

**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 for the period ended March 31, 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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

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 May 12, 2023, was 8,518,981.

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<sup>®</sup> 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 in 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 tests or future diagnostic 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;
  - our reliance on third parties;
  - 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;
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- 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 tests and therapeutic product candidates, the size and growth of the potential markets for our current diagnostic tests 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 ongoing 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;
- our anticipated uses of net proceeds from our initial public offering (“IPO”);
- 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](http://www.bioaffinitytech.com) and [ir.bioaffinitytech.com](http://ir.bioaffinitytech.com)) and at times our corporate Twitter account (@bioAffinity) and LinkedIn account ([www.linkedin.com/company/bioaffinitytechnologies](http://www.linkedin.com/company/bioaffinitytechnologies)) to distribute company information. The information we post through these channels may be deemed material. Accordingly, investors should monitor these channels and review our press releases, filings with the SEC, and public conference calls and webcasts. In addition, investors and others can be automatically notified in real time when new information is posted on our websites by visiting the homepage of our Company website at [www.bioaffinitytech.com](http://www.bioaffinitytech.com) and subscribing to “News from bioAffinity Technologies” or visiting the “Email Alerts” section of our investor relations website at [ir.bioaffinitytech.com/news-events/email-alerts](http://ir.bioaffinitytech.com/news-events/email-alerts) and enrolling an email address. 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.

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**PART I**  
**FINANCIAL STATEMENTS**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED).**

**BIOAFFINITY TECHNOLOGIES, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

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

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

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

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

	<b>For the Three Months Ended March 31, 2023</b>						
	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	—	—	81,728	572	157,041	—	157,613
Net loss	—	—	—	—	—	(1,532,790)	(1,532,790)
Balance at March 31, 2023 (Unaudited)	—	\$ —	8,463,052	\$ 59,241	\$ 47,809,283	\$ (38,200,258)	\$ 9,668,266

	<b>For the Three Months Ended March 31, 2022</b>						
	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	—	—	15,772	110	105,937	—	106,047
Beneficial conversion feature for bridge notes	—	—	—	—	213,942	—	213,942
Debt discount for warrants issued	—	—	—	—	217,973	—	217,973
Net loss	—	—	—	—	—	(1,472,020)	(1,472,020)
Balance at March 31, 2022 (Unaudited)	756,558	\$ 4,044,318	2,692,912	\$ 18,850	\$ 13,241,748	\$ (29,985,375)	\$ (16,724,777)

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

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

	Three Months Ended March 31,,	
	2023	2022
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,532,790)	\$ (1,472,020)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,685	1,039
Accretion of debt issuance costs	—	978,217
Fair value adjustments on convertible notes payable	—	(404,194)
Stock-based compensation expense	157,613	106,047
Changes in operating assets and liabilities:		
Accounts and other receivables	(538)	(5,331)
Inventory	(5,795)	(5,803)
Prepaid expenses and other assets	89,847	11,143
Accounts payable	(198,505)	17,284
Accrued expenses	(60,558)	(29,649)
Accrued interest	—	169,300
<b>Net cash used in operating activities</b>	<b>(1,529,041)</b>	<b>(633,967)</b>
<b>Cash flows from investing activities</b>		
Purchase of equipment	(32,314)	—
<b>Net cash used in investing activities</b>	<b>(32,314)</b>	<b>—</b>
<b>Cash flows from financing activities</b>		
Payment on loan payable	(83,316)	—
Proceeds from issuance of convertible notes payable	—	475,000
Payment of deferred offering costs	—	(117,986)
Payment of debt issuance costs	—	(55,651)
<b>Net cash (used in) provided by financing activities</b>	<b>(83,316)</b>	<b>301,363</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(1,644,671)</b>	<b>(332,604)</b>
Cash and cash equivalents at beginning of period	11,413,759	1,360,638
<b>Cash and cash equivalents at end of period</b>	<b>\$ 9,769,088</b>	<b>\$ 1,028,034</b>
<b>Supplemental disclosures of cash flow information:</b>		
Income taxes paid in cash	\$ 11,819	\$ 2,159
Interest expense paid in cash	\$ 1,655	\$ —
<b>Noncash financing activities:</b>		
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,” or “our”), addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung. Our 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 and cancer therapeutics using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Our first diagnostic test, CyPath<sup>®</sup> 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 our 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<sup>®</sup> 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 Company’s Form 10-K filed with the SEC on March 31, 2023.

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 \$38.2 million at March 31, 2023. The Company’s cash and cash equivalents at March 31, 2023, were approximately \$9.8 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 March 31, 2023, is sufficient to fund the Company’s ongoing operations for a period of a 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 of the pandemic 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; the useful lives of fixed assets; and the fair value of the convertible notes payable.

