

**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 March 31, 2024**

**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 or other jurisdiction of  
incorporation or organization)

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

**46-5211056**

(I.R.S. Employer  
Identification No.)

**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(s)</u>	<u>Name of each exchange on which registered</u>
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 May 08, 2024, was 11,657,537.

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 subsidiaries, OncoSelect<sup>®</sup> Therapeutics, LLC, a Delaware limited liability company, and Precision Pathology Laboratory Services, LLC, a Texas 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, 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 impact of a 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;
- anticipated uses of net proceeds from our direct offering (“the Direct Offering”).
- 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, the war in the Middle East, escalating tensions between China and Taiwan, increasing economic uncertainty and inflationary pressures, 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), [ir.bioaffinitytech.com](http://ir.bioaffinitytech.com), [www.cypathlung.com](http://www.cypathlung.com) and [www.precisionpath.us/](http://www.precisionpath.us/)) to share Company information. Information contained on or that can be accessed through our websites is not, however, incorporated by reference in this Quarterly Report. Investors should not consider any such information to be part of this Quarterly Report.

bioAffinity Technologies, Inc.

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**PART I**  
**FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.**

**bioAffinity Technologies, Inc.**  
**Condensed Consolidated Balance Sheets**

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,453,165	\$ 2,821,570
Accounts and other receivables, net	1,123,609	811,674
Inventory	9,487	18,484
Prepaid expenses and other current assets	344,900	321,017
Total current assets	<u>3,931,161</u>	<u>3,972,745</u>
Non-current assets:		
Property and equipment, net	461,209	458,633
Operating lease right-of-use asset, net	347,860	370,312
Finance lease right-to-use, net	1,069,601	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	818,889	833,472
Other assets	16,060	16,060
Total assets	<u>\$ 8,049,266</u>	<u>\$ 8,221,552</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 383,993	\$ 604,789
Accrued expenses	883,319	1,149,811
Unearned revenue	30,174	33,058
Operating lease liability, current portion	96,631	94,708
Finance lease liability, current portion	372,787	365,463
Notes payable, current portion	4,686	—
Total current liabilities	<u>1,771,590</u>	<u>2,247,829</u>
Non-current liabilities:		
Finance lease liability, net of current portion	739,478	835,467
Operating lease liability, net of current portion	258,110	283,001
Notes payable, net of current portion	23,037	—
Total liabilities	<u>2,792,215</u>	<u>3,366,297</u>
Commitments and contingencies (See Note 11)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at March 31, 2024, and December 31, 2023	—	—
Common stock, par value \$0.007 per share; 25,000,000 shares authorized; 11,216,491 and 9,394,610 issued and outstanding at March 31, 2024, and at December 31, 2023, respectively.	78,515	65,762
Additional paid-in capital	51,744,830	49,393,972
Accumulated deficit	(46,566,294)	(44,604,479)
Total stockholders' equity	<u>5,257,051</u>	<u>4,855,255</u>
Total liabilities and stockholders' equity	<u>\$ 8,049,266</u>	<u>\$ 8,221,552</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,	
	2024	2023
	(unaudited)	
<b>Net Revenue</b>	\$ 2,406,391	\$ 921
<b>Operating expenses:</b>		
Direct costs and expenses	1,573,441	87
Research and development	393,639	369,617
Clinical development	48,960	19,628
Selling, general and administrative	2,185,944	1,147,875
Depreciation and amortization	149,637	21,684
<b>Total operating expenses</b>	<b>4,351,621</b>	<b>1,558,891</b>
<b>Loss from operations</b>	<b>(1,945,230)</b>	<b>(1,557,970)</b>
Other income (expense):		
Interest income	6,127	38,654
Interest expense	(23,550)	(1,655)
Other expense	4,510	—
<b>Total other expense</b>	<b>(12,913)</b>	<b>36,999</b>
<b>Net loss before provision for income taxes</b>	<b>(1,958,143)</b>	<b>(1,520,971)</b>
Income tax expense	(3,672)	(11,819)
<b>Net loss</b>	<b>\$ (1,961,815)</b>	<b>\$ (1,532,790)</b>
Net loss per common share, basic and diluted	\$ (0.20)	\$ (0.18)
Weighted average common shares outstanding, basic and diluted	9,915,426	8,433,689

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

**bioAffinity Technologies, Inc.**  
**Unaudited Condensed Consolidated Statements of Stockholders' Equity**

	<b>For the Three Months Ended March 31, 2024</b>						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at December 31, 2023	—	\$ —	9,394,610	\$ 65,762	\$ 49,393,972	\$ (44,604,479)	\$ 4,855,255
Stock-based compensation expense	—	—	157,033	1,099	282,613	—	283,712
Exercise of stock options	—	—	64,848	454	74,445	—	74,899
Sale of common stock	—	—	1,600,000	11,200	2,488,800	—	2,500,000
Offering costs	—	—	—	—	(495,000)	—	(495,000)
Net loss	—	—	—	—	—	(1,961,815)	(1,961,815)
Balance at March 31, 2024 (unaudited)	<u>—</u>	<u>\$ —</u>	<u>11,216,491</u>	<u>\$ 78,515</u>	<u>\$ 51,744,830</u>	<u>\$ (46,566,294)</u>	<u>\$ 5,257,051</u>

	<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)	<u>—</u>	<u>\$ —</u>	<u>8,463,052</u>	<u>\$ 59,241</u>	<u>\$ 47,809,283</u>	<u>\$ (38,200,258)</u>	<u>\$ 9,668,266</u>

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

**bioAffinity Technologies, Inc.**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
**(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,961,815)	\$ (1,532,790)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	149,637	21,684
Stock-based compensation expense	283,712	157,613
Changes in operating assets and liabilities:		
Accounts and other receivables	(311,935)	(538)
Inventory	8,997	(5,795)
Prepaid expenses and other assets	(23,883)	89,847
Accounts payable	(220,796)	(198,505)
Accrued expenses	(266,492)	(60,557)
Unearned revenue	(2,884)	—
Operating lease right-of-use asset	(516)	—
<b>Net cash used in operating activities</b>	<b>(2,345,975)</b>	<b>(1,529,041)</b>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(41,387)	(32,314)
<b>Net cash used in investing activities</b>	<b>(41,387)</b>	<b>(32,314)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock from direct offering, net of underwriting discounts, commissions and offering expenses of approximately \$495,000	2,005,000	—
Proceeds from exercised stock options	74,899	—
Proceeds from loans payable	27,723	—
Payment on loans payable	—	(83,316)
Principal repayments on finance leases	(88,665)	—
<b>Net cash provided by (used in) financing activities</b>	<b>2,018,957</b>	<b>(83,316)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(368,405)</b>	<b>(1,644,671)</b>
Cash and cash equivalents at beginning of period	2,821,570	11,413,759
<b>Cash and cash equivalents at end of period</b>	<b>\$ 2,453,165</b>	<b>\$ 9,769,088</b>
<b>Supplemental disclosures of cash flow information:</b>		
Interest expense paid in cash	\$ 23,550	\$ 11,819
Income taxes paid in cash	3,672	1,655

