

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549
FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

COMMISSION FILE NUMBER: 001-41463

bioAffinity Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

46-5211056
(I.R.S. Employer Identification No.)

22211 W. Interstate 10, Suite 1206, San Antonio, Texas
(Address of principal executive offices)

78257
(Zip Code)

(210) 698-5334
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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 Sec 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the issuer's common stock outstanding as of August 14, 2023, was 8,782,548.

Throughout this Quarterly Report on Form 10-Q (this “Quarterly Report”), the terms “bioAffinity,” “bioAffinity Technologies,” “we,” “us,” “our” or “the Company” refer to bioAffinity Technologies, Inc., a Delaware corporation, and its wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC, a Delaware limited liability company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements are predictive in nature, depend on or refer to future events or conditions, and are sometimes identified by words such as “may,” “could,” “plan,” “project,” “predict,” “pursue,” “believe,” “expect,” “estimate,” “anticipate,” “intend,” “target,” “seek,” “potentially,” “will likely result,” “outlook,” “budget,” “objective,” “trend,” or similar expressions of a forward-looking nature and the negative versions of such expressions. The forward-looking information contained in this report is generally located under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” but may be found in other locations as well. The forward-looking statements in this report generally relate to the plans and objectives for future operations of bioAffinity Technologies, Inc. and are based on our management’s reasonable estimates of future results or trends. Although we believe these forward-looking statements are reasonable, all forward-looking statements are subject to various risks and uncertainties, and our projections and expectations may be incorrect. The factors that may affect our expectations regarding our operations include, among others, the following:

- our projected financial position and estimated cash burn rate;
 - our estimates regarding expenses, future revenues, and capital requirements;
 - the success, cost, and timing of our clinical trials;
 - our ability to obtain funding for our operations necessary to complete further development and commercialization of our diagnostic tests or therapeutic product candidates;
 - our dependence on third parties, including the conduct of our clinical trials;
 - our ability to obtain the necessary regulatory approvals to market and commercialize our diagnostic tests or therapeutic product candidates;
 - the potential that the results of our pre-clinical and clinical trials indicate our current diagnostic tests or any future diagnostic tests or therapeutic product candidates we may seek to develop are unsafe or ineffective;
 - the results of market research conducted by us or others;
 - our ability to obtain and maintain intellectual property (“IP”) protection for our current diagnostic test or future diagnostic tests and therapeutic product candidates;
 - our ability to protect our IP rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our IP rights;
 - the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their IP rights and that we may incur substantial costs and be required to devote substantial time defending against such claims;
 - the success of competing therapies, diagnostic tests, and therapeutic products that are or will become available;
 - our ability to expand our organization to accommodate potential growth and to retain and attract key personnel;
-

- our potential to incur substantial costs resulting from product liability lawsuits against us and the potential for such lawsuits to cause us to limit the commercialization of our diagnostic tests and therapeutic product candidates;
- market acceptance of our diagnostic test and diagnostic tests in development and therapeutic product candidates, the size and growth of the potential markets for our current diagnostic test and diagnostic tests in development and therapeutic product candidates, and any future diagnostic tests and therapeutic product candidates we may seek to develop, and our ability to serve those markets;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- compliance with government regulations, including environmental, health, and safety regulations and liabilities thereunder;
- the ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems, or the global economy as a whole;
- general instability of economic and political conditions in the United States, including inflationary pressures, increased interest rates, economic slowdown or recession, and escalating geopolitical tensions;
- compliance with government regulations, including environmental, health, and safety regulations, and liabilities thereunder;
- the increased expenses associated with being a public company; and
- other factors discussed elsewhere in this Quarterly Report.

Many of the foregoing risks and uncertainties, as well as risks and uncertainties that are currently unknown to us, are, and may be, exacerbated by factors such as the ongoing conflict between Ukraine and Russia, escalating tensions between China and Taiwan, increasing economic uncertainty and inflationary pressures, the evolving nature of the COVID-19 pandemic and the emergence of new viral variants, and any consequent worsening of the global business and economic environment. New factors emerge from time to time, and it is not possible for us to predict all such factors. Should one or more of the risks or uncertainties described in this Quarterly Report or any other filing with the Securities and Exchange Commission (the “SEC”) occur or should the assumptions underlying the forward-looking statements we make herein and therein prove incorrect, our actual results and plans could differ materially from those expressed in any forward-looking statements. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

You should read this Quarterly Report and the documents that we reference within it with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

Website and Social Media Disclosure

We use our websites (www.bioaffinitytech.com and ir.bioaffinitytech.com) and at times our corporate Twitter account (@bioAffinity), LinkedIn account (www.linkedin.com/company/bioaffinitytechnologies) and Facebook account (<https://www.facebook.com/bioaffinitytechnologies>) to distribute company information. Information contained on or that can be accessed through our websites and social media channels is not, however, incorporated by reference in this Quarterly Report. Investors should not consider any such information to be part of this Quarterly Report.

FORM 10-Q
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PART I
FINANCIAL STATEMENTS

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

BIOAFFINITY TECHNOLOGIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2023	December 31, 2022
	<u>(Unaudited)</u>	
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
	<u>8,659,203</u>	<u>11,961,687</u>
Total current assets	8,659,203	11,961,687
Property and equipment, net	207,377	214,438
Other assets	6,920	6,000
	<u>6,920</u>	<u>6,000</u>
Total assets	<u>\$ 8,873,499</u>	<u>\$ 12,182,125</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 174,404	\$ 345,042
Accrued expenses	515,663	541,894
Unearned revenue	42,750	—
Loan payable	42,334	251,746
	<u>775,151</u>	<u>1,138,682</u>
Total current liabilities	775,151	1,138,682
Total liabilities	<u>775,151</u>	<u>1,138,682</u>
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	<u>8,098,348</u>	<u>11,043,443</u>
Total liabilities and stockholders' equity	<u>\$ 8,873,499</u>	<u>\$ 12,182,125</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

BIOAFFINITY TECHNOLOGIES, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)		(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)	\$ (88,052)	\$ (3,272,963)	\$ (1,560,072)
Net loss per common share, basic and diluted	\$ (0.20)	\$ (0.03)	\$ (0.38)	\$ (0.58)
Weighted average common shares outstanding, basic and diluted	8,520,714	2,693,511	8,477,656	2,687,431