### *Principles of Consolidation*

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

### *Advertising expense*

The Company expenses all advertising costs as incurred. Advertising expense was approximately \$6,000 and \$3,000 for the three months ended March 31, 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 Common Shares 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 Common Shares outstanding during the period and the weighted-average number of dilutive Common Share equivalents outstanding during the period, using the treasury stock method. Dilutive Common Share 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 outstanding as of March 31, 2023 and 2022, as they would be anti-dilutive:

	As of March 31,	
	2023	2022
Convertible preferred stock	—	756,558
Shares underlying options outstanding	806,392	884,094
Shares underlying warrants outstanding	4,649,952	2,057,740
Shares underlying convertible notes	—	2,511,345
	<u>5,556,344</u>	<u>6,209,737</u>

### Revenue Recognition

Revenue is generated exclusively from royalties for the Company's first diagnostic test, CyPath<sup>®</sup> Lung, from sales by Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and the Company's licensee, that began a limited market launch in the second quarter of 2022 to pulmonologists in the South Texas area, designed to refine future positioning and develop strategic insight for the Company's CyPath<sup>®</sup> 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 \$42,000 from research and development to selling, general and administrative for the three months ended March 31, 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 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:

	March 31, 2023	December 31, 2022
Prepaid insurance	\$ 222,742	\$ 340,078
Legal and professional	84,077	72,048
Other	134,313	119,773
Total prepaid expenses and other current assets	<u>\$ 441,132</u>	<u>\$ 531,899</u>

### Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	March 31, 2023	December 31, 2022
Lab equipment	\$ 488,718	\$ 462,155
Computers and software	27,214	21,463
	515,932	483,618
Accumulated depreciation	(290,865)	(269,180)
Total property and equipment, net	<u>\$ 225,067</u>	<u>\$ 214,438</u>

Depreciation expense was approximately \$22,000 and \$1,000 for the three months ended March 31, 2023 and 2022, respectively.

**Note 5. ACCRUED EXPENSES**

Accrued expenses are summarized below:

	March 31, 2023	December 31, 2022
Compensation	\$ 281,085	\$ 340,680
Legal and professional	131,819	144,440
Clinical	58,262	50,922
Other	10,170	5,852
Total accrued expenses	<u>\$ 481,336</u>	<u>\$ 541,894</u>

**Note 6. 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.

**Note 7. 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 8. 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 \$26,000 and \$13,000 for each of the three months ended March 31, 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 9. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

In June 2022, the Company completed a 1-for-7 reverse stock split of its Common Stock. All share and per share amounts have been adjusted on a retroactive basis in these condensed consolidated financial statements to reflect the effect of the reverse stock split. The Company made a cash payment to stockholders for all fractional shares that it would otherwise be required to issue as a result of the stock split. In addition, the stock split resulted in the par value of the Company's Common Stock increasing to \$0.007 per share.

***Convertible Preferred Stock***

The Company has authorized a total of 20,000,000 shares of preferred stock, \$0.001 par value per share. Prior to the initial public offering ("IPO"), the Company issued 5,296,044 shares of preferred stock, designated as Series A. In July 2017, the Company completed a private placement of securities in which 1.3 million shares of Series A Preferred Stock were sold, resulting in net proceeds of \$1.5 million. As part of the closing, the Company issued 4.0 million shares of Series A Preferred Stock in exchange for \$2.6 million of the Company's convertible notes payable and related accrued interest.

In accordance with the Certificate of Designation of the Series A Preferred Stock, all of the shares of Series A Preferred Stock that were issued and outstanding at the time of the IPO closing were automatically converted into 745,558 fully paid and nonassessable shares of Common Stock at a 1-for-7 conversion rate (as adjusted for the 1-for-7 reverse stock split). The shares of Series A Preferred Stock that were so converted ceased to be part of the Company's authorized stock and will never again be issued by the Company. As of March 31, 2023, and December 31, 2022, no Preferred Stock was outstanding.

### Common Stock

The Company has authorized a total of 14,285,714 shares of Common Stock, \$0.007 par value per share. In November 2021, the Company received stockholder approval to increase the number of authorized shares from 7,142,857 shares to 14,285,714 shares. The Company has issued 8,463,052 shares of Common Stock as of March 31, 2023, and 8,381,324 shares of Common Stock as of December 31, 2022.