*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,” 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 identifies cancer cells and cell populations indicative of a diseased state for analysis using proprietary platforms developed using artificial intelligence (“AI”). The Company’s first diagnostic test, CyPath<sup>®</sup> Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. CyPath<sup>®</sup> Lung is offered for sale to physicians by the Company’s subsidiary, Precision Pathology Laboratory Services, LLC (“PPLS”). Research and optimization of the Company’s proprietary platform for *in vitro* diagnostics and technologies are conducted in laboratories at PPLS and The University of Texas at San Antonio. The Company is developing its 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. On August 14, 2023, the Company formed a wholly owned subsidiary, Precision Pathology Laboratory Services, LLC (“PPLS”), as a Texas limited liability company, to acquire the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services (“Village Oaks”), including the clinical pathology laboratory it owned.

***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 Securities and Exchange Commission (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. The condensed consolidated balance sheet as of December 31, 2023, was derived from the audited consolidated financial statements at that date but does not include all the information and footnotes required by GAAP. Operating results for the periods presented are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2024, 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on April 1, 2024 (the “2023 Form 10-K”) filed with the SEC on April 1, 2024.

***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 \$46.6 million at March 31, 2024. The Company’s cash and cash equivalents at March 31, 2024, were approximately \$2.5 million, representing 30% of total assets. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at March 31, 2024, management concludes that there is substantial doubt about the Company’s ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying condensed consolidated financial statements. Therefore, 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 revenue from operations does not significantly increase. If such funding is not available or not available on terms acceptable to the Company, the Company’s current development plan may be curtailed. On March 8, 2024, the Company issued to certain investors, pursuant to a Securities Purchase Agreement (the “Purchase Agreement”) (1) 1,600,000 shares of the Company’s common stock (the “Shares”), par value \$0.007 per share (“Common Stock”) in a registered direct offering, and (2) warrants to purchase an aggregate of 1,600,000 shares of Common Stock (the “Common Warrants”) with an exercise price of \$1.64, in a concurrent private placement. The direct offering resulted in net proceeds of \$2.05 million. Furthermore, an alternative source of funding to the sale of additional equity or debt securities is the exercising of outstanding warrants for which there can be no guarantee. No adjustments have been made to the presented condensed consolidated financial statements as a result of this uncertainty.

**Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Use of Estimates***

The preparation of condensed consolidated financial statements in conformity with 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 condensed 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, stock-based compensation, valuation of goodwill and intangible assets related to the business combination, allowance for contractual adjustments and discounts related to service revenues, and the useful lives of fixed assets.

***Principles of Consolidation***

The Company’s condensed consolidated financial statements reflect its financial statements, those of its wholly owned subsidiaries, and certain variable interest entities where the Company is the primary beneficiary. The accompanying condensed consolidated financial statements include all the accounts of the Company, its wholly owned subsidiaries, OncoSelect<sup>®</sup> Therapeutics, LLC and PPLS, and the variable interest entity, Village Oaks. All significant intercompany balances and transactions have been eliminated.

In determining whether the Company is the primary beneficiary of a variable interest entity, it applies a qualitative approach that determines whether it has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. The Company continuously assesses whether it is the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in the Company consolidating or deconsolidating one or more of its collaborators or partners.

### ***Business Combination***

On September 18, 2023, the Company, in connection with the Asset Purchase Agreement it entered into with Village Oaks (the “Seller”) and Roby P. Joyce, M.D., dated September 18, 2023, acquired substantially all the assets and assumed certain liabilities of Village Oaks in exchange for total consideration of \$3,500,000, which consists of: (1) \$2.5 million in cash paid at closing and (2) 564,972 shares of the Company’s common stock valued at \$1 million. The assets purchased included a clinical pathology laboratory regulated by the Centers for Medicare and Medicaid Services (“CMS”) and accredited by the College of American Pathologists (“CAP”) and certified under the Clinical Laboratory Improvement Amendments (“CLIA”) of 1988. The primary reason for the acquisition is control of the laboratory in which CyPath<sup>®</sup> Lung is ordered and processed.

The Company recognized goodwill of \$1,404,000 arising from the acquisition. The acquisition is being accounted for as a business combination in accordance with ASC 805. The Company has determined the preliminary fair values of the accounts receivable, accounts payable, and accrued expenses that make up the majority of the net working capital assumed in the acquisition. These values are subject to change as the Company performs additional reviews of its assumptions utilized, and any future period adjustments would impact the consolidated statement of operations post-acquisition.

The following table summarizes the purchase price and preliminary purchase price allocations relating to the acquisition:

Cash	\$	2,500,000
Common Stock		1,000,000
Total purchase consideration	\$	<u>3,500,000</u>
Assets		
Net working capital (including cash)	\$	912,000
Property and equipment		326,000
Other assets		8,000
Customer relationships		700,000
Trade names and trademarks		150,000
Goodwill		1,404,000
Total net assets	\$	<u>3,500,000</u>

Goodwill represents the excess fair value after the allocation to the identifiable net assets. The calculated goodwill is not deductible for tax purposes.

The preliminary purchase price allocations relating to the acquisition previously reported in the Quarterly Report on Form 10-Q filed October 14, 2023, reported Net Working Capital of \$1,167,000 and Goodwill of \$1,149,000. The amounts have been updated to reflect the purchase price adjustments to accounts payable and accounts receivable that existed at the time of the acquisition. The Company incurred approximately \$811,000 in acquisition costs.

For prior year comparative purposes, the pro-forma statement of operations as if combined on January 1, 2022, would result in net revenues of \$1,806,196, net loss of (\$1,779,300) and loss per share of (\$0.21) for the three months ended March 31, 2023.

### ***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 \$11,920 and \$6,049 for the three months ended March 31, 2024 and 2023, respectively.

