April 1, 2024

bioAffinity Technologies Reports Fourth Quarter and Full Year 2023 Financial Results

SAN ANTONIO--(BUSINESS WIRE)--**bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW),** a biotechnology company focused on commercializing noninvasive tests for the detection of early-stage cancer and lung disease, today reported financial results for the three and 12 months ended December 31, 2023.

Fiscal Year 2023 and Recent Highlights

- Reported fiscal year 2023 revenue of $2.5 million, a significant increase from $5,000 in 2022, driven by the September 2023 acquisition of Precision Pathology Laboratory Services (PPLS) and increasing sales of CyPath® Lung, the Company's noninvasive test to detect early-stage lung cancer.
- Reported accelerating growth of 350% in CyPath® Lung tests ordered and processed in Q1 2024 as compared to Q4 2023, exceeding the Company's targeted sales forecast for the quarter. The Company continues with its limited market launch in Texas to refine future positioning and strategic insight for CyPath® Lung in preparation for expanding to the national market.
- Achieved a milestone with the Centers for Medicare and Medicaid Services (CMS) final determination for payment for CyPath® Lung for the 2024 calendar year, a significant step in the Company's strategic plan to accelerate the commercialization of CyPath® Lung.
- Initiated the sale of CyPath® Lung tests to the Department of Defense for observational studies and research. This research expands the test's use and includes the development of a companion test for bronchoalveolar lavage (BAL) samples to be used in conjunction with bronchoscopy.
- Announced the appointment of Michael Dougherty, CPA, MBA, as Chief Financial Officer, bringing extensive experience from his previous role as CFO of Amazon's Alexa Commercial Domains.
- Developed marketing materials for CyPath® Lung in collaboration with leading marketing and advertising firms and began utilizing them with physicians and patients in January 2024, focusing on the test's value as a tool to assist physicians with patient care decisions.
- Announced the appointment of Dallas Coleman as National Director of Sales and the ongoing expansion of the sales team. Mr. Coleman has more than 15 years of experience in medical sales and marketing, most recently as Executive Account Manager for the respiratory portfolio of Olympus America's therapeutic solutions division.

- Successfully passed the bi-annual College of American Pathologists (CAP) inspection in January 2024, affirming the high standards of quality and patient care attained by the Company's commercial laboratory, Precision Pathology Laboratory Services.
- Expanded the Company's Medical and Scientific Advisory Board with the appointment of Sandeep Bansal, M.D., Medical Director of Pennsylvania's Lung Innovations Network, a patient-centered practice that offers comprehensive lung care to more than 10,000 patients in central and western Pennsylvania.
- Strengthened the Company's Board of Directors with the appointment of Jamie Platt, Ph.D., Managing Director and Chief Executive Officer of Pictor Limited, where she is leading a turnaround by restructuring and accelerating product development. Dr. Platt was instrumental in merger and acquisition exits for two diagnostic companies with a combined value of approximately $1 billion.

Management Commentary

"As we reflect on the monumental achievements of bioAffinity Technologies over the past year, I am filled with immense pride and optimism for the future," said Maria Zannes, President and Chief Executive Officer of bioAffinity Technologies. "Our fiscal year 2023 revenue of $2.5 million, up from less than $5,000 in 2022, is not just a number – it's a testament to the dedication of our team, the quality of Precision Pathology's operations, the trust of our healthcare partners, and what we believe is the growing recognition of CyPath® Lung's critical role in the early detection of lung cancer."

Ms. Zannes continued, "The CMS's final payment determination for CyPath® Lung for the 2024 calendar year was a major accomplishment that supports our strategic plan to accelerate commercialization. This milestone, coupled with our successful acquisition of Precision Pathology Services and expanding the reach of CyPath® Lung through partnerships such as with the Department of Defense, positions us at the forefront of noninvasive lung cancer detection. Our revenue growth is a beacon of our potential and the impact we aim to have on millions of lives by providing accessible, accurate, and noninvasive diagnostic solutions. As we look ahead, we are more committed than ever to building on this momentum and expanding our market to fulfill the promise of early cancer detection and treatment."

Fourth Quarter Financial Results

Revenue for the fourth quarter of 2023 was approximately $2.2 million, up from no revenue for the prior-year period. Revenue was derived from sales and services of the Company's commercial laboratory, Precision Pathology Laboratory Services, including its sale of CyPath® Lung as a Laboratory Developed Test (LDT).

Research and development expenses were $432,000 for the fourth quarter of 2023, compared with $429,000 for the comparable period in 2022. Selling, general and administrative expenses were $2.2 million for the fourth quarter of 2023, compared with $1.2 million for the comparable period in 2022.

Net loss for the fourth quarter of 2023 was $2.4 million, compared with a net loss of $1.7 million for the comparable period in 2022.