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BIOAFFINITY TECHNOLOGIES, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	For the Six Months Ended June 30, 2023						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at December 31, 2022	—	\$ —	8,381,324	\$ 58,669	\$ 47,652,242	\$ (36,667,468)	\$ 11,043,443
Stock-based compensation expense	—	—	174,041	1,218	326,650	—	327,868
Net loss	—	—	—	—	—	(3,272,963)	(3,272,963)
Balance at June 30, 2023 (Unaudited)	—	\$ —	8,555,365	\$ 59,887	\$ 47,978,892	\$ (39,940,431)	\$ 8,098,348
	For the Three Months Ended June 30, 2023						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at March 31, 2022	—	\$ —	8,463,052	\$ 59,241	\$ 47,809,283	\$ (38,200,258)	\$ 9,668,266
Stock-based compensation expense	—	—	92,313	646	169,609	—	170,255
Net loss	—	—	—	—	—	(1,740,173)	(1,740,173)
Balance at June 30, 2023 (Unaudited)	—	\$ —	8,555,365	\$ 59,887	\$ 47,978,892	\$ (39,940,431)	\$ 8,098,348
	For the Six Months Ended June 30, 2022						
	Convertible Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Deficit
Balance at December 31, 2021	756,558	\$ 4,044,318	2,677,140	\$ 18,740	\$ 12,703,896	\$ (28,513,355)	\$ (15,790,719)
Stock-based compensation expense	—	—	17,319	121	132,426	—	132,732
Beneficial conversion feature for bridge notes	—	—	—	—	213,942	—	213,942
Debt discount for warrants issued	—	—	—	—	217,973	—	217,973
Net loss	—	—	—	—	—	(1,560,072)	(1,560,072)
Balance at June 30, 2022 (unaudited)	756,558	\$ 4,044,318	2,694,459	\$ 18,861	\$ 13,268,237	\$ (30,073,427)	\$ (16,786,329)
	For the Three Months Ended June 30, 2022						
	Convertible Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Deficit
Balance at March 31, 2022	756,558	\$ 4,044,318	2,692,912	\$ 18,850	\$ 13,241,748	\$ (29,985,375)	\$ (16,724,777)
Stock-based compensation expense	—	—	1,547	11	26,674	—	26,685
Debt discount for warrants issued	—	—	—	—	(185)	—	(185)
Net loss	—	—	—	—	—	(88,052)	(88,052)
Balance at June 30, 2022 (unaudited)	756,558	\$ 4,044,318	2,694,459	\$ 18,861	\$ 13,268,237	\$ (30,073,427)	\$ (16,786,329)

The accompanying notes are an integral part of these condensed consolidated financial statements.

BIOAFFINITY TECHNOLOGIES, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30, 2023	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (3,272,963)	\$ (1,560,072)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	43,236	2,079
Accretion of debt issuance costs	—	1,205,255
Fair value adjustments on convertible notes payable	—	(1,186,992)
Stock-based compensation expense	327,868	132,732
Gain on extinguishment of debt	—	(212,258)
Changes in operating assets and liabilities:		
Accounts and other receivables	(79,743)	(6,287)
Inventory	(4,561)	(5,657)
Prepaid expenses and other assets	251,292	28,304
Accounts payable	(170,638)	354,560
Accrued expenses	(26,231)	(42,730)
Accrued interest	—	337,566
Unearned revenue	42,750	
Net cash used in operating activities	<u>(2,888,990)</u>	<u>(1,010,108)</u>
Cash flows from investing activities		
Purchase of equipment	(36,175)	—
Net cash used in investing activities	<u>(36,175)</u>	<u>—</u>
Cash flows from financing activities		
Payment on loan payable	(209,412)	—
Payment of debt		(100,000)
Issuance of loan payable		65,031
Proceeds from issuance of convertible notes payable	—	475,000
Payment of deferred offering costs	—	(520,506)
Payment of debt issuance costs	—	(55,651)
Net cash used in financing activities	<u>(209,412)</u>	<u>(136,126)</u>
Net decrease in cash and cash equivalents	(3,134,577)	(1,146,234)
Cash and cash equivalents at beginning of period	11,413,759	1,360,638
Cash and cash equivalents at end of period	<u>\$ 8,279,182</u>	<u>\$ 214,404</u>
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	\$ 16,406	\$ 2,159
Interest expense paid in cash	\$ 3,015	\$ —
Noncash financing activities:		
Fair value of warrants issued to placement agents	\$ —	\$ 217,973
Beneficial conversion feature for bridge notes	\$ —	\$ 213,942

The accompanying notes are an integral part of these condensed consolidated financial statements.

BIOAFFINITY TECHNOLOGIES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. NATURE OF OPERATIONS, ORGANIZATION, AND BASIS OF PRESENTATION

Description of Business

bioAffinity Technologies, Inc., a Delaware corporation (the “Company,” “we,” “our” or “bioAffinity Technologies”), addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung. The Company also is conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. bioAffinity Technologies develops proprietary noninvasive diagnostic tests using technology that preferentially target cancer cells and cell populations indicative of a diseased state. Our first diagnostic test, CyPath[®] Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. Research and optimization of our proprietary platform for *in vitro* diagnostics and technologies are conducted in laboratories at The University of Texas at San Antonio. We are developing our platform technologies so that in the future, they will be able to detect, monitor, and treat diseases of the lung and other cancers.

Organization

The Company was formed on March 26, 2014, as a Delaware corporation with its corporate offices located in San Antonio, Texas. On June 15, 2016, the Company formed a wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC, as a Delaware limited liability company.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) and pursuant to the rules and regulations of the SEC for interim financial reporting. The condensed consolidated financial statements are unaudited and in management’s opinion include all adjustments, including normal recurring adjustments and accruals, necessary for a fair presentation of the results for the interim periods presented. Operating results for the periods presented are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2023, or any future period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited annual consolidated financial statements and notes included in the 2022 Form 10-K filed with the SEC.

Liquidity and Capital Resources

In accordance with Accounting Standards Update (“ASU”) 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern for at least one year after the date the condensed consolidated financial statements are issued.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to continue to incur losses and negative cash flows for the foreseeable future. As a result, the Company had an accumulated deficit of \$39.9 million at June 30, 2023. The Company’s cash and cash equivalents at June 30, 2023, were approximately \$8.3 million, representing 93% of total assets. Based on the Company’s current expected level of operating expenditures, the Company believes its cash on hand at June 30, 2023, is sufficient to fund the Company’s ongoing operations for a period of at least twelve (12) months subsequent to the issuance of the accompanying unaudited condensed consolidated financial statements. Thereafter, the Company may need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations. If such funding is not available or not available on terms acceptable to the Company, the Company’s current development plan may be curtailed.

COVID-19

The rapid global spread of the COVID-19 virus since December 2019 has affected production and sales worldwide, disrupted supply chains across a range of industries, and created significant economic volatility. The impact of COVID-19 on the Company’s operational and financial performance will depend on numerous factors, including the spread, duration, and intensity of the pandemic (including resurgences), the emergence of new viral variants, and the impact of the pandemic on the Company’s customers, employees, clinical trial sites, and vendors.

