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bioAffinity Technologies' CyPath® Lung Test Unit Sales Surged 146% Year-Over-Year in Q1 2026

Noninvasive diagnostic continues to gain traction in the current and expanding U.S. addressable market of $3.58 billion for pulmonary nodule management and surveillance of lung cancer survivors

Flow cytometry+AI technology has potential to improve lung cancer risk assessment and nodule management

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)**, a biotechnology company focused on noninvasive diagnostics and early cancer detection, today announced that unit sales for its CyPath® Lung diagnostic in the first quarter of 2026 exceeded internal projections and, based on preliminary unaudited data, achieved 146% growth compared to the first quarter of 2025, reflecting accelerating physician adoption and expanding clinical use of the Company's noninvasive lung cancer diagnostic test.

"The stronger than expected unit growth in the first quarter of 2026 reflects growing recognition of the value that CyPath® Lung brings to clinical decision-making and patient outcomes," said Maria Zannes, President and CEO of bioAffinity Technologies. "Physicians are seeking more accurate, noninvasive tools to assess lung cancer risk and detect disease at its earliest, most treatable stage. CyPath® Lung is designed to address a critical gap in the diagnostic pathway by supporting lung cancer risk assessment, pulmonary nodule management and post-treatment surveillance. Our growing body of evidence – including real-world case studies – further supports CyPath® Lung's potential clinical utility."

Addressing a Large and Growing Clinical Need

The number of patients identified with indeterminate pulmonary nodules continues to rise, driven in part by increases in incidental findings and screening by low-dose CT for high-risk patients. This expanding patient population poses a diagnostic challenge for physicians who have to weigh the benefits and risks of "watchful waiting" versus invasive procedures like biopsy.

Consistent with estimates from the U.S. 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. The number of people living with a prior lung cancer diagnosis is projected to increase from 680,000 to more than 871,000 by 2030. Capturing only 10% of both markets represents

sales of $358 million for CyPath® Lung, growing to more than $560 million over the next five years. 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.

CyPath® Lung's flow cytometry+AI technology is designed to provide actionable information to support clinical decision-making by delivering a binary result – "likely" or "unlikely" malignancy – to the ordering physician. Real-world patient cases have suggested the test's potential to:

- Help detect lung cancer at Stage 1A, when it is most treatable, as observed in real-world clinical cases.
- Help avoid unnecessary invasive, risky, and costly procedures when the test result is negative ("unlikely" malignancy), based on clinical experience to date.

Executing a Focused Commercial Strategy

bioAffinity Technologies has prioritized CyPath® Lung as its core commercial focus, aligning resources to accelerate adoption and scale. Growth has been driven by:

- Expansion of ordering physician sites.
- Increased peer-to-peer education among pulmonologists.
- Integration of CyPath® Lung into clinical workflows for lung cancer risk assessment and nodule management.

Based on audited financial results, CyPath® Lung revenue increased 87% year over year in 2025, while test units sold grew 99% compared to 2024. These milestones, together with preliminary unaudited growth data for Q1 2026, support the initial phase of the Company's commercialization strategy and position CyPath® Lung for continued growth.

Positioned for Continued Expansion

The Company is advancing multiple initiatives to further expand the clinical impact of its proprietary technology platform, including:

- A large-scale longitudinal clinical study designed to generate additional validation data for CyPath® Lung.
- Broader use of CyPath® Lung to monitor lung cancer survivors after treatment.
- An R&D pipeline that includes diagnostic tests for asthma and COPD that will help guide personalized treatment with targeted therapies.

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. CyPath® Lung 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. Results may vary in broader clinical use.

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. LDTs are overseen under the Clinical Laboratory Improvement Amendments (CLIA), administered by the Centers for Medicare & Medicaid Services. 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 achieve and sustain profitability, the preliminary and unaudited nature of certain financial and operating data presented herein, the Company's reliance on a single commercial product, the outcome of ongoing and future clinical studies, the Company's ability to obtain and maintain adequate reimbursement from third-party payors, the regulatory environment for laboratory developed tests, the Company's ability to attract and retain qualified personnel, the Company's need for additional capital to fund operations, competition from existing and new diagnostic technologies, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, 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.

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