

**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

May 15, 2023

Date of Report (Date of earliest event reported)

BIOAFFINITY TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41463
(Commission
File Number)

46-5211056
(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 2.02. Results of Operations and Financial Condition.

On May 15, 2023, bioAffinity Technologies, Inc. issued a press release regarding its financial results for the three months ended March 31, 2023. The press release is attached as Exhibit 99.1 to this Form 8-K.

The information contained in this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of bioAffinity Technologies, Inc., dated May 15, 2023.
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: May 15, 2023



News Release

bioAffinity Technologies Reports First Quarter 2023 Financial Results

SAN ANTONIO, Texas (May 15, 2023) – **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 months ended March 31, 2023.

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

Corporate and Commercial Highlights

- Appointed Michael Dougherty as Chief Financial Officer. Mr. Dougherty most recently served as CFO of Amazon’s Alexa commercial domains, where he was responsible for financial strategy over Alexa’s multibillion-dollar investments in AI-generated customer experiences.
- Engaged Havas Health & You and Trinity Life Sciences to create the branding and marketing strategy for CyPath® Lung.
- Continued with the initial rollout of CyPath® Lung to select test markets in Texas with encouraging user feedback and survey responses.
- Management rang the Nasdaq Stock Market closing bell on April 5 to commemorate the Company’s IPO in September 2022.

Research and Development Highlights

- Received Notice of Allowance from the U.S. Patent and Trademark Office for a patent titled “*Porphyrim Compounds and Compositions Useful for Treating Cancer*” for the targeted delivery of novel cancer treatments. This patent is owned by the Company’s wholly owned subsidiary OncoSelect® Therapeutics and grants protection through 2037.
- Expanded geographic coverage for this OncoSelect® Therapeutics patent to include issuance in Hong Kong, which joins the U.S., Australia, China and Mexico, with patent applications pending in Canada, the European Union, India and Japan.
- CyPath® Lung clinical validation study results were published in *Respiratory Research* and demonstrated 92% sensitivity and 87% specificity in high-risk patients with nodules smaller than 20 millimeters or no nodules in the lung, with an area under the ROC curve of 94%.

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- The article “*Porphyrim-Modified Beads for Use as Compensation Controls in Flow Cytometry*” was published in the peer-reviewed *Journal of Visualized Experiments* (JoVE) and describes the protocol for preparing porphyrin-labeled compensation beads to optimize the ability of CyPath® Lung to detect early-stage lung cancer.
 - Presented advancements in CyPath® Lung at the Cleveland Clinic’s invitation-only fourth annual “*Advances in Early Lung Cancer Detection*” Symposium, which brings together global leaders in the field of lung cancer, including physicians, advocates and industry, to accelerate the development and implementation of new technologies and methods for early lung cancer detection.

Management Commentary

“Our first quarter results reflect our focus on positioning bioAffinity Technologies both financially and organizationally to achieve our most important near-term objective: expanding the commercial launch of CyPath® Lung into additional markets to optimize our rollout for maximum success. Preliminary commercial results are encouraging, and with constructive initial feedback from physicians, we’re fine-tuning the CyPath® Lung branding and marketing strategy. A survey of pulmonologists, internists and primary care physicians shows that they understand the need for a noninvasive, accurate lung cancer diagnostic and are receptive to including the test as part of their clinical decision-making for high-risk patients,” bioAffinity President and Chief Executive Officer Maria Zannes said.

“CyPath® Lung is currently commercially available as a laboratory developed test through our licensee, Precision Pathology Services. The launch of our pivotal clinical trial later this year is a critical step toward securing FDA clearance as a Class II *in vitro* diagnostic, which would enable us to market directly to U.S. physicians and their patients and facilitate dialogues with payers,” Ms. Zannes added.

First Quarter Financial Results

Revenue for the first quarter of 2023 was \$1,000, compared with no revenue for the prior-year period. Revenue is currently generated exclusively from royalties from the Company’s licensee, Precision Pathology Services, from sales of CyPath® Lung as a laboratory developed test.