As the COVID-19 pandemic continues to evolve, the ultimate impact on the Company's operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, additional or modified government actions, and the actions taken to contain COVID-19 or address its impact, among others. Management does not yet know the full extent of potential delays or impacts on the Company, clinical trials, research programs, healthcare systems, or the global economy but continues to monitor the situation closely.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the valuation allowance on the Company's deferred tax assets, and the useful lives of fixed assets.

Principles of Consolidation

The accompanying condensed consolidated financial statements include all of the accounts of the Company and its wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC. All significant intercompany balances and transactions have been eliminated.

Cash and Cash Equivalents

For the purpose of the statement of cash flows, the Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at cost, which approximates market value, because of the short maturity of these instruments.

Concentration of Risk

The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of \$250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flow.

Advertising expense

The Company expenses all advertising costs as incurred. Advertising expense was approximately \$28,000 and \$3,000 for the six months and \$22,000 and \$0 for the three months ended June 30, 2023 and 2022, respectively.

Loss Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of the Company's common stock, par value \$0.007 per share (the "Common Stock") outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to common stockholders by the sum of the weighted-average number of shares of Common Stock outstanding during the period and the weighted-average number of dilutive Common Stock equivalents outstanding during the period, using the treasury stock method. Dilutive Common Stock equivalents are comprised of in-the-money stock options, convertible notes payable, and warrants based on the average stock price for each period using the treasury stock method.

The following potentially dilutive securities have been excluded from the computations of weighted average shares of Common Stock outstanding as of June 30, 2023 and 2022, as they would be anti-dilutive:

	As of June 30,	
	2023	2022
Convertible preferred stock	—	776,871
Shares underlying options outstanding	806,392	883,690
Shares underlying warrants outstanding	4,649,952	2,057,740
Shares underlying convertible notes	—	2,552,435
	<u>5,556,344</u>	<u>6,270,736</u>

Revenue Recognition

Revenue is generated in three ways for the six months and three months, respectively, ended June 30, 2023: (1) royalties from the Company's diagnostic test, CyPath® Lung for approximately \$8,000 and \$7,000 and \$, (2) clinical flow cytometry services provided to Precision Pathology Services related to the Company's CyPath® Lung test for approximately \$3,000 and \$3,000, and (3) CyPath® Lung tests purchased by the U.S. Department of Defense ("DOD") for approximately \$10,000 and \$10,000 for an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay (NCT05870592)," and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee, began a limited market launch in the second quarter of 2022 to pulmonologists, internists, and general practitioners in the South Texas area designed to refine future positioning and develop strategic marketing insight for our CyPath® Lung test. The services are completed upon release of a patient's test result to the ordering healthcare provider.

To determine revenue recognition for the arrangements that the Company determines are within the scope of ASC 606, *Revenue from Contracts with Customers*, the Company performs the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. The Company reclassified patent expenses and annuity costs of approximately \$101,000 and \$59,000 from research and development to selling, general and administrative for the six months and three months ended June 30, 2022, respectively.

Recent Accounting Pronouncements

The Company continues to monitor new accounting pronouncements issued by the Financial Accounting Standards Board ("FASB") and does not believe any accounting pronouncements issued through the date of this Quarterly Report will have a material impact on the Company's condensed consolidated financial statements.

Note 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

	June 30, 2023	December 31, 2022
Prepaid insurance	\$ 104,294	\$ 340,078
Legal and professional	47,200	72,048
Other	128,193	119,773
Total prepaid expenses and other current assets	<u>\$ 279,687</u>	<u>\$ 531,899</u>

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	June 30, 2023	December 31, 2022
Lab equipment	\$ 488,718	\$ 462,155
Computers and software	31,076	21,463
	519,794	483,618
Accumulated depreciation	(312,417)	(269,180)
Total property and equipment, net	<u>\$ 207,377</u>	<u>\$ 214,438</u>

Depreciation expense was approximately \$41,000 and \$2,000 for the six months ended and \$21,000 and \$1,000 for the three months ended June 30, 2023 and 2022, respectively

Note 5. ACCRUED EXPENSES

Accrued expenses are summarized below:

	June 30, 2023	December 31, 2022
Compensation	\$ 276,519	\$ 340,680
Legal and professional	179,416	144,440
Clinical	54,728	50,922
Other	5,000	5,852
Total accrued expenses	<u>\$ 515,663</u>	<u>\$ 541,894</u>

Note 6. UNEARNED REVENUE

During the three months ended June 30, 2023, the Company engaged in an observational study of CyPath® Lung with the DOD. A total of 70 CyPath® Lung units were ordered and shipped. However, in compliance with FASB ASC 606, the performance obligation was complete for only 13 units as of June 30, 2023. The performance obligation is deemed complete after samples have been collected and processed and results analyzed. The unearned revenue balance amounted to approximately \$43,000 as of June 30, 2023.

Note 7. LOAN PAYABLE

In September 2022, the Company obtained short-term financing of approximately \$0.5 million with ten monthly payments of approximately \$42,000 and interest at a 4.3% fixed annual rate for director and officer insurance policies. The loan amount was approximately \$42,000 and \$252,000 as of June 30, 2023 and December 31, 2022, respectively.

Note 8. FAIR VALUE MEASUREMENTS

The Company analyzes all financial instruments with features of both liabilities and equity under the FASB accounting standard for such instruments. Under this standard, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts and other receivables, prepaid and other current assets, accounts payable, accrued expenses, and loan payable, are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

Note 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its corporate offices under a month-to-month agreement and leases its laboratory and additional office space under an operating lease that is renewable annually by written notice by the Company and will require renewal in February 2024. Rent expense for office and lab space amounted to approximately \$53,000 and \$26,000 for the six months and \$26,000 and \$13,000 for the three months ended June 30, 2023 and 2022, respectively.

Legal Matters

From time to time, the Company is involved in various disputes and litigation matters that arise in the ordinary course of business. To date, the Company has no material pending legal proceedings.

Note 10. COMMON STOCK

Common Stock

The Company has authorized a total of 25,000,000 shares of Common Stock, \$0.007 par value per share. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 14,285,715 shares to 25,000,000 shares. The Company has issued 8,555,365 shares of Common Stock as of June 30, 2023, and 8,381,324 shares of Common Stock as of December 31, 2022.

Note 11. STOCK-BASED COMPENSATION

The Company grants options and restricted stock awards under its 2014 Equity Incentive Plan (the “Plan”). Under the Plan, the Company is authorized to grant options or restricted stock for up to 2,000,000 million shares of Common Stock. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 1,142,857 to 2,000,000. Options or restricted stock awards may be granted to employees, the Company’s board of directors, and external consultants who provide services to the Company. Options and restricted stock awards granted under the Plan have vesting schedules with terms of one to three years and become fully exercisable based on specific terms imposed at the date of grant. The Plan will terminate according to the respective terms of the Plan in September 2026.