### ***Loss Per Share***

Basic loss per share is computed by dividing net 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 loss per share is computed by dividing net loss 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 March 31, 2024 and 2023, as they would be anti-dilutive:

	As of March 31,	
	2024	2023
Shares underlying options outstanding	618,847	806,392
Shares underlying warrants outstanding	8,838,717	4,649,952
	<u>9,457,564</u>	<u>5,456,344</u>

### Revenue Recognition

The Company recognizes as revenue the amount that reflects the consideration to which it expects to be entitled in exchange for goods sold or services rendered primarily upon completion of the testing process (when results are reported) or when services have been rendered.

#### Patient Service Fee revenue

Net revenues from patient service fees accounted for greater than 95% of the Company's consolidated net revenues for the three months ended March 31, 2024 and are primarily comprised of a high volume of relatively low-dollar transactions. The laboratory which provides clinical testing services and other services, satisfies its performance obligation and recognizes revenues primarily upon completion of the testing process (when results are reported) or when services have been rendered. The Company estimates the amount of consideration it expects to be entitled to receive from payer customer groups in exchange for providing services using the portfolio approach. These estimates include the impact of contractual allowances (including payer denials), and patient price concessions. The portfolios determined using the portfolio approach consist of the following groups of payer customers: healthcare insurers, government payers (Medicare and Medicaid programs), client payers and self-pay. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience and other factors (including the period of time that the receivables have been outstanding), to estimate contractual allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, may be recorded upon settlement.

	For the three months ended March 31,	
	2024	2023
Patient service fees <sup>1</sup>	\$ 2,149,049	\$ —
Histology service fees	237,972	—
Medical director fees	16,058	—
Department of Defense observational studies	2,885	—
Other revenues <sup>2</sup>	427	921
Total net revenue	<u>\$ 2,406,391</u>	<u>\$ 921</u>

<sup>1</sup> Patient services fees include direct billing for CyPath<sup>®</sup> Lung diagnostic test.

<sup>2</sup> Other revenues include pre-acquisition CyPath<sup>®</sup> Lung royalty income and laboratory services.

### Property and Equipment

In accordance with ASC 360-10, *Accounting for the Impairment of Long-Lived Assets*, the Company periodically reviews the carrying value of its long-lived assets, such as property, equipment, and definite-lived intangible assets, to test whether current events or circumstances indicate that such carrying value may not be recoverable. When evaluating assets for potential impairment, the Company compares the carrying value of the asset to its estimated undiscounted future cash flows. If an asset's carrying value exceeds such estimated cash flows (undiscounted and with interest charges), the Company records an impairment charge for the difference. The Company did not record any impairment for the three months ended March 31, 2024, or fiscal year ended December 31, 2023.

Property and equipment are carried at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of the asset. Amortization of leasehold improvements is computed using the shorter of the lease term or estimated useful life of the asset. Additions and improvements are capitalized, while repairs and maintenance are expensed as incurred. Useful lives of each asset class are as follows:

Asset Category	Useful Life
Computer equipment	3-5 years
Computer software	3 years
Equipment	3-5 years
Furniture and fixtures	5-7 years
Vehicles	5 years
Leasehold improvements	Lesser of lease term or useful life

### Intangible Assets

Intangible assets, net of accumulated amortization, are summarized as follows as of March 31, 2024:

Description	Date Acquired	Useful Life	Cost	Amortization	Net
Goodwill	9/18/2023		\$ 1,404,486	\$ —	\$ 1,404,486
Trade names and trademarks	9/18/2023	18 years	150,000	(4,444)	145,556
Customer relationships	9/18/2023	14 years	700,000	(26,667)	673,333
<b>Total Intangible Assets</b>			<b>\$ 2,254,486</b>	<b>\$ (31,111)</b>	<b>\$ 2,223,375</b>

For the three months ended March 31, 2024, amortization of intangible assets totaled \$14,583 compared to \$0 in the prior year comparative period.

### 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.

The Company adopted FASB issued Accounting Standards Update (ASU) No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures on December 31, 2023. The Company used the 5 steps to ASC 280 to evaluate what, if any, segment reporting would be beneficial for shareholders. These 5 steps included: 1) Evaluate operating segments for aggregation, 2) Perform quantitative threshold tests, 3) Evaluate remaining operating segments for aggregation, 4) Ensure that 75 percent of revenue is reported, and 5) Consider practical limit. Based on the analysis above against those 5 steps, management concludes that segment reporting is required for two segment operations: 1) diagnostic R&D and 2) laboratory services.

### Segment Information

The Company is organized in two operating segments, Diagnostic Research and Development (R&D) and Laboratory Services, whereby its chief operating decision maker (“CODM”) assesses the performance of and allocates resources. The CODM is the Chief Executive Officer. Diagnostic R&D includes research and development and clinical development on diagnostic tests. Any revenues assigned to Diagnostic R&D are proceeds received from observational studies. Laboratory services include all the operations from Village Oaks and PPLS in addition to sales and marketing costs of CyPath<sup>®</sup> Lung from bioAffinity.

	As of March 31,	
	2024	2023
Net revenues:		
Diagnostic R&D	\$ 2,885	\$ —
Laboratory services <sup>1</sup>	2,403,506	921
Total net revenues	2,406,391	921
Operating expenses:		
Diagnostic R&D	(442,599)	(389,245)
Laboratory services	(2,736,999)	(87)
General corporate activities	(1,172,023)	(1,169,559)
Total operating loss	(1,945,230)	(1,557,970)
Non-operating income (expense), net	(12,913)	36,999
Net loss before income taxes	(1,958,143)	(1,520,971)
Income tax expense	(3,672)	(11,819)
Net loss	\$ (1,961,815)	\$ (1,532,790)

<sup>1</sup>The majority of the increase versus the prior year is from the acquisition of Precision Pathology Laboratories Services, LLC on September 18, 2024.

### Research and Development

Research and development costs are charged to expense as incurred. The Company’s research and development expenses consist primarily of expenditures for lab operations, preclinical studies, compensation, and consulting costs.

The Company incurred research and development expenses of \$393,639 and \$369,617 for the three months ended March 31, 2024 and 2023, respectively.

### Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by service providers, which include preclinical studies. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses in the accompanying condensed consolidated balance sheets and within research and development expense in the accompanying condensed consolidated statements of operations.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with service providers. The Company makes significant judgments and estimates in determining the accrued expenses balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

### Regulatory Matters

Regulations imposed by federal, state, and local authorities in the U.S. are a significant factor in providing medical care. In the U.S., drugs, biological products, and medical devices are regulated by the Federal Food, Drug, and Cosmetic Act (“FDCA”), which is administered by the Food and Drug Administration (“FDA”) and the CMS. The

Company has not yet obtained marketing authorization from the FDA but is able to market its CyPath<sup>®</sup> Lung test as a laboratory developed test (“LTD”) sold by Precision Pathology Laboratory Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and wholly owned subsidiary.

