

# bioAffinity Technologies Reports Second Quarter 2023 Financial Results and Provides Business Update

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies**, Inc. (Nasdaq: BIAF; BIAFW), a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer and other diseases of the lung, today reported financial results for the three and six months ended June 30, 2023, and provided a business update.

Highlights from the second quarter of 2023 and subsequent weeks included:

### **Corporate and Commercial Highlights**

- The American Medical Association (AMA) issued a Current Procedural Terminology (CPT) code for use with CyPath<sup>®</sup> Lung with an effective date of Oct. 1, 2023. CPT codes provide a uniform system to identify medical services and procedures and seek reimbursement from private payers and public health insurance programs, including Medicare and Medicaid.
- The Department of Defense (DOD) purchased CyPath Lung<sup>®</sup> tests for use in an observational study on active military personnel at high risk for developing lung cancer (<u>NCT05870592</u>) and for research on the use of bronchoalveolar lavage fluid to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection.
- Michael Dougherty joined the management team as Chief Financial Officer. Previously, he served as CFO of Amazon's Alexa commercial domains with responsibility for financial strategy over Alexa's multibillion-dollar investments in Al-generated customer experiences.
- The Company launched a pilot marketing and sales program in select cities in Texas to provide insights and strategies for the successful product rollout for CyPath<sup>®</sup> Lung.

### **Research and Development Highlights**

- Presented advancements in CyPath<sup>®</sup> Lung at the Cleveland Clinic's invitation-only fourth annual "*Advances in Early Lung Cancer Detection*" symposium, which focuses on accelerating the development and implementation of new technologies and methods for the early detection of lung cancer.
- Presented a poster titled "Development of porphyrin-stained polystyrene compensation beads for use on an automated analysis platform" at CYTO 2023, the annual Congress for the International Society for the Advancement of Cytometry, that demonstrated the suitability of the Company's proprietary compensation beads for commercial use with

flow cytometry, including with CyPath<sup>®</sup> Lung.

 Presented a poster titled "Vitamin B12 deprivation does not phenocopy selective cytotoxicity of CD320 and LRP2 silencing" at the University of Massachusetts T.H. Chan Medical School's fifth annual RNA Therapeutics Symposium demonstrating that deprivation of vitamin B12 does not play a role in the selective cytotoxicity of cancer cells observed after silencing the expression of CD320 and LRP2; this research follows the Company's discovery that using small interfering RNA (siRNA) to knock down CD320 and LRP2 killed cancer cells *in vitro* without harming healthy cells.

## Management Commentary

"Our sales team is implementing a test market pilot program of CyPath<sup>®</sup> Lung across various target markets in Texas, and we are encouraged with their progress. The pilot program is a tactical program to test various marketing and selling approaches to accelerate the development of a successful regional and then national roll out of the CyPath<sup>®</sup> Lung test. Issuance of a CPT code by the AMA specifically for CyPath<sup>®</sup> Lung is another important milestone that we believe signals the value our diagnostic adds to the clinical care of patients at high risk for developing lung cancer," bioAffinity President and Chief Executive Officer Maria Zannes said.

"We are building brand awareness and finetuning our market positioning at the same time we are showcasing our innovation at prestigious medical and scientific conferences. The result is increased recognition and adoption of CyPath<sup>®</sup> Lung, including interest by the DOD. We expect revenues from CyPath<sup>®</sup> Lung to grow as we expand our geographic reach, add prescribing physicians and focus on larger medical systems," Ms. Zannes added.

### Second Quarter Financial Results

Revenue for the second quarter of 2023 was \$20,000, compared with \$1,000 for the prioryear period. Revenue is generated from royalties from the Company's licensee, Precision Pathology Services, from sales of CyPath<sup>®</sup> Lung as a laboratory developed test, from clinical flow cytometry services provided to Precision Pathology Services related to CyPath<sup>®</sup> Lung and from CyPath<sup>®</sup> Lung tests purchased by the DOD. Sales to the DOD were \$10,000 for the second quarter of 2023.

Research and development expenses were \$335,000 for the second quarter of 2023, compared with \$248,000 for the comparable period in 2022. The increase was primarily due to higher compensation costs from adding research personnel and higher costs for lab supplies and reagents.

Clinical development expenses were \$35,000 for the second quarter of 2023, compared with \$28,000 for the second quarter of 2022. The increase was primarily due to higher professional fees related to clinical strategy evaluation as the Company prepares to launch the CyPath<sup>®</sup> Lung pivotal trial.

Selling, general and administrative expenses were \$1.4 million for the second quarter of 2023, compared with \$409,000 for the comparable period in 2022. The increase was primarily attributed to higher consulting, legal and professional fees related to being a

publicly traded company, higher board compensation, and sales and marketing costs for commercialization of CyPath® Lung.

Net loss for the second quarter of 2023 was \$1.7 million, or \$0.20 per share, compared with a net loss of \$88,000, or \$0.03 per share, for the comparable period in 2022.