The Company has recorded stock-based compensation expense (credit) related to the issuance of restricted stock awards in the following line items in the accompanying condensed consolidated statement of operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 10,620	\$ 2,363	\$ 21,889	\$ 7,860
General and administrative	159,634	24,322	305,979	124,872
	<u>\$ 170,255</u>	<u>\$ 26,685</u>	<u>\$ 327,868</u>	<u>\$ 132,732</u>

The following table summarizes stock option activity under the Plan:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2022	806,392	\$ 4.33		
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Outstanding at June 30, 2023	806,392	\$ 4.33	3.8	\$ 271,298
Vested and exercisable at June 30, 2023	803,813	\$ 4.32	3.7	\$ 271,298

As of June 30, 2023, there was no unrecognized compensation cost related to non-vested stock options. During the six months ended June 30, 2023 and 2022, no options were exercised. During the six months ended June 30, 2023, no options were issued by the Company to purchase shares of Common Stock. During the six months ended June 30, 2022, the Company issued options to purchase 7,142 shares of Common Stock. The per share weighted-average fair value of the options granted during 2022 was estimated at \$2.84 on the date of grant.

The following table summarizes restricted stock award activity under the Plan:

	Number of restricted stock awards (RSA)	Weighted- average grant price	FMV on grant date	Vested number of RSA	Unvested number of RSA
Balance at December 31, 2022	114,920	\$ 3.56	\$ 409,437	32,008	82,912
Granted	219,812	1.82	401,079	174,043	
Forfeited	—	—	—	—	—
Balance at June 30, 2023	806,392	\$ 4.33	\$ 810,517	206,051	128,681

During the six months ended June 30, 2023, the Company issued restricted stock awards (RSAs) for 219,812 shares of Common Stock to employees, non-employees, and the board of directors. The shares vest in equal monthly installments over terms of between immediately up to three years, subject to the employees and non-employees providing continuous service through the vesting date. During the six months ended June 30, 2023, 31,020 shares vested from RSAs granted prior to January 1, 2023, and 143,023 shares vested from RSAs granted during the six months ended June 30, 2023.

During the six months ended June 30, 2022, the Company issued RSAs for 14,999 shares of Common Stock to employees and non-employees. The shares vest in equal monthly installments over terms of between immediately up to one year, subject to the employees and non-employees providing continuous service through the vesting date. During the six months ended June 30, 2022, approximately 5,000 shares vested from RSAs previously issued.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the six months ended June 30, 2022. No stock options have been issued during the six months ended June 30, 2023:

	2022
Fair value of Common Stock	\$ 4.62
Volatility	63.9%
Expected term (years)	6.0
Risk-free interest rate	2.20%
Dividend yield	0%

Note 12. WARRANTS

The Company accounts for Common Stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Warrants are accounted for as derivative liabilities if the warrants allow for cash settlement or provide for modification of the warrant exercise price in the event subsequent sales of Common Stock by the Company are at a lower price per share than the then-current warrant exercise price. The Company classifies derivative warrant liabilities on the condensed consolidated balance sheet at fair value, and changes in fair value during the periods presented in the condensed consolidated statement of operations, which is revalued at each balance sheet date subsequent to the initial issuance of the stock warrant.

As of June 30, 2023, and December 31, 2022, the Company had 4,649,952 warrants outstanding to purchase one share of the Company's Common Stock for each warrant at a weighted average exercise price of \$6.15 and expire at various dates through September 2027. During the six months ended June 30, 2023 and 2022, no warrants were exercised into an equivalent number of Common Shares.

Note 13. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the condensed consolidated financial statements were available to be issued. Based upon this review, the Company did not identify any subsequent events that would have required adjustment or disclosure in the condensed consolidated financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This section presents management's perspective on our financial condition and results of operations. The following discussion and analysis (the "MD&A") is intended to highlight and supplement data and information presented elsewhere in this Quarterly Report, and should be read in conjunction with our interim unaudited condensed consolidated financial statements and notes elsewhere in this Quarterly Report and our audited consolidated financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2022, included in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023 (the "2022 Form 10-K"). The MD&A is also intended to provide you with information that will assist you in understanding our consolidated financial statements, the changes in key items in those consolidated financial statements from year to year, and the primary factors that accounted for those changes. To the extent that this discussion describes prior performance, the descriptions relate only to the periods listed, which may not be indicative of our future financial outcomes. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties, and assumptions that could cause the Company's financial results to differ materially from management's expectations. Factors that could cause such differences are discussed in the "Cautionary Note Regarding Forward-Looking Statements" section of this Quarterly Report and in the "Risk Factors" section of the 2022 Form 10-K.

Data as of and for the six months ended June 30, 2023 and 2022, has been derived from our unaudited condensed consolidated financial statements appearing at the beginning of this Quarterly Report. Results for any interim period should not be construed as an inference of what our results would be for any full fiscal year or future period.

Our MD&A is organized as follows:

- *Company Overview* – Discussion of our business plan and strategy to provide context for the remainder of the MD&A.
- *Results of Operations* – Analysis of our financial results comparing the six months ended June 30, 2023, to the comparable period in 2022.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Estimates* – Accounting estimates that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

Company Overview

Business

bioAffinity Technologies, Inc. (the "Company," "we," or "our") develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We also are conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. We develop proprietary noninvasive diagnostic tests using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Research and optimization of our platform technologies are conducted in laboratories at The University of Texas at San Antonio.

Our diagnostic test, CyPath[®] Lung, addresses the need for noninvasive detection of early-stage lung cancer. Lung cancer is the leading cause of cancer-related deaths. Physicians are able to order CyPath[®] Lung to assist in their assessment of patients who are at high risk for lung cancer. The CyPath[®] Lung test enables physicians to more confidently distinguish between patients who will likely benefit from timely intervention and more invasive follow-up procedures from patients who are likely without lung cancer and should continue annual screening. CyPath[®] Lung has the potential to increase overall diagnostic accuracy of lung cancer, which could lead to increased survival, fewer unnecessary invasive procedures, reduced patient anxiety, and lower medical costs.

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, our research has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells. We are focused on expanding our broad-spectrum platform technologies to develop tests that detect and therapies that target various types of cancer and potentially other diseases.

Recent Developments

In June 2023, the American Medical Association (“AMA”) publicly approved and released a new Current Procedural Terminology (“CPT®”) Proprietary Laboratory Analysis (“PLA”) code specifically for use with CyPath® Lung. The new PLA code alphanumeric will be finalized and effective October 1, 2023. Prior to and in the interim until the new code is effective, CyPath® Lung is reported with a non-specific CPT code, for which payment is determined by the payer on a case-by-case basis. Payment for the new PLA code was discussed on July 19, 2023, by the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests. The Centers for Medicare and Medicaid Services (“CMS”) preliminary determination will be released in September followed by a 30-day comment period. A final payment determination will be made by CMS in November, effective January 1, 2024. There is an opportunity for reconsideration if the Company disagrees with the CMS decision.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our diagnostic test, CyPath® Lung. As a result, since our inception in 2014, we have funded our operations principally through private sales of our equity or debt securities. As of June 30, 2023, we had cash and cash equivalents of \$8.3 million. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of the filing of this Quarterly Report with the SEC.