**Note 3. ACCOUNTS AND OTHER RECEIVABLES, NET**

The following is a summary of accounts receivable:

	March 31, 2024	December 31, 2023
Patient service fees	\$ 951,636	\$ 657,717
Histology service fees	112,790	121,301
Medical director fees	3,040	3,103
Other receivables	56,143	29,553
Total accounts and other receivables, net	<u>\$ 1,123,609</u>	<u>\$ 811,674</u>

**Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets are summarized below:

	March 31, 2024	December 31, 2023
Prepaid insurance	\$ 120,215	\$ 171,855
Legal and professional	25,042	24,476
Other	199,643	124,686
Total prepaid expenses and other current assets	<u>\$ 344,900</u>	<u>\$ 321,017</u>

**Note 5. PROPERTY AND EQUIPMENT, NET**

Property and equipment are summarized below:

	March 31, 2024	December 31, 2023
Lab equipment	\$ 647,214	\$ 647,214
Computers and software	68,682	68,682
Leasehold improvements	9,941	9,941
Vehicles	148,102	105,919
	<u>873,939</u>	<u>831,756</u>
Accumulated depreciation	(412,730)	(373,123)
Total property and equipment, net	<u>\$ 461,209</u>	<u>\$ 458,633</u>

Depreciation expense was \$38,811 and \$21,685 for the three months ended March 31, 2024 and 2023, respectively.

**Note 6. ACCRUED EXPENSES**

Accrued expenses are summarized below:

	March 31, 2024	December 31, 2023
Compensation	\$ 670,488	\$ 857,037
Legal and professional	196,553	257,926
Clinical	3,356	15,350
Other	12,922	19,498
Total accrued expenses	<u>\$ 883,319</u>	<u>\$ 1,149,811</u>

**Note 7. UNEARNED REVENUE**

The Company engaged in an observational study of CyPath<sup>®</sup> Lung with the DOD. A total of 70 CyPath<sup>®</sup> Lung units were ordered and shipped. However, in compliance with FASB ASC 606, the performance obligation was complete for only 30 units as of March 31, 2024. The performance obligation is deemed complete after samples have been collected and processed and results analyzed. The unearned revenue balance amounted to \$30,174 and \$33,058 as of March 31, 2024, and December 31, 2023, 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. LEASES**

The Company has one operating lease for its real estate and office space for the CAP/CLIA laboratory, as well as multiple finance leases for lab equipment in Texas that were acquired through the September 18, 2023, acquisition. The operating lease has a remaining lease term of 3.33 years as of March 31, 2024. The Company has finance leases consisting of office and lab equipment with remaining lease terms ranging from approximately 2.5 to 4.25 years as of March 31, 2024, for which the Company has determined that it will use the equipment for a major part of its remaining economic life.

The lease agreements generally do not provide an implicit borrowing rate. Therefore, the Company used a benchmark approach as of September 18, 2023, to derive an appropriate incremental borrowing rate to discount remaining lease payments. The Company benchmarked itself against other companies of similar credit ratings and comparable quality and derived imputed interest rates ranging from 8.01% to 8.07% for the lease term lengths.

Leases with an initial term of 12 months or less are not recorded on the balance sheet. There are no material residual guarantees associated with any of the Company's leases, and there are no significant restrictions or covenants included in the Company's lease agreements. Certain leases include variable payments related to common area maintenance and property taxes, which are billed by the landlord, as is customary with these types of charges for office space. The Company has not entered into any lease arrangements with related parties, and the Company is not the sublessor in any arrangement.

The Company's existing leases contain escalation clauses and renewal options. The Company has evaluated several factors in assessing whether there is reasonable certainty that the Company will exercise a contractual renewal option. For leases with renewal options that are reasonably certain to be exercised, the Company included the renewal term in the total lease term used in calculating the right-of-use asset and lease liability.

The components of lease expense, which are included in selling, general and administrative expense and depreciation and amortization for the three months ended March 31, 2024 and 2023, are as follows:

<b>Components of lease expense:</b>	<b>2024</b>	<b>2023</b>
Amortization of right-of-use assets - finance lease	\$ 96,243	\$ —
Interest on lease liabilities - finance lease	23,550	—
Operating lease cost	29,915	—
Total lease cost	<u>\$ 149,708</u>	<u>\$ —</u>

Supplemental balance sheet information relating to leases was as follows as of March 31, 2024, and December 31, 2023:

<b>Operating leases:</b>	<b>2024</b>	<b>2023</b>
Operating lease right-of-use assets	\$ 347,860	\$ 370,312
Operating lease liability, current	\$ 96,631	\$ 94,708
Operating lease liability, long-term	<u>\$ 258,110</u>	<u>\$ 283,001</u>
<b>Finance leases:</b>	<b>2024</b>	<b>2023</b>
Finance lease right-of-use asset, gross	\$ 1,294,168	\$ 1,294,168
Accumulated amortization	(224,567)	(128,324)
Finance lease right-of-use asset, net	1,069,601	1,165,844
Finance lease liability, current portion	372,787	365,463
Finance lease liability, long-term	739,478	835,467
Total finance lease liabilities	<u>\$ 1,112,265</u>	<u>\$ 1,200,930</u>
<b>Weighted-average remaining lease term:</b>	<b>2024</b>	<b>2023</b>
Operating leases (in years)	3.33	3.58
Finance leases (in years)	3.04	3.25
<b>Weighted-average discount rate:</b>	<b>2024</b>	<b>2023</b>
Operating leases	8.07%	8.07%
Finance leases	8.01%	8.01%

Future minimum lease payment under non-cancellable lease as of March 31, 2024, are as follows:

	<b>Operating Leases</b>	<b>Finance Leases</b>
Remaining for 2024	\$ 91,294	\$ 336,378
2025	121,726	448,505
2026	121,726	270,395
2027 and thereafter	71,007	202,970
Total undiscounted cash flows	<u>405,753</u>	<u>1,258,248</u>
Less discounting	(51,012)	(145,983)
Present value of lease liabilities	<u>\$ 354,741</u>	<u>\$ 1,112,265</u>

#### **Note 10. NOTES PAYABLE**

##### *Toyota Corolla - 2024*

On March 18, 2024, the Company entered into a Finance Agreement to purchase a 2024 Toyota Corolla for \$33,620 with a maturity date of February 18, 2030. The loan bears fixed interest at a rate of 5.99% per annum, with monthly payments of \$467, which is comprised of principal and interest. This loan is collateralized by the underlying vehicle. The balance of this loan as of March 31, 2024, and December 31, 2023, is \$27,723 and \$0, respectively. The current portion of the balance of this loan as of March 31, 2024, and December 31, 2023, is \$4,686 and \$0.