### Note 10. STOCK-BASED COMPENSATION

The Company grants options under its 2014 Equity Incentive Plan (the "Plan"). Under the Plan, the Company is authorized to grant options for up to 1.1 million shares of Common Stock. The Company has reserved 1.0 million shares to be used under the Plan. Options may be granted to employees, the Company's board of directors, and external consultants who provide services to the Company. Options 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 stock option awards in the following line items in the accompanying condensed consolidated statement of operations:

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 11,268	\$ 4,643
General and administrative	146,345	101,404
	<u>\$ 157,613</u>	<u>\$ 106,047</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 March 31, 2023	<u>806,392</u>	<u>\$ 4.33</u>	<u>3.8</u>	<u>\$ 271,298</u>
Vested and exercisable at March 31, 2023	<u>803,218</u>	<u>\$ 4.31</u>	<u>3.7</u>	<u>\$ 271,298</u>

As of March 31, 2023, there was no unrecognized compensation cost related to non-vested stock options. During the three months ended March 31, 2023 and 2022, no options were exercised. During the three months ended March 31, 2023, no options were issued by the Company to purchase shares of Common Stock. During the three months ended March 31, 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.

During the three months ended March 31, 2023, the Company issued restricted stock units (RSUs) for 64,016 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 one year, subject to the employees and non-employees providing continuous service through the vesting date. During the three months ended March 31, 2023, approximately 82,000 shares vested from RSUs previously issued.

During the three months ended March 31, 2022, the Company issued RSUs 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 three months ended March 31, 2022, approximately 16,000 shares vested from RSUs 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 three months ended March 31, 2022:

	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 11. WARRANTS**

We account 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. We classify 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 March 31, 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 \$6.39 and expire at various dates through September 2027. During the three months ended March 31, 2023 and 2022, no warrants were exercised into an equivalent number of Common Shares.

#### **Note 12. 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 Form 10-K filed with the SEC on March 31, 2023. 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 our Form 10-K.

Data as of and for the three months ended March 31, 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 three months ended March 31, 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 Policies and Use of Estimates* – Accounting policies 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, early-stage diagnostics to detect lung cancer and other diseases of the lung. Our Company also is conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. We develop proprietary noninvasive diagnostic tests and cancer therapeutics 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 our laboratories at The University of Texas at San Antonio.

Our first 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 therapeutics that specifically and selectively target cancer cells. We are focused on expanding our broad-spectrum platform technologies to continue developing tests that detect and therapies that target various types of cancer and potentially other diseases.

### ***Recent Developments***

- On May 2, 2023, the Company announced that Michael Dougherty, CPA, MBA, will be the Chief Financial Officer (“CFO”) of bioAffinity Technologies. Mr. Dougherty most recently was CFO of Amazon’s Alexa AI and Voice division, where he was responsible for financial strategy over Alexa’s multi-billion-dollar investments in AI-generated customer experiences. Michael Edwards stepped down as bioAffinity CFO but continues to assist Mr. Dougherty in a consulting capacity.

### ***Financial***

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our first 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 March 31, 2023, we had cash and cash equivalents of \$9.8 million. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of this Quarterly Report.

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 March 31, 2023, we had total working capital of \$9.4 million and an accumulated deficit of approximately \$38.2 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and therapeutic products 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 March 31, 2023, Compared to Three Months Ended March 31, 2022***

Net loss for the three months ended March 31, 2023, was approximately \$1.5 million, compared to a net loss of approximately \$1.5 million for the three months ended March 31, 2022, resulting from the operational activities described below.

### ***Revenue***

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology. Although Precision Pathology placed CyPath® Lung on its list of tests offered to physicians in second quarter 2022, there has been limited marketing of the product as we assemble a marketing team of experts focused on demonstrating the clinical value of CyPath® Lung in the marketplace. 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. We had revenue of approximately \$1,000 during the three months ended March 31, 2023, from the sale of CyPath® Lung as a laboratory developed test (“LDT”), compared to no revenue in 2022.

We expect our from CyPath® Lung revenue to continue to grow as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas. 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.

### *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 March 31, 2023, is primarily due to sales of our diagnostic kits during the quarter, compared to no sales in the prior year.

### *Operating Expenses*

	<b>Three Months Ended</b>		<b>Change in 2023</b>	
	<b>March 31,<sup>(1)</sup></b>		<b>Versus 2022</b>	
	<b>2023</b>	<b>2022</b>	<b>\$</b>	<b>%</b>
	(amount in thousands)			
Operating Expenses				
Research and development	\$ 370	\$ 280	\$ 90	32%
Clinical development	20	53	(33)	-62%
Selling, general and administrative	1,170	395	775	196%
<b>Total operating expenses</b>	<b>\$ 1,560</b>	<b>\$ 728</b>	<b>\$ 832</b>	<b>114%</b>

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the three-month period ended March 31, 2023 and 2022, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Operating expenses totaled approximately \$1.5 million and \$0.7 million during the three months ended March 31, 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 studies, compensation, and consulting costs.