In the second quarter of 2022, we started to recognize revenue from sales of the CyPath® Lung test by our licensee, Precision Pathology Services (“Precision Pathology”), a CAP-accredited, CLIA-certified clinical pathology laboratory. We have never been profitable, and as of June 30, 2023, we had total working capital of \$7.9 million and an accumulated deficit of approximately \$39.9 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and advance our diagnostic tests through clinical trials. We intend to license our therapeutic products for clinical development should animal and pre-clinical studies prove successful.

We anticipate raising additional cash needed through the private or public sales of equity or debt securities, collaborative arrangements, or a combination thereof to continue to fund our operations and develop our products. There is no assurance that any such collaborative arrangement will be entered into or that financing will be available to us when needed in order to allow us to continue our operations or, if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, we may be forced to curtail operations, delay our clinical trials, cease operations altogether, or file for bankruptcy.

Results of Operations

Three Months Ended June 30, 2023, Compared to Three Months Ended June 30, 2022

Net loss for the three months ended June 30, 2023, was approximately \$1.7 million, compared to a net loss of approximately \$88,000 for the three months ended June 30, 2022, resulting from the operational activities described below and a prior year non-cash FMV adjustment of \$783,000 relating to convertible notes. The increase in net loss was primarily attributed to a prior year non-cash adjustment of \$783,000 related to the fair value of convertible notes that were outstanding during the quarter ended June 30, 2022 and were no longer outstanding during the quarter ended June 30, 2023.

Revenue

Revenue is generated in three ways: (1) royalties from our diagnostic test, CyPath® Lung, (2) clinical flow cytometry services provided to Precision Pathology Services related to our CyPath® Lung test, and (3) CyPath® Lung tests purchased by the DOD for an observational study, “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay (NCT05870592),” and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee, began a limited market launch in the second quarter of 2022 to pulmonologists, internists, and general practitioners in the South Texas area designed to refine future positioning and develop strategic marketing insight for our CyPath® Lung test. The services are completed upon release of a patient’s test result to the ordering healthcare provider.

In the first quarter of 2023, we engaged the marketing and advertising firms of Havas Health & You and Trinity Life Sciences to build the CyPath® Lung brand and position it for success in the cancer diagnostics sector. Havas Health & You, a large global health network, is creating the branding to align with the need for a patient-friendly diagnostic that gives physicians another tool to assess the potential or presence of lung cancer in their high-risk patients. Trinity Life Sciences is using the insights and analytics it has gathered from healthcare practitioners to focus the short-term objectives of our marketing strategy for CyPath® Lung. The limited test market launch in South Texas is designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market.

In addition to introducing pulmonologists, family practitioners, and other providers to CyPath® Lung, we are selling CyPath® Lung tests to the DOD for an observational study, “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay,” and for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. The DOD represents a significant potential market for CyPath® Lung. Including sales to the DOD, clinical services provided to Precision Pathology and direct sales of CyPath® Lung as a laboratory developed test (“LDT”) to physicians, we had revenue of approximately \$20,000 during the three months ended June 30, 2023, compared to \$1,000 revenue in 2022. Sales to the DOD represented \$10,000 (50%), royalty income represented \$7,000 (35%), and services represented \$3,000 (15%) of total revenues.

We expect revenues from CyPath[®] Lung to continue to grow as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas and larger medical systems. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

(amounts in thousands)	Three Months Ended June 30,		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(unaudited)			
Revenue				
Royalty income (CyPath [®] Lung sales)	\$ 7	\$ 1	\$ 6	423%
Clinical services (flow cytometry)	3	—	3	100%
DoD observational study (CyPath [®] Lung)	10	—	10	100%
Total Revenue	\$ 20	\$ 1	\$ 19	1411%

Cost of Sales

Cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers. The increase in cost of sales for the three months ended June 31, 2023, is primarily due to sales of our diagnostic kits during the quarter, compared to no sales in the prior year.

Operating Expenses

(amount in thousands)	Three Months Ended June 30, ⁽¹⁾		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(unaudited)			
Operating expenses				
Research and development	\$ 335	\$ 248	\$ 87	35%
Clinical development	35	28	7	25%
Selling, general and administrative	1,427	409	1,018	249%
Total operating expenses	\$ 1,797	\$ 685	\$ 1,112	162%

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the three-month period ended June 30, 2023 and 2022, respectively.

Operating expenses totaled approximately \$1.8 million and \$0.7 million during the three months ended June 30, 2023 and 2022, respectively. The increase in operating expenses is the result of the following factors.

Research and Development Expenses

Our research and development expenses consist primarily of expenditures for lab operations, preclinical and clinical studies, compensation, and consulting costs.

Research and development expenses totaled approximately \$335,000 and \$248,000 for the three months ended June 30, 2023, and 2022, respectively. The increase of approximately \$87,000, or 35%, for the three months ended June 30, 2023, compared to the same period in 2022, was primarily due to an increase in compensation costs and benefits as we added research personnel, as well as a related increase in costs for lab supplies and reagents. Additionally, equipment costs, including depreciation and maintenance costs, increased as we purchased capital equipment to support research and development efforts.

Clinical Development

Clinical development expenses totaled approximately \$35,000 and \$28,000 for the six months ended June 30, 2023 and 2022, respectively. The increase of approximately \$7,000, or 25%, for the six months ended June 30, 2023, compared to the same period in 2022, was primarily attributable to an increase in professional fees, including consulting fees, related to evaluating the clinical strategy in the prior year for our pivotal clinical trial designed to confirm the sensitivity and specificity of CyPath[®] Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate pulmonary nodules between 6mm and 30mm in size which often present a challenge in diagnosis.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of expenditures related to employee compensation, legal, accounting and tax, other professional services, and general operating expenses.

Selling, general and administrative expenses totaled approximately \$1.4 million and \$409,000 for the three months ended June 30, 2023 and 2022, respectively. The increase of approximately \$1.0 million, or 249%, for the three months ended June 30, 2023, compared to the same period in 2022, was primarily attributable to an increase in consulting, legal and professional fees incurred in 2023 compared to 2022 to comply with the reporting requirements of a public company, as well as an increase related to board compensation. Patent costs increased in the current year as we maintain and expand our patent portfolio to protect our diagnostic and therapeutic platforms. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath[®] Lung.

