evidence behind CyPath® Lung and real-world case studies continues to grow.

- **Positive Findings Presented at AAAAI on Expansion of Platform Technology to Asthma.** In February 2026, the Company presented research on the ability of our innovative diagnostic platform to identify antibody drug receptors in sputum, including receptors for dupilumab, a leading therapy for asthma and chronic obstructive pulmonary disease (COPD), and benralizumab, another asthma therapy. The research supports advancement of the Company's pipeline tests aimed at guiding personalized treatment decisions and improving disease monitoring for asthma and COPD sufferers.

**2025 Financial Results**

- Revenue was $6.2 million, compared with $9.4 million for 2024. The decrease reflects targeted strategic actions to discontinue certain unprofitable services and reallocate resources toward CyPath® Lung. Testing revenue for CyPath® Lung increased 87% year-over-year, driven by increased adoption by physicians and clinics, including the VA.

- Operating expenses decreased 9% to $16.7 million in 2025, primarily due to strategic actions aimed at streamlining and reducing lab operation costs.

- Research and development expenses were $1.4 million in 2025, slightly lower than the prior year, reflecting ongoing investment in lab operations and preclinical development.

- Selling, general and administrative expenses remained flat at $9.9 million.

- Net loss for the year ended December 31, 2025, was $14.9 million, compared to $9.0 million for 2024. The increase was primarily attributable to changes in the fair value of warrants, expanded sales activities and increased clinical development.

- Cash and cash equivalents as of December 31, 2025, were $6.5 million, compared with $1.1 million at the end of 2024. The Company raised $16.9 million in multiple financings in 2025 to support ongoing operations.

**About CyPath® Lung**

CyPath® Lung by bioAffinity Technologies is a noninvasive test designed to improve the early detection of lung cancer in patients at high risk for the disease. CyPath® Lung uses advanced flow cytometry and proprietary artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters.

**About bioAffinity Technologies, Inc.**

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and other 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. For more information, visit www.bioaffinitytech.com.

**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 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 Company's ability to successfully commercialize and achieve market acceptance of CyPath® Lung; the Company's ability to raise additional capital to fund operations; the Company's history of losses and ability to achieve profitability; the Company's reliance on CyPath® Lung as its primary revenue-generating product; changes in the regulatory landscape for laboratory developed tests, including potential FDA oversight; the Company's ability to obtain and maintain adequate reimbursement from third-party payors; the outcome of the Company's clinical trials and studies; the Company's ability to attract and retain qualified personnel; competition from existing and new diagnostic techniques; the Company's ability to protect its intellectual property; the Company's ability to maintain its Nasdaq listing; general economic, political, and market conditions; and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 to be filed with the Securities and Exchange Commission today, 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.

**Contact**

**bioAffinity Technologies**

Julie Anne Overton
Director of Communications
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**bioAffinity Technologies, Inc.**
**Consolidated Balance Sheets**
**As of December 31, 2025 and 2024**

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 6,449,782 | $ 1,105,291 |
| Accounts and other receivables, net | 541,962 | 1,139,204 |
| Inventory | 53,548 | 27,608 |
| Prepaid expenses and other current assets | 519,916 | 422,995 |
| Total current assets | 7,565,208 | 2,695,098 |
| Non-current assets: | | |
| Property and equipment, net | 265,593 | 375,385 |
| Operating lease right-of-use asset, net | 334,289 | 463,011 |
| Finance lease right-of-use asset, net | 661,575 | 780,872 |
| Goodwill | 1,404,486 | 1,404,486 |
| Intangible assets, net | 716,806 | 775,139 |
| Other assets | 12,815 | 19,676 |
| Total assets | $ 10,960,772 | $ 6,513,667 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 761,901 | $ 987,311 |
| Accrued expenses | 1,717,989 | 1,398,722 |
| Unearned revenue | 42,405 | 24,404 |
| Operating lease liability, current portion | 139,220 | 127,498 |
| Finance lease liability, current portion | 139,490 | 395,301 |
| Notes payable, current portion | 105,161 | 171,669 |
| Total current liabilities | 2,906,166 | 3,104,905 |
| Non-current liabilities | | |
| Operating lease liability, net of current portion | 202,878 | 342,098 |
| Finance lease liability, net of current portion | 532,759 | 444,448 |
| Notes payable, net of current portion | 41,313 | 20,180 |
| Total liabilities | 3,683,116 | 3,911,631 |
| Stockholders' equity: | | |
| Preferred stock, $0.001 per share; 20,000,000 shares authorized; 700 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively | 1 | — |
| Common Stock, par value $0.007 per share; 350,000,000 shares authorized; 4,498,675 and 519,158 issued and outstanding at December 31, 2025 and 2024, respectively(1) | 31,461 | 106,593 |
| Additional paid-in capital(1) | 75,800,258 | 56,139,753 |
| Accumulated deficit | (68,554,064) | (53,644,310) |
| Total stockholders' equity | 7,277,656 | 2,602,036 |
| Total liabilities and stockholders' equity | $ 10,960,772 | $ 6,513,667 |

(1) The values of Common Stock and paid-in capital, as well as the number of shares issued and outstanding, have been retroactively adjusted in order to give effect to the Company's 1-for-30 reverse stock split.

**bioAffinity Technologies, Inc.**
**Consolidated Statements of Operations**
**For the Years Ended December 31, 2025 and 2024**

| | 2025 | 2024 |
|---|---|---|
| **Net Revenue** | $ 6,161,959 | $ 9,362,022 |
| **Operating expenses:** | | |
| Direct costs and expenses | 4,226,799 | 5,983,475 |
| Research and development | 1,383,359 | 1,461,227 |
| Clinical development | 705,744 | 321,655 |
| Selling, general and administrative | 9,913,729 | 9,943,473 |
| Depreciation and amortization | 504,836 | 605,637 |
| **Total operating expenses** | 16,734,467 | 18,315,467 |
| **Loss from operations** | (10,572,508) | (8,953,445) |
| Other income (expense): | | |
| Interest income | 23,385 | 17,610 |
| Interest expense | (44,372) | (92,475) |
| Other income | 40,490 | 10,323 |
| Other expense | (502,429) | (10,194) |
| Change in fair value of warrants issued | (3,810,278) | — |
| **Loss before income tax expense** | (14,865,712) | (9,028,181) |
| Income tax expense | (44,042) | (11,650) |
| **Net loss** | $ (14,909,754) | $ (9,039,831) |
| Net loss per common share, basic and diluted[(2)] | $ (8.66) | $ (22.50) |
| Weighted average common shares outstanding[(2)] | 1,721,082 | 404,167 |

(2) The values of Common Stock and paid-in capital, as well as the number of shares issued and outstanding, have been retroactively adjusted in order to give effect to the Company's 1-for-30 reverse stock split.