#### **Note 11. COMMITMENTS AND CONTINGENCIES**

##### *Operating Leases*

In addition to the operating lease listed in Note 9, the Company leases its corporate offices under a month-to-month agreement and leases laboratory and additional office space under an operating lease that is renewable annually by written notice by the Company and will require renewal in September 2024. Rent expense for office and lab space amounted to approximately \$31,000 and \$26,000 for the three months ended March 31, 2024, and 2023, 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 12. 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 11,514,354 shares of Common Stock of which 297,862 are unvested restricted stock shares as of March 31, 2024, and 9,505,255 shares of Common Stock of which 110,664 are unvested as of December 31, 2023.

#### **Note 13. 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 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 2014 Equity Incentive Plan expired according to the respective 10 year terms of the Plan in March 2024. A new 2024 Employee Incentive Plan ("2024 Plan") has been drafted for resolution to a majority Shareholder vote held at the Annual Meeting of Shareholders on June 4, 2024.

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

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 21,882	\$ 11,268
Selling, general and administrative	260,731	146,345
Total stock-based compensation expense	<u>\$ 282,613</u>	<u>\$ 157,613</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, 2023	683,695	\$ 3.99	2.9	158,332
Granted	—	—	—	—
Exercised	(64,848)	1.155	—	—
Forfeited	—	—	—	—
Outstanding at March 31, 2024	618,847	\$ 4.28	2.7	\$ 243,097
Vested and exercisable at March 31, 2024	618,053	\$ 4.28	2.7	\$ 243,097

As of March 31, 2024, there was no unrecognized compensation cost related to non-vested stock options.

During the three months ended March 31, 2024, 64,848 options were exercised at an exercise price of \$1.155 for proceeds of \$74,899. During the three months ended March 31, 2023, there were no options exercised.

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, 2023	540,967	\$ 2.24	\$ 1,209,391	441,059	99,908
Granted	344,251	1.53	528,013	146,297	197,954
Forfeited	—	—	—	—	—
Balance at March 31, 2024	885,218	\$ 1.96	\$ 1,737,404	587,356	297,862

During the three months ended March 31, 2024, the Company issued restricted stock awards (“RSAs”) for 344,251 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 three months ended March 31, 2024, 10,736 shares vested from RSAs granted prior to January 1, 2024, and 146,297 shares vested from RSAs granted during the three months ended March 31, 2024.

#### Note 14. WARRANTS

The Company’s outstanding Common Stock warrants are equity classified. As of March 31, 2024, and December 31, 2023, the Company had 8,838,717 and 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 \$3.53 and expire at various dates through March 2029. During the three months ended March 31, 2024, no warrants were exercised into an equivalent number of Common Shares as compared to 1,036,486 warrants being exercised during the three months ended March 31, 2023.

On March 8, 2024, the Company issued to certain investors (i) in a registered direct offering, 1,600,000 shares of the Company’s common stock and (ii) in a concurrent private placement, warrants to purchase an aggregate of 1,600,000 shares of Common Stock, with an exercise price of \$1.64 (collectively, the “Transaction”), which Transaction constitutes a Dilutive Issuance under the terms of the Warrants. In addition, the placement agent was granted warrants to purchase 32,000 shares of Common Stock, with an exercise price of \$1.64.

Section 3(b) of the Warrant Agreement executed during the IPO in September 2022 provides that in the event of a Dilutive Issuance, the Exercise Price of the Warrants shall be reduced and only reduced to equal the effective price per share of the Dilutive Issuance (the “Base Share Price”), and the number of Warrant Shares issuable thereunder shall be increased such that the aggregate Exercise Price payable pursuant to the Warrant, after taking into account the decrease in the Exercise Price, shall be equal to the aggregate Exercise Price prior to such adjustment, provided that the Base Share Price shall not be less than \$3.0625 (50% of the public offering price of the Units sold in the Company’s IPO) (subject to adjustment for reverse and forward stock splits, recapitalizations, and similar transactions).

The effect of the Transaction is such that the Exercise Price of the Warrants shall be reduced to \$3.0625 per share. The new number of Warrant Shares is calculated by dividing (x) the number of Warrant Shares underlying the Warrant immediately prior to the Transaction multiplied by the Exercise Price in effect immediately prior to the Transaction, by (y) \$3.0625. The calculations will be made to the nearest cent or the nearest 1/100th of a share.

As of March 8, 2024, and prior to the Transaction, there were Tradeable Warrants to purchase up to an aggregate of 1,601,259 shares of common stock outstanding and Non-Tradeable Warrants to purchase an aggregate of up to 2,704,554 shares of common stock outstanding.

	Number of Warrants issued	Weighted-average exercise price	Number of warrants exercised	Number of warrants outstanding
Pre-IPO convertible notes	2,900,904	\$ 5.31	—	2,900,904
IPO tradeable	2,326,834	3.06	(725,576)	1,601,259
IPO non-tradeable	3,015,464	3.06	(310,910)	2,704,554
Direct offering March 8, 2024	1,600,000	1.64	—	1,600,000
Placement agent direct offering March 8, 2024	32,000	1.64	—	32,000
Balance at March 31, 2024	9,875,202	\$ 3.53	(1,036,486)	8,838,717

#### Note 15. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the condensed consolidated 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.

On April 10, 2024, the Company entered into a new office lease agreement to lease the office facility space beginning on September 1, 2024. The lease term is 6 years (September 1, 2024, to August 30, 2030) with monthly base rent payments beginning at \$2,970 (annual \$35,640) for the first year and ending at \$3,615 (annual \$43,380) for the final year. In addition to the base rent, the Company will pay additional rent, as a tenant share, equal to 5.49% (based on square footage of the entire office premise) of monthly operating expenses.

## **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, 2023, included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on April 1, 2024 (the "2023 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 2023 Form 10-K.

Data as of and for the three months ended March 31, 2024 and 2023, 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, 2024, to the comparable period in 2023.
- *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," "bioAffinity Technologies," "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 identifies cancer cells and cell populations indicative of a diseased state for analysis using proprietary platforms developed using AI. Research and optimization of our platform technologies are conducted in laboratories at our wholly owned subsidiary, Precision Pathology Laboratory Services, LLC ("PPLS"), and The University of Texas at San Antonio.