Other Income (Expense)

	Three Months Ended		Change in 2023	
	June 30,		Versus 2022	
	2023	2022	\$	%
(amount in thousands)	(unaudited)			
Interest income (expense), net	\$ 43	\$ (399)	\$ 442	111%
Gain (loss) on change in fair value of convertible notes	—	995	(995)	-100%
Total other income (expense)	\$ 37	\$ 596	\$ (553)	-93%

Other income (expense), net totaled approximately \$37,000 and \$0.6 million for the three-month period ended June 30, 2023 and 2022, respectively.

Interest Income (Expense), net

Interest income (expense), net was approximately \$43,000 for the three months ended June 30, 2023, compared to (\$0.4) million for the three months ended June 30, 2022. The change was due to no convertible notes being outstanding during the current year compared to the same period in the prior year, as all convertible and bridge notes were converted as a result of our initial public offering (“IPO”) in the prior year. Additionally, in 2022 the Company recorded interest expense for the amortization of debt discount related to the issuance of bridge notes.

Gain (loss) on change in fair value of convertible notes

There was a gain of approximately \$1.0 million on the change in fair value of convertible notes during the three months ended June 30, 2022, compared to no gain during the three months ended June 30, 2023. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term, and other assumptions during the reported periods. All convertible and bridge notes were converted as a result of our IPO in the prior year, resulting in no additional changes in fair value related to the convertible and bridge notes.

Six Months Ended June 30, 2023, Compared to Six Months Ended June 30, 2022

Net loss for the six months ended June 30, 2023, was approximately \$3.2 million, compared to a net loss of approximately \$1.6 million for the six months ended June 30, 2022, resulting from the operational activities described below and a prior year non-cash FMV adjustment of \$1.2 million relating to convertible notes. The increase in net loss was primarily attributed to a prior year non-cash adjustment of \$1.6 million related to the fair value of convertible notes that were outstanding during the quarter ended June 30, 2022 and were no longer outstanding during the quarter ended June 30, 2023.

Revenue

Revenue is generated in three ways: (1) royalties from the Company’s diagnostic test, CyPath[®] Lung, (2) clinical flow cytometry services provided to Precision Pathology Services related to our CyPath[®] Lung test, and (3) CyPath[®] Lung tests purchased by the DOD for an observational study, “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath[®] Lung Assay (NCT05870592),” and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee, began a limited market launch in the second quarter of 2022 to pulmonologists, internists, and general practitioners in the South Texas area designed to refine future positioning and develop strategic marketing insight for our CyPath[®] Lung test. The services are completed upon release of a patient’s test result to the ordering healthcare provider.

In the first quarter of 2023, the Company engaged the marketing and advertising firms of Havas Health & You and Trinity Life Sciences to build the CyPath[®] Lung brand and position it for success in the cancer diagnostics sector. Havas Health & You, a large global health network, is creating the branding to align with the need for a patient-friendly diagnostic that gives physicians another tool to assess the potential or presence of lung cancer in their high-risk patients. Trinity Life Sciences is using the insights and analytics it has gathered from healthcare practitioners to focus the short-term objectives of our marketing strategy for CyPath[®] Lung. The limited test market launch in South Texas is designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath[®] Lung test before expanding to a larger market.

In addition to introducing pulmonologists, family practitioners, and other providers to CyPath[®] Lung, we are selling CyPath[®] Lung tests to the DOD for an observational study, “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath[®] Lung Assay,” and for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. The DOD represents a significant potential market for CyPath[®] Lung. Including sales to the DOD, clinical services provided to Precision Pathology, and direct sales of CyPath[®] Lung as a laboratory developed test (“LDT”) to physicians, we had revenue of approximately \$21,000 during the six months ended June 30, 2023, compared to no revenue in 2022. Sales to the DOD represented \$10,000 (48%), royalty income represented \$8,000 (38%) and services represented \$3,000 (14%) of total revenues.

We expect revenues from CyPath® Lung to continue to grow as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas and larger medical systems. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

	Six Months Ended June 30, ⁽¹⁾		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(unaudited)			
(amount in thousands)				
Revenue				
Royalty income (CyPath® Lung sales)	\$ 8	\$ 1	\$ 7	493%
Clinical services (flow cytometry)	3	—	3	100%
DoD observational study (CyPath® Lung)	10	—	10	100%
Total revenue	\$ 21	\$ 1	\$ 20	1566%

Cost of Sales

Cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers. The increase in cost of sales for the six months ended June 30, 2023, is primarily due to sales of our diagnostic kits during the quarter, compared to no sales in the prior year.

Operating Expenses

	Six Months Ended June 30, ⁽¹⁾		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(unaudited)			
(amount in thousands)				
Operating expenses				
Research and development	\$ 705	\$ 528	\$ 176	33%
Clinical development	55	81	(26)	-32%
Selling, general and administrative	2,596	803	1,793	223%
Total operating expenses	\$ 3,356	\$ 1,412	\$ 1,943	138%

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the six-month period ended June 30, 2023 and 2022, respectively.

Operating expenses totaled approximately \$3.4 million and \$1.4 million during the six months ended June 30, 2023 and 2022, respectively. The increase in operating expenses is the result of the following factors.

Research and Development Expenses

Our research and development expenses consist primarily of expenditures for lab operations, clinical and preclinical studies, compensation, and consulting costs.

Research and development expenses totaled approximately \$705,000 and \$528,000 for the six months ended June 30, 2023 and 2022, respectively. The increase of approximately \$176,000, or 33%, for the six months ended June 30, 2023, compared to the same period in 2022, was primarily due to an increase in compensation costs and benefits due to additional research personnel, as well as a related increase in costs for lab supplies and reagents. Additionally, equipment costs, including depreciation and maintenance costs, increased as we purchased capital equipment to support research and development efforts.

Clinical Development

Clinical development expenses totaled approximately \$55,000 and \$81,000 for the six months ended June 30, 2023 and 2022, respectively. The decrease of approximately \$26,000, or 32%, for the six months ended June 30, 2023, compared to the same period in 2022, was primarily attributable to a decrease in professional fees, including consulting fees, related to evaluating the clinical strategy in the prior year for our pivotal clinical trial designed to confirm the sensitivity and specificity of CyPath® Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate lung nodules between 6mm and 30mm in size which often present a challenge in diagnosis.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of expenditures related to employee compensation, legal, accounting and tax, other professional services, and general operating expenses.

Selling, general and administrative expenses totaled approximately \$2.6 million and \$803,000 for the six months ended June 30, 2023 and 2022, respectively. The increase of approximately \$1.8 million, or 223%, for the six months ended June 30, 2023, compared to the same period in 2022, was primarily attributable to an increase in consulting, legal, and professional fees incurred in 2023 compared to 2022 to comply with the reporting requirements of a public company, as well as an increase related to board compensation. Patent costs increased in the current year as we maintain and expand our patent portfolio to protect our diagnostic and therapeutic platforms. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath[®] Lung.