Full Year Financial Results

Revenue for 2023 was $2.5 million, up from approximately $5,000 for 2022.

Research and development expenses were $1.5 million in 2023, compared with $1.4 million in 2022. The increase was primarily attributable to an increase in compensation costs and benefits as we added research personnel.

Selling, general and administrative expenses were $6.8 million in 2023, compared with $2.5 million in 2022. The increase was primarily attributable to general and administration costs acquired from PPLS, accounting, legal, and professional fee costs associated with the acquisition of PPLS, the accounting, legal, and professional fee costs associated with the SEC filing of a registration statement on Form S-1, increase in stock-based compensation, increase in employee compensation as we added sales and administrative personnel, increase in branding and marketing collateral, increase in directors and officers insurance, increase in public company-related expenses as well as an increase related to board compensation, and other operational expenses. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Net loss for 2023 was $7.9 million, or $0.91 per share, down from a net loss for 2022 of $8.1 million, or $1.81 per share.

Cash and cash equivalents as of December 31, 2023, were $2.8 million.

About CyPath® Lung

CyPath® Lung uses advanced flow cytometry and artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. Automated data analysis helps determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin, meso-tetra (4-carboxyphenyl) porphyrin (TCPP), that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated that CyPath® Lung had 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. Diagnosing and treating early-stage cancer can improve outcomes and increase patient survival.

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. 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 continuing with the Company's limited market launch in Texas to refine future positioning and strategic insight for CyPath® Lung in preparation for expanding to the national market, the growing recognition of CyPath® Lung's critical role in the early detection of lung cancer, being positioned at the forefront of noninvasive lung cancer detection, the Company's revenue growth being a beacon of its potential and the impact it aims to have on millions of lives by providing accessible, accurate, and noninvasive diagnostic solutions, being more committed than ever to building on the Company's recent momentum and expanding its market to fulfill the promise of early cancer detection and treatment. 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 build on its recent momentum and expand its market to fulfill the promise of early cancer detection and treatment and the other factors discussed in the Company's Annual Report on Form 10-K, 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.

bioAffinity Technologies, Inc.
Consolidated Balance Sheets

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,821,570	$ 11,413,759
Accounts and other receivables, net	811,674	10,489
Inventory	18,484	5,540
Prepaid expenses and other current assets	321,017	531,899
Total current assets	3,972,745	11,961,687
Non-current assets:		
Property and equipment, net	458,633	214,438
Operating lease right-of-use asset, net	370,312	—
Finance lease right-of-use asset, net	1,165,844	—
Goodwill	1,404,486	—
Intangible assets, net	833,472	—
Other assets	16,060	6,000

Total assets	$ 8,221,552	$ 12,182,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 604,789	$ 345,042
Accrued expenses	1,149,811	541,894
Unearned revenue	33,058	—
Operating lease liability, current portion	94,708	—
Finance lease liability, current portion	365,463	—
Loan payable	—	251,746
Total current liabilities	2,247,829	1,138,682
Non-current liabilities		
Operating lease liability, net of current portion	283,001	—
Finance lease liability, net of current portion	835,467	—
Total liabilities	3,366,297	1,138,682
Commitments and contingencies (See Note 10)	-	-
Stockholders' equity:		
Preferred stock, no shares issued or outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, par value $0.007 per share; 25,000,000 and 14,285,714 shares authorized; 9,394,610 and 8,381,324 shares issued and outstanding as of December 31, 2023 and 2022, respectively	65,762	58,669
Additional paid-in capital	49,393,972	47,652,242
Accumulated deficit	(44,604,479)	(36,667,468)
Total stockholders' equity	4,855,255	11,043,443
Total liabilities and stockholders' equity	$ 8,221,552	$ 12,182,125

bioAffinity Technologies, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2023 and 2022

	2023	2022
Net Revenue	$ 2,532,499	$ 4,803
Operating expenses:		
Direct costs and expenses	1,740,884	467
Research and development	1,467,936	1,378,624
Clinical development	256,661	145,546
Selling, general and administrative	6,790,654	2,481,042
Depreciation and amortization	249,592	10,182
Total operating expenses	10,505,727	4,015,861
Loss from operations	(7,973,228)	(4,011,058)
Other income (expense):		
Interest income	122,131	46,708
Interest expense	(37,125)	(2,532,640)
Other Income	3,325	—
Other Expense	(31,121)	—
Gain on extinguishment of debt	—	212,258

Fair value adjustments on convertible notes payable	—	(1,866,922)
Loss before income taxes	(7,916,018)	(8,151,654)
Income tax expense	(20,993)	(2,459)
Net loss	$ (7,937,011)	$(8,154,113)
Net loss per common share, basic and diluted	$ (0.91)	$ (1.81)
Weighted average common shares outstanding	8,747,509	4,498,964

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