Our diagnostic test, CyPath<sup>®</sup> 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<sup>®</sup> Lung to assist in their assessment of patients who are at high risk for lung cancer. The CyPath<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.

Through our wholly owned subsidiary PPLS, we acquired the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services, including the clinical pathology laboratory it owned, and we now operate the laboratory.

#### ***Recent Developments***

On March 6, 2024, we received aggregate gross proceeds of \$2.5 million from the sale to four institutional investors (the "Purchasers") of (1) 1,600,000 shares of our Common Stock in a registered direct offering, and (2) Common Warrants to purchase an aggregate of 1,600,000 shares of Common Stock (the "Common Warrants") with an exercise price of \$1.64 in a concurrent private placement (the "Transactions").

The Common Stock was offered pursuant to a shelf registration statement on Form S-3 (File No. 333-275608), which was declared effective on November 27, 2023, (as amended from time to time, the "Registration Statement"). The Common Warrants and the shares of Common Stock issuable upon exercise of the Common Warrants (the "Common Warrant Shares") were issued in a concurrent private placement and were registered on a resale registration statement that was declared effective by the Securities and Exchange Commission on April 15, 2024. The Common Warrants will be exercisable commencing on the effective date of stockholder approval for the issuance of the shares of Common Stock issuable upon exercise of the Common Warrants (the "Stockholder Approval Date") and will expire on the fifth anniversary of the Stockholder Approval Date. We are seeking stockholder approval of such issuance at our Annual Meeting of Stockholders being held on June 4, 2024.

Pursuant to the terms of the Purchase Agreement, until 60 days following the closing of the Transactions, we were prohibited from issuing (or enter into any agreement to issue) any shares of Common Stock or Common Stock equivalents, subject to certain exceptions. We have further agreed not to enter into an agreement involving a variable rate transaction until 12 months following the closing of the Transactions, provided however that the prohibition on "at-the-market offerings" and the issuance of common stock pursuant to an equity line of credit shall expire on the six-month anniversary of the closing date of this offering. In addition, our Chief Executive Officer and each of our directors have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 60 days from the closing of the Transactions, offer, sell, transfer, or otherwise dispose of our securities, subject to certain exceptions. In addition, from the date of the Purchase Agreement until the date that is nine (9) months after the date of the Purchase Agreement, upon any issuance by the Company or any of its subsidiaries of Common Stock, common stock equivalents for cash consideration, Indebtedness (as defined in the Purchase Agreement) or a combination of units thereof for capital raising purposes other than an at-the-market offering (a "Subsequent Financing"), the Purchasers shall have the right to participate in the Subsequent Financing in an amount up to the percentage of such Purchaser's participation in the Transactions on the same terms, conditions, and price provided for in the Subsequent Financing.

WallachBeth Capital LLC acted as the placement agent for the offering and received a cash fee of 9.0% of the aggregate gross proceeds paid to us for the securities sold in the transactions and reimbursement of certain out-of-pocket expenses. As additional compensation we issued to WallachBeth Capital LLC a warrant (the “Placement Agent Warrant”) to purchase an aggregate of 32,000 shares of Common Stock, such number of shares equal to two percent (2.0%) of the number of shares of Common Stock issued in the registered direct offering, at an exercise price per share equal to \$1.64, which is equal to the exercise price of the Common Warrants. The Placement Agent Warrant is exercisable via “cashless exercise” in certain circumstances.

We also agreed to file a registration statement to register the resale of the Common Warrant Shares and the shares of Common Stock issuable upon exercise of the Placement Agent Warrant (the “Placement Agent Warrant Shares”) within 30 days of the date of the Purchase Agreement and to use commercially reasonable efforts to keep such registration statement effective at all times until no Purchaser owns any Warrants or Warrant Shares and until the Placement Agent does not own the Placement Agent Warrant or any Placement Agent Warrant Shares. We are also obligated to hold a stockholders’ meeting 90 days after the closing date and every three months thereafter seeking approval of the exercise of the Common Warrants. The registration statement was filed on April 4, 2024, and was declared effective by the SEC on April 15, 2024. We are seeking stockholder approval of such issuance at our Annual Meeting of Stockholders being held on June 4, 2024.

### ***Financial***

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our diagnostic test, CyPath<sup>®</sup> 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, 2024, we had cash and cash equivalents of \$2.5 million.

Prior to the acquisition, Village Oaks, under the trade name Precision Pathology Services, had licensed and developed CyPath<sup>®</sup> Lung as an LDT for sale to physicians. The license agreement provided that revenues from the sale would be split evenly between the Company and Village Oaks. In the second quarter of 2022, prior to the acquisition, we started to recognize revenue as part of a limited beta market testing program of the CyPath<sup>®</sup> Lung test. We have never been profitable, and as of March 31, 2024, we had total working capital of \$2.1 million and an accumulated deficit of approximately \$46.7 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; however, we do expect revenue to increase due to the acquisition. 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, 2024, Compared to Three Months Ended March 31, 2023

Net loss for the three months ended March 31, 2024, was approximately \$2.1 million, compared to a net loss of approximately \$1.5 million for the three months ended March 31, 2023.

#### Revenue

Post-acquisition, additional revenue streams have been consolidated starting September 19, 2023. PPLS generates three sources of revenue: (1) patient service fees, (2) histology service fees, and (3) medical director fees. Pre-acquisition, bioAffinity Technologies' revenue was generated in three ways: (1) royalties from the Company's diagnostic test, CyPath® Lung, (2) clinical flow cytometry services provided to Village Oaks related to the Company's CyPath® Lung test, and (3) CyPath® Lung tests purchased by the U.S. Department of Defense ("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. The royalty income from CyPath® Lung and clinical flow cytometry services income, beginning September 19, 2023, are related party income and, therefore, eliminated from consolidated net revenues. See net revenue summarized in the table below.

	For the three months ended March 31,	
	2024	2023
Patient service fees <sup>1</sup>	\$ 2,149,049	\$ —
Histology service fees	237,972	—
Medical director fees	16,058	—
Department of Defense observational studies	2,885	—
Other revenues <sup>2</sup>	427	921
Total net revenue	<u>\$ 2,406,391</u>	<u>\$ 921</u>

<sup>1</sup> Patient services fees include direct billing for CyPath® Lung diagnostic test.

<sup>2</sup> Other revenues include pre-acquisition CyPath® Lung royalty income and laboratory services.