Research and development expenses were \$370,000 for the first quarter of 2023, compared with \$280,000 for the comparable period in 2022. The increase was primarily due to higher compensation costs from adding research personnel and higher R&D equipment costs.

Clinical development expenses were \$20,000 for the first quarter of 2023, compared with \$53,000 for the first quarter of 2022. The decline was primarily attributed to lower professional fees related to clinical strategy evaluation as the Company prepares to launch the CyPath® Lung pivotal trial.

Selling, general and administrative expenses were \$1.2 million for the first quarter of 2023, compared with \$395,000 for the comparable period in 2022. The increase was primarily attributed to higher consulting, legal and professional fees incurred to comply with public company reporting requirements.

Net loss for the first quarter of 2023 was \$1.5 million, or \$0.18 per share, compared with a net loss of \$1.5 million, or \$0.55 per share, for the comparable period in 2022.

Cash and cash equivalents as of March 31, 2023, were \$9.8 million, 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, CyPath[®]Lung, is a noninvasive test that has shown high sensitivity and specificity for the detection of early-stage lung cancer. CyPath[®] Lung is marketed as a laboratory developed test (LDT) by Precision Pathology Services. OncoSelect[®] 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 www.bioaffinitytech.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the anticipated use of proceeds from the Company's offering of common shares. Forward-looking statements can be identified by words such as "believes," "expects," "estimates," "intends," "may," "plans," "will" and similar expressions, or the negative of these words. 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. Readers of this press release are cautioned not to place undue reliance on any forward-looking statements. 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

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bioAffinity Technologies, Inc. Condensed Consolidated Balance Sheets

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,769,088	\$ 11,413,759
Accounts and other receivables, net	11,027	10,489
Inventory	11,335	5,540
Prepaid and other current assets	441,132	531,899
	<u>10,232,582</u>	<u>11,961,687</u>
Total current assets	10,232,582	11,961,687
Property and equipment, net	225,067	214,438
Other assets	6,920	6,000
	<u>10,464,569</u>	<u>12,182,125</u>
Total assets	<u>\$ 10,464,569</u>	<u>\$ 12,182,125</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 146,537	\$ 345,042
Accrued expenses	481,336	541,894
Loan payable	168,430	251,746
	<u>796,303</u>	<u>1,138,682</u>
Total current liabilities	796,303	1,138,682
Total liabilities	<u>796,303</u>	<u>1,138,682</u>
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at March 31, 2023, and December 31, 2022	—	—
Common stock, par value \$0.007 per share; 14,285,714 shares authorized; 8,463,052 issued and outstanding at March 31, 2023; and 8,381,324 shares issued and outstanding at December 31, 2022	59,241	58,669
Additional paid-in capital	47,809,283	47,652,242
Accumulated deficit	(38,200,258)	(36,667,468)
Total stockholders' equity	<u>9,668,266</u>	<u>11,043,443</u>
Total liabilities and stockholders' equity	<u>\$ 10,464,569</u>	<u>\$ 12,182,125</u>

	Three Months Ended March 31,	
	2023	2022
Revenue	\$ 921	\$ —
Cost of sales	87	—
Gross profit	834	—
Operating expenses:		
Research and development	369,617	279,848
Clinical development	19,628	52,503
Selling, general and administrative	1,169,559	394,692
Total operating expenses	1,558,804	727,043
Loss from operations	(1,557,970)	(727,043)
Other income (expense):		
Interest income (expense), net	36,999	(1,147,012)
Fair value adjustments on convertible notes payable	—	404,194
Loss before income taxes	(1,520,971)	(1,469,861)
Income tax expense	11,819	2,159
Net loss	\$ (1,532,790)	\$ (1,472,020)
Net loss per common share, basic and diluted	\$ (0.18)	\$ (0.55)
Weighted average common shares outstanding	8,433,689	2,681,221

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