Other Income (Expense)

	Six Months Ended June 30,		Change in 2023 Versus 2022	
	2023	2022	\$	%
(amount in thousands)	(unaudited)			
Interest income (expense), net	\$ 80	\$ (1,546)	\$ 1,626	105%
Gain (loss) on change in fair value of convertible notes	—	1,399	(1,399)	-100%
Total other income (expense)	\$ 80	\$ (148)	\$ 228	154%

Other income (expense), net totaled approximately \$80,000 and (\$148,000) for the six-month period ended June 30, 2023 and 2022, respectively.

Interest Income (Expense), net

Interest income (expense), net was approximately \$80,000 for the six months ended June 30, 2023, compared to (\$1.5) million for the six months ended June 30, 2022. The change was due to no convertible notes outstanding during the current year compared to the same period in the prior year, as all convertible and bridge notes were converted as a result of our IPO in the prior year. Additionally, in 2022 the Company recorded interest expense for the amortization of debt discount related to the issuance of bridge notes.

Gain (loss) on change in fair value of convertible notes

There was a gain of approximately \$1.4 million on the change in fair value of convertible notes during the six months ended June 30, 2022, compared to no loss during the six months ended June 30, 2023. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term, and other assumptions during the reported periods. All convertible and bridge notes were converted as a result of our IPO in the prior year, resulting in no additional changes in fair value related to the convertible and bridge notes.

Liquidity and Capital Resources

To date, we have funded our operations primarily through our IPO, exercise of warrants, and the sale of our equity and debt securities, resulting in gross proceeds of approximately \$34.3 million.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic test or therapeutic products to generate revenue. For the six months ended June 30, 2023 and 2022, we had net losses of \$3.2 million and \$1.6 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$39.9 million as of June 30, 2023. Cash and cash equivalents were approximately \$8.3 million as of June 30, 2023. Based on our current level of expected operating expenditures, we expect to be able to fund our operations for at least 12 months following the date of this Quarterly Report.

We continue to seek sources of financing to fund our continued operations and research and development programs. To raise additional capital, we may sell additional equity or debt securities, or enter into collaborative, strategic, and/or licensing transactions. There can be no assurance that we will be able to complete any financing transaction in a timely manner or on acceptable terms or otherwise enter into a collaborative or strategic transaction. If we are not able to raise additional cash, we may be forced to delay, curtail, or cease development of our diagnostic tests or therapeutic products, or cease operations altogether.

Summary Statements of Cash Flows

The following information reflects cash flows for the periods presented:

	Six Months Ended	
	June 30,	
	2023	2022
(amounts in thousands)	(unaudited)	
Cash and cash equivalents at beginning of period	\$ 11,414	\$ 1,361
Net cash used in operating activities	(2,889)	(1,010)
Net cash used in investing activities	(36)	—
Net cash used in financing activities	(210)	(136)
Cash and cash equivalents at end of period	\$ 8,279	\$ 215

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$2.9 million and \$1.0 million for the six months ended June 30, 2023 and 2022, respectively. The increase of approximately \$1.8 million in cash used by operations during the six months ended June 30, 2023, compared to the same period in 2022, was primarily attributable to an increase of \$1.7 million in our loss from operations as compared to the prior year as described above.

Net Cash Used in Investing Activities

The Company used approximately \$36,000 for the six months ended June 30, 2023, in investing activities related to the purchase of computer and lab equipment, compared to no cash used in investing activities for the six months ended June 30, 2022.

Net Cash Used by Financing Activities

Cash used in financing activities was approximately \$209,000 compared to cash used in financing activities of approximately \$136,000 for the six months ended June 30, 2023, and 2022, respectively. The change in cash used in financing activities for the six months ended June 30, 2023, compared to 2022, was a result of the short-term financing we obtained for director and officer insurance policies, compared to net proceeds from bridge notes of approximately \$0.5 million in the same period in the prior year, offset by the payment of deferred issuance costs related to the anticipated IPO completed in September 2022.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials and other services and products used for research and development and operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that any non-cancelable obligations under these agreements are not material.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make significant judgments and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases these significant judgments and estimates on historical experience and other assumptions it believes to be reasonable based upon information presently available. Actual results could differ from those estimates under different assumptions, judgments, or conditions.

Stock-Based Compensation

We follow ASC 718, *Compensation – Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, directors, and non-employees based on estimated fair values. We have used the Black-Scholes option pricing model to estimate grant date fair value for all option grants. The assumptions we use in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. Since we use different assumptions based on a change in factors, our stock-based compensation expense could be materially different in the future.

Accounting for Income Taxes

We are governed by U.S. income tax laws, which are administered by the Internal Revenue Service ("IRS"). We follow ASC 740, *Accounting for Income Taxes*, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which the related temporary difference becomes deductible.

Emerging Growth Company Status

We are both an "emerging growth company" and a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are therefore subject to reduced public company reporting requirements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a smaller reporting company, pursuant to Item 305(e) of Regulation S-K promulgated under the Securities Act, we are not required to provide the information required by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act) Rules 13a-15(e) and 15d-15(e)). Rule 13a-15(e) under the Exchange Act defines "disclosure controls and procedures" as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to a company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that due to limited resources and limited number of employees, its internal control over financial reporting was ineffective as of June 30, 2023, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. To mitigate the limited resources and employees, we rely heavily on direct management oversight of transactions, along with the use of legal and accounting professionals. As we grow, we expect to increase the number of employees, which we believe will enable us to implement adequate segregation of duties within the internal control framework.

Changes in Internal Control over Financial Reporting

On May 1, 2023, Michael Dougherty, Chief Financial Officer, joined the Company. Further segregation of duty over financial transactions and reconciliations have been put in place as of June 30, 2023. In addition, a new Senior Accountant was hired in July 2023 to increase the resources required to implement preparer and reviewer financial controls. A risk control approach has begun to evaluate all material risk, mitigating controls and identify any gaps related to financial reporting. In addition, the Company will rely on heavy direct management oversight of transactions, along with the use of legal and accounting professionals.

PART II

ITEM 1. LEGAL PROCEEDINGS.

From time to time, we are involved in various disputes and litigation matters that arise in the ordinary course of business. To date, we have had no material pending legal proceedings, and we are not engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse impact on our financial position or results of operations.

ITEM 1A. RISK FACTORS.

As a smaller reporting company, we are not required to provide disclosure pursuant to this Item 1A. However, in addition to other information set forth in this Quarterly Report, you should carefully consider the “Risk Factors” discussed in the 2022 Form 10-K filed with the SEC on March 31, 2023, pursuant to Rule 424(b)(4) under the Securities Act for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Quarterly Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition, and operating results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Unregistered Sales of Equity Securities

We did not sell any equity securities during the six months ended June 30, 2023 in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC and as described below. We believe that each transaction was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof.