#### Operating Expenses

	Three Months Ended March 31,		Change in 2024 Versus 2023	
	2024	2023	\$	%
Operating expenses:				
Direct costs and expenses	\$ 1,573,441	\$ 87	\$ 1,573,354	1,808,453%
Research and development	393,639	369,617	24,022	6%
Clinical development	48,960	19,628	29,332	149%
Selling, general and administrative	2,185,994	1,147,875	1,038,069	90%
Depreciation and amortization	149,637	21,684	127,953	590%
Total operating expenses	<u>\$ 4,351,621</u>	<u>\$ 1,558,891</u>	<u>\$ 2,792,730</u>	<u>179%</u>

Operating expenses totaled \$4.4 million and \$1.6 million during the three months ended March 31, 2024 and 2023, respectively. The increase in operating expenses is the result of the following factors.

#### Direct costs and expenses

Our direct costs and expenses are primarily direct labor for pathology services, laboratory supplies and reagents, laboratory equipment, and allocated shared facilities. Direct costs and expenses totaled \$1.6 million and \$87 during the three months ended March 31, 2024 and 2023, respectively. The increase of approximately \$1.6 million for 2024 compared to 2023 was primarily attributable to the laboratory operations of the newly acquired PPLS.

#### 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 \$393,639 and \$369,617 for the three months ended March 31, 2024 and 2023, respectively. The increase of approximately \$24,000, or 6%, for the three months ended March 31, 2024, compared to the same period in 2023 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.

#### Clinical Development

Clinical development expenses totaled \$48,960 and \$19,628 for the three months ended March 31, 2024 and 2023, respectively. The increase of approximately \$29,000 or 149%, for the three months ended March 31, 2024, compared to the same period in 2023 was primarily attributable to an increase in compensation costs and benefits as we added clinical development personnel,

### *Selling, General and Administrative*

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

Selling, general and administrative expenses totaled approximately \$2.2 million and \$1.1 million for the three months ended March 31, 2024 and 2023, respectively. The increase of approximately \$1.0 million, or 90%, for the three months ended March 31, 2024, compared to the same period in 2023 was primarily attributable to acquired general and administrative costs from PPLS (\$824,000) and an increase in employee compensation related to administrative and sales (\$212,000) due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath<sup>®</sup> Lung.

### *Other Income (Expense)*

Other income (expense), net totaled (\$12,913) and \$36,999 for the three-month period ended March 31, 2024, and 2023, respectively. The decrease in the net income of \$49,912 is mostly contributed to a reduction in interest income of \$32,527 is due to lower cash balance in money market savings account, and an increase in interest expense of \$21,895 related to equipment finance lease from the acquired PPLS lab as compared to the same period last year.

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

Interest income (expense), net was \$6,127 for the three months ended March 31, 2024, compared to \$38,654 for the three months ended March 31, 2023. The decrease in interest income of \$32,527 is due to a lower cash balance in our money market savings account.

### **Liquidity, Capital Resources, and Going Concern**

To date, we have funded our operations primarily through our IPO, subsequent registered direct offering, exercise of warrants, and the sale of our securities, resulting in gross proceeds of approximately \$36.8 million. We have evaluated whether there are conditions and events that raise substantial doubt about our ability to continue as a going concern for at least one year after the date the condensed consolidated financial statements are issued.

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, 2024 and 2023, we had net losses of \$2.1 million and \$1.5 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$46.7 million as of March 31, 2024. Based on the Company's current expected level of operating expenditures, current expected levels of revenue, and the cash and cash equivalents on hand at March 31, 2024, of \$2.5 million, management concludes that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying unaudited condensed consolidated financial statements. We need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or through exercised outstanding warrants to support our future operations unless our revenue increases significantly. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. There can be no assurance that we will be successful in accomplishing these objectives.

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:

	Three Months Ended	
	March 31,	
	2024	2023
(amounts in thousands)		
Cash and cash equivalents at beginning of period	\$ 2,822	\$ 11,414
Net cash used in operating activities	(2,346)	(1,529)
Net cash used in investing activities	(42)	(32)
Net cash provided by (used in) financing activities	2,019	(83)
Cash and cash equivalents at end of period	\$ 2,453	\$ 9,769

### *Net Cash Used in Operating Activities*

Net cash used in operating activities was approximately \$2.3 million and \$1.5 million for the three months ended March 31, 2024 and 2023, respectively. The increase of approximately \$0.8 million in cash used by operations during the three months ended March 31, 2024, compared to the same period in 2023 was primarily attributable to an increase of \$528,000 in our loss from operations and an increase in Patient Accounts Receivables of \$311,000 due to change in external professional medical billing providers effective March 1, 2024. The transition period from the previous to the new medical billing provider has caused a temporary delay in billing, as anticipated.

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

The Company used \$41,000 for the three months ended March 31, 2024, in investing activities related primarily to the purchase of computer and lab equipment, compared to \$32,000 cash used in investing activities for the three months ended March 31, 2023.

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

Cash provided in financing activities was approximately \$2.0 million compared to cash used in financing activities of approximately \$83,000 for the three months ended March 31, 2024 and 2023, respectively. The change in proceeds from prior year was primarily related to net proceeds from the direct offering of common stock securities for \$2.5 million on March 8, 2024.

#### **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.

#### *Patient Fee Revenues*

We follow ASC 606, *Revenue from Contracts with Customers*, which requires revenue recognition in the period in which the service was performed. To be able to report timely net revenues for the period, estimates are used for a portion of uncollected balances. These estimates relate to third-party historical contractual discounts and adjustments (e.g., insurance providers) and patient historical uncollectible amounts. There can be a significant delay from the time a patient has been serviced to the invoicing of that service and then the net proceeds collected. Historical data is used to determine estimates for those “in service” revenues that have not been billed or collected at the reporting period.

#### *Patient Fee Receivables and Considerations for Credit Losses*

We follow accounting considerations of CECL - *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. With the acquisition of PPLS and control of Village Oaks, the Company’s board-certified pathologists provide anatomic and clinical pathology services for patients and other customers. The Company’s other customer types include contract research organizations (“CROs”), hospitals, and independent laboratories. The Company enters into contracts with its customers for these services. The majority of the Company’s revenues stem from fees for services provided to patients, and thus in those arrangements the patient is the customer, although the services may be requested by a physician on the patient’s behalf. Furthermore, in addition to its contracts with patients, the Company separately contracts with third-party payors (insurance companies and governmental payors), who are typically responsible for all or the majority of the fees agreed upon for such services provided to patients. Historically, material amounts of gross charges are not collected due to various agreements with insurance companies, capped pricing levels for government payors, and uncollectible balances from individual payors. To estimate these allowances of credit losses, the Company assesses the portfolio risk segments and historical data on collection rates. These estimated allowances offset patient revenues and accounts receivables.