Research and development expenses totaled approximately \$370,000 and \$280,000 for the three months ended March 31, 2023, and 2022, respectively. The increase of approximately \$90,000, or 32%, for the three months ended March 31, 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 \$20,000 and \$53,000 for the three months ended March 31, 2023 and 2022, respectively. The decrease of approximately \$33,000, or 62%, for the three months ended March 31, 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 \$1.2 million and \$395,000 for the three months ended March 31, 2023 and 2022, respectively. The increase of approximately \$775,000, or 196%, for the three months ended March 31, 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<sup>®</sup> Lung.

### ***Other Income (Expense)***

	Three Months Ended March 31,		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(amount in thousands)			
Interest income (expense), net	\$ 37	\$ (1,146)	\$ 1,183	103%
Gain (loss) on change in fair value of convertible notes	—	404	(404)	-100%
Total other income (expense)	<u>\$ 37</u>	<u>\$ (742)</u>	<u>\$ 779</u>	<u>105%</u>

Other income (expense), net totaled approximately \$37,000 and (\$0.7) million for the three-month period ended March 31, 2023 and 2022, respectively.

### ***Interest Income (Expense), net***

Interest income (expense), net was approximately \$37,000 for the three months ended March 31, 2023, compared to (\$0.7) million for the three months ended March 31, 2022. The change was due to no convertible notes outstanding during the current year compared to the same period in the prior year, as substantially 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 loss of approximately \$0.4 million on the change in fair value of convertible notes during the three months ended March 31, 2022, compared to no loss during the three months ended March 31, 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. Substantially 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 initial public offering, 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 three months ended March 31, 2023 and 2022, we had net losses of \$1.5 million and \$1.5 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$38.2 million as of March 31, 2023. Cash and cash equivalents were approximately \$9.8 million as of March 31, 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 or 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:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
	(amounts in thousands)	
Cash and cash equivalents at beginning of period	\$ 11,414	\$ 1,361
Net cash used in operating activities	(1,529)	(634)
Net cash used in investing activities	(32)	—
Net cash (used in) provided by financing activities	(83)	301
Cash and cash equivalents at end of period	\$ 9,769	\$ 1,028

#### *Net Cash Used in Operating Activities*

Net cash used in operating activities was approximately \$1.5 million and \$0.6 million for the three months ended March 31, 2023 and 2022, respectively. The increase of approximately \$0.9 million in cash used by operations during the three months ended March 31, 2023, compared to the same period in 2022, was attributable to an increase of \$0.1 million in our loss from operations as compared to the prior year as described above. This increase was partially offset by fair value adjustments of approximately \$1.0 million and the amortization of debt discount of \$0.4 million related to the issuance of bridge notes in the prior year, as well as changes in prepaid and other assets, accounts payable and accrued interest.

#### *Net Cash Used in Investing Activities*

The Company used approximately \$32,000 for the three months ended March 31, 2023, in investing activities related to the purchase of computer and lab equipment, compared to no cash used in investing activities for the three months ended March 31, 2022.

#### *Net Cash Provided by Financing Activities*

Cash used in financing activities was approximately \$83,000 compared to cash provided by financing activities of approximately \$0.3 million for the three months ended March 31, 2023, and 2022, respectively. The change in cash used in financing activities for the three months ended March 31, 2023, compared to 2022, was a result of the Company obtaining short-term financing 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 Policies and Use of 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. As such, as 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)). 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 March 31, 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***

There were no changes in our internal controls (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) over financial reporting during the three months ended March 31, 2023, covered by this Quarterly Report that could materially affect, or are reasonably likely to materially affect, our financial reporting.

## **PART II**

### **ITEM 1. LEGAL PROCEEDINGS.**

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 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 our Final Prospectus filed with the SEC on September 2, 2022, 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***

None

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

### **ITEM 5. OTHER INFORMATION.**

Not applicable.

**ITEM 6. EXHIBITS.**

<b>Exhibit No.</b>	<b>Title of Document</b>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</a>
32.1†	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002</a>
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 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 March 31, 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.

† Furnished herewith.

**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

By: /s/ Michael Dougherty

Vice President and Chief Financial Officer

**Certification**  
**For the Quarterly Period Ended March 31, 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)) 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) [intentionally omitted];
  - (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: May 15, 2023

*/s/ Maria Zannes*

\_\_\_\_\_  
Maria Zannes

President and Chief Executive Officer

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**Certification**  
**For the Quarterly Period Ended March 31, 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)) 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) [intentionally omitted];
  - (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: May 15, 2023

*/s/ Michael Dougherty*

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Michael Dougherty  
Vice President and Chief Financial Officer

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**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 March 31, 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 March 31, 2023 (the last date of the period covered by the Report).

*/s/ Maria Zannes*

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Maria Zannes  
President and Chief Executive Officer  
Date: May 15, 2023

*/s/ Michael Dougherty*

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Michael Dougherty  
Vice President and Chief Financial Officer  
Date: May 15, 2023

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