On January 1, 2023, we issued an aggregate of 57,589 restricted shares of the Company’s Common Stock to our seven directors, which shares of restricted stock will vest ratably over three months of continued service and which represents a restricted stock award to each director valued at \$18,750 granted by us to each of our directors each quarter during the calendar year as part of our director compensation policy.

On April 15, 2023, we issued an aggregate of 69,440 restricted shares of the Company’s Common Stock to our seven directors, which shares of restricted stock will vest one-third on the date of grant, one-third on May 1, 2023, and the remaining shares on June 1, 2023, provided each individual continues to service as a director, and which represents a restricted stock award to each director valued at \$18,750 granted by us to each of our directors each quarter during the calendar year as part of our director compensation policy.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable.

ITEM 6. EXHIBITS.

Exhibit No.	Title of Document
3.1	<u>Amended and Restated Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (Incorporated by reference as Exhibit 3.1 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
3.2*	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016</u>
3.3	<u>Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
3.4*	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021</u>
3.5	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
3.6	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)</u>
3.7	<u>Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
10.1+	<u>Offer Letter between bioAffinity Technologies, Inc. and Michael Dougherty dated April 11, 2023 (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 1, 2023)</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002</u>
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheet, (ii) Condensed Consolidated Statement of Operations, (iii) Condensed Consolidated Statement of Stockholders' Equity, (iv) Condensed Consolidated Statement of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104*	The cover page from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, formatted in Inline XBRL
101.INS	Inline XBRL Instance Document *
101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *

* Filed herewith.

† Indicates management contract or compensatory plan.

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 thereunto duly authorized.

bioAffinity Technologies, Inc.
(Registrant)

By: /s/ Maria Zannes
Maria Zannes
Chief Executive Officer, President, Founder, and Director
Date: August 14, 2023

By: /s/ Michael Dougherty
Vice President and Chief Financial Officer
Date: August 14, 2023

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT
COPY OF THE CERTIFICATE OF AMENDMENT OF "BIOAFFINITY
TECHNOLOGIES, INC.", FILED IN THIS OFFICE ON THE TWENTY-NINTH
DAY OF NOVEMBER, A.D. 2021, AT 12:08 O`CLOCK P.M.



5505424 8100
SR# 20213910017

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 204824501
Date: 12-01-21

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:08 PM 11/29/2021
FILED 12:08 PM 11/29/2021
SR 20213910017 - File Number 5505424

**CERTIFICATE OF AMENDMENT OF
CERTIFICATE OF INCORPORATION OF
BIOAFFINITY TECHNOLOGIES, INC.**

bioAffinity Technologies, Inc. (the "**Corporation**"), a corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certifies as follows:

1. This Certificate of Amendment (the "**Certificate of Amendment**") amends the provisions of the Corporation's Certificate of Incorporation filed with the Secretary of State on March 26, 2014, as previously amended by that Certificate of Amendment filed with the Secretary of State on May 31, 2016 (the "**Certificate of Incorporation**").
2. The Corporation's board of directors adopted resolutions setting forth this amendment to the Corporation's Certificate of Incorporation declaring said amendment to be advisable and soliciting the approval of the Corporation's stockholders. Thereafter, the necessary number of shares as required by statute approved this amendment at a properly noticed and duly convened meeting of the Corporation's stockholders.
3. Section 4 of the Certificate of Incorporation is hereby amended and restated in its entirety as follows:
 - "4. The total number of shares of common stock which the corporation is authorized to issue is 100,000,000, at a par value of \$0.001 per share and the total number of shares of preferred stock which the corporation is authorized to issue is 20,000,000, at a par value of \$0.001 per share."
4. This amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.
5. All other provisions of the Certificate of Incorporation shall remain in full force and effect.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by Maria Zannes, its President and Chief Executive Officer, this 24th day of November 2021.

DocuSigned by:
Maria Zannes

Maria Zannes
President and Chief Executive Officer

State of Delaware
 Secretary of State
 Division of Corporations
 Delivered 06:14 PM 05/31/2016
 FILED 06:14 PM 05/31/2016
 SR 20164123560 - File Number 5505424

**CERTIFICATE OF AMENDMENT OF
 CERTIFICATE OF INCORPORATION OF
 BIOAFFINITY TECHNOLOGIES, INC.**

bioAffinity Technologies, Inc. (the "**Corporation**"), a corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certifies as follows:

1. This Certificate of Amendment (the "**Certificate of Amendment**") amends the provisions of the Corporation's Certificate of Incorporation filed with the Secretary of State on March 26, 2014 (the "**Certificate of Incorporation**").
2. The Corporation's board of directors adopted resolutions setting forth this amendment to the Corporation's Certificate of Incorporation declaring said amendment to be advisable and soliciting the approval of the Corporation's stockholders. Thereafter, the necessary number of shares as required by statute approved this amendment at a properly noticed and duly convened meeting of the Corporation's stockholders.
3. Section 4 of the Certificate of Incorporation is hereby amended and restated in its entirety as follows:

"4. The total number of shares of common stock which the corporation is authorized to issue is 50,000,000, at a par value of \$0.001 per share and the total number of shares of preferred stock which the corporation is authorized to issue is 20,000,000, at a par value of \$0.001 per share."
4. This amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.
5. All other provisions of the Certificate of Incorporation shall remain in full force and effect.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by Maria Zannes, its President and Chief Executive Officer, this 31st day of May 2016.


 Maria Zannes
 President and Chief Executive Officer

**Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended June 30, 2023**

I, Maria Zannes, certify that:

1. I have reviewed this report on Form 10-Q of bioAffinity Technologies, Inc. (“registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 14, 2023

/s/ Maria Zannes

Maria Zannes

President and Chief Executive Officer
(Principal Executive Officer)

**Certification of the Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended June 30, 2023**

I, Michael Dougherty, certify that:

1. I have reviewed this report on Form 10-Q of bioAffinity Technologies, Inc. (“registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 14, 2023

/s/ Michael Dougherty

Michael Dougherty
Vice President and Chief Financial Officer
(Principal Financial Officer)

**Certification Pursuant to
18 U.S.C. Section 1350
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of bioAffinity Technologies, Inc., a Delaware Corporation ("Company"), for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof ("Report"), each of the undersigned officers of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer's knowledge:

- 1) the Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of June 30, 2023 (the last date of the period covered by the Report).

/s/ Maria Zannes

Maria Zannes
President and Chief Executive Officer
(Principal Executive Officer)
Date: August 14, 2023

/s/ Michael Dougherty

Michael Dougherty
Vice President and Chief Financial Officer
(Principal Financial Officer)
Date: August 14, 2023