Cash and cash equivalents were \$8.3 million as of June 30, 2023, compared with \$11.4 million as of December 31, 2022. bioAffinity Technologies believes that its available cash will be sufficient to fund planned operations for at least the next 12 months.

## About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer treatment. The Company's first product, <u>CyPath<sup>®</sup></u> Lung, is a noninvasive test that has shown high sensitivity and specificity for the detection of early-stage lung cancer. CyPath<sup>®</sup> Lung is marketed as a laboratory developed test (LDT) by <u>Precision Pathology Services</u>. OncoSelect<sup>®</sup> 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. For more information, visit <u>www.bioaffinitytech.com</u>.

# **Forward-Looking Statements**

This press release contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are identified by the use of the words "could," "believe," "anticipate," "intend," "estimate," ""expect," "may," "continue," "predict," "potential," "project" and similar expressions that are intended to identify forward-looking statements and include statements regarding implementing a test market pilot program of CyPath<sup>®</sup> Lung across various target markets in Texas, accelerating the development of a successful regional and then national roll out of the CyPath<sup>®</sup> Lung test, building brand awareness and market positioning while showcasing the Company at prestigious medical and scientific conferences, and growing revenues from CyPath<sup>®</sup> Lung as the Company expands its geographic reach, adds prescribing physicians and focuses on larger medical systems. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of 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 accelerate the development of a successful regional and then national roll out of the CyPath<sup>®</sup> Lung test, the Company's ability to build brand awareness and market positioning for the CyPath<sup>®</sup> Lung test, the Company's ability to grow revenues from CyPath<sup>®</sup> Lung by expanding its geographic reach, adding prescribing physicians and focusing on larger medical systems, and the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company's Quarterly Reports on Form 10-Q, the Company's Current Reports on Form 8-K and subsequent filings filed with the Securities and Exchange Commission. The

information in this release is provided only as of the date of this release, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events, except as required by law.

#### bioAffinity Technologies, Inc. Condensed Consolidated Balance sheets

		June 30, 2023		December 31, 2022	
	(	Unaudited)			
ASSETS					
Current assets:					
Cash and cash equivalents	\$	8,279,182	\$	11,413,759	
Accounts and other receivables, net		90,233		10,489	
Inventory		10,101		5,540	
Prepaid and other current assets		279,687		531,899	
Total current assets		8,659,203		11,961,687	
Property and equipment, net		207,377		214,438	
Other assets		6,920		6,000	
Total assets	\$	8,873,499	\$	12,182,125	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	174,404	\$	345,042	
Accrued expenses		515,663		541,894	
Unearned revenue		42,750			
Loan payable		42,334		251,746	
Total current liabilities		775,151		1,138,682	
Total liabilities		775,151		1,138,682	
Commitments and contingencies (See Note 9)					
Stockholders' equity:					
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at June 30, 2023, and December 31, 2022		_		_	
Common stock, par value \$0.007 per share; 25,000,000 shares authorized; 8,555,365 issued and outstanding at June 30, 2023; and 8,381,324 shares issued and outstanding at December 31, 2022		59,887		58,669	
Additional paid-in capital		47,978,892		47,652,242	
Accumulated deficit		(39,940,431)		(36,667,468	
Total stockholders' equity		8,098,348		11,043,443	
Total liabilities and stockholders' equity	\$	8,873,499	\$	12,182,125	

#### bioAffinity Technologies, Inc. Unaudited Condensed Consolidated Statements of Operations

		Three Months Ended June 30,			Six Months Ended June 30,				
		2023		2022		2023		2022	
	(L	naudited)			(Unaudited)				
Revenue	\$	19,738	\$	1,306	\$	20,659	\$	1,306	
Cost of sales		1,234		146		1,322		146	

Gross profit	18,504	1,160	19,337	1,160
Operating expenses:				
Research and development	335,125	248,419	704,741	528,267
Clinical development	35,260	28,240	54,888	80,744
General and administrative	1,426,469	408,619	2,596,027	803,311
Total operating expenses	1,796,854	685,279	3,355,657	1,412,322
Loss from operations	(1,778,350)	(684,119)	(3,336,320)	(1,411,162)
Other income (expense):				
Interest income	44,124	276	82,778	847
Interest expense	(1,360)	(399,265)	(3,015)	(1,546,848)
Gain on extinguishment of debt	—	212,258	—	212,258
Fair value adjustments on convertible notes payable		782,798		1,186,992
Net loss before provision for income taxes	(1,735,586)	(88,052)	(3,256,557)	(1,557,913)
Income tax expense	4,587		16,406	2,159
Net loss	\$ (1,740,173 <sub>)</sub>	\$ (88,052 <sub>)</sub>	\$ (3,272,963 <sub>)</sub>	\$ (1,560,072 <sub>)</sub>
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Net loss per common share, basic and diluted	\$ (0.20)	\$ (0.03)	\$ (0.38)	\$ (0.58)
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Weighted average common shares outstanding	8,520,714	2,693,511	8,477,656	2,687,431

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# bioAffinity Technologies

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