#### *Discount Rate for Finance Leased Equipment*

We follow ASC 842, *Leases*, under which a lessee is required to recognize most leases on its balance sheet. The Company has elected to apply a third-party valuation increment borrowing rate (IBR) as the discount rate by class of underlying assets when the rate is not implicit in the lease.

#### *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.

### ***Going Concern***

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our consolidated financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of our diagnostic tests and therapeutic products are inherently subject to uncertainty.

### ***Off-Balance Sheet Arrangements***

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

### ***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***

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report, is collected, recorded, processed, summarized, and reported within the time periods specified under the rules of the SEC. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that 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 rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized, and reported within the time periods specified in the rules of the SEC. The Company’s disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As of March 31, 2024, 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 Rule 13a-15(e) under the Exchange Act. The Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our disclosure controls and procedures as of March 31, 2024. Based on their assessment, they have concluded that, as of March 31, 2024, our disclosure controls and procedures are effective.

### ***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, 2024, 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, 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 2023 Form 10-K filed with the SEC on April 1, 2024, 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. The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, “Risk Factors,” contained in our 2023 Form 10-K filed with the SEC on April 1, 2024. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2023 Form 10-K filed with the SEC on April 1, 2024.

#### **Risks Related to Our Financial Position**

*Our business plan relies upon our ability to obtain additional sources of capital and financing. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, we may be required to cease operations.*

During the three months ended March 31, 2024, and March 31, 2023 we generated revenue of approximately \$2.4 million and \$921, respectively and for the years ended December 31, 2023, and December 31, 2022, we generated revenue of approximately \$2.5 million and \$5,000, respectively. During the three months ended March 31, 2024, and March 31, 2023, we generated \$2.1 million from laboratory patient services (of which approximately \$47,700 related to our first diagnostic test, CyPath<sup>®</sup> Lung), and approximately \$238,000 from histology laboratory tests, approximately \$16,000 from medical director fees, and in connection with CyPath<sup>®</sup> Lung tests purchased by the DOD in the approximate amount of \$3,000 for an observational study. During the year ended December 31, 2023, we generated \$2.2 million from laboratory patient services (of which approximately \$37,000 related to our first diagnostic test, CyPath<sup>®</sup> Lung), and approximately \$273,000 from histology laboratory tests, approximately \$19,000 from medical director fees, and in connection with CyPath<sup>®</sup> Lung tests purchased by the DOD in the approximate amount of \$19,000 for an observational study.

To become and remain profitable, we must succeed in generating additional laboratory revenue and developing and commercializing our diagnostic tests and therapeutic products that we expect will generate significant income in the planned timeframe. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our diagnostic and therapeutic technologies, obtaining regulatory approval for our diagnostic and therapeutic technologies, manufacturing, marketing, and selling any diagnostic tests and therapeutic products for which we may obtain regulatory approval, and establishing and managing our collaborations at various phases of each diagnostic test and therapeutic product candidate’s development. We are in the preliminary phases of these activities. We may never succeed in these activities and, even if we do, may never generate sufficient income to achieve profitability.

To become profitable, we must develop our diagnostic tests and therapeutic products, which will depend in large part on our ability to:

- Develop, enhance, and protect our diagnostic tests and therapeutic products;
- Raise sufficient funding to support our diagnostic tests and therapeutic product development program(s);
- Complete pre-clinical testing;

- Work with our partners to expand commercialization of our first diagnostic test, CyPath<sup>®</sup> Lung, as an LDT under the CAP/CLIA guidelines and regulations administered by CMS and CAP;
- Obtain *de novo* classification from FDA for our CyPath<sup>®</sup> Lung as a Class II in vitro diagnostic;
- Work with our partners to develop and commercialize our first diagnostic test, CyPath<sup>®</sup> Lung, as a CE-marked test in accordance with the In Vitro Diagnostic Device Regulation (the “IVDR”) of the EU;
- Synthesize, test, and attract licensing partners for drug conjugates, siRNAs, and other therapeutics (and methods for their use) developed by us;
- Develop and conduct human clinical studies to support the regulatory approval and marketing of our diagnostic test(s) and therapeutic product(s);
- Develop and manufacture the test(s) and product(s) to FDA standards, appropriate EU standards, and appropriate standards required for the commercialization of our tests and products in countries in which we seek to sell our diagnostic test(s) and therapeutic product(s);
- Obtain the necessary regulatory approvals to market our diagnostic test(s) and therapeutic product(s);
- Secure the necessary personnel and infrastructure to support the development, commercialization, and marketing of our diagnostic test(s) and therapeutic product(s); and
- Develop strategic relationships to support development, manufacturing, and marketing of our diagnostic test(s) and therapeutic product(s).

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain the research and development efforts, diversify our diagnostic tests and therapeutic product offerings, or even continue our operations. A decline in the value of our Company could also cause our investors to lose all or part of their investment.

***We must raise additional capital to fund our operations in order to continue as a going concern.***

As of March 31, 2024, we had an accumulated deficit of \$46.6 million. We 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 our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that our cash resources are sufficient to continue operations through August 2024. Our future is dependent upon our ability to obtain financing and upon future profitable operations from the development of new business opportunities. There can be no assurance that we will be successful in accomplishing these objectives. Without such additional capital, we may be required to curtail or cease operations and be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. WithumSmith+Brown, PC, our independent registered public accounting firm for the fiscal year ended December 31, 2023, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2023, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

**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 quarter ended March 31, 2024, in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC.

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

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

During the three months ended March 31, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

**ITEM 6. EXHIBITS.**

Exhibit No.	Title of Document
1.1	<a href="#">Placement Agency Agreement, dated March 6, 2024, by and among the Company and Wallachbeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)</a>
3.2	<a href="#">Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on June 16, 2022)</a>
3.3	<a href="#">Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016 (Incorporated by reference as Exhibit 3.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)</a>
3.4	<a href="#">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 Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</a>
3.5	<a href="#">Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021 (Incorporated by reference as Exhibit 3.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)</a>
3.6	<a href="#">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 Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</a>
3.7	<a href="#">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 Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)</a>
4.1	<a href="#">Form of Warrant to Purchase Common Stock (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)</a>
4.2	<a href="#">Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)</a>
10.1†	<a href="#">bioAffinity Technologies, Inc. Management Incentive Bonus Plan (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 January 31, 2024)</a>
10.2†	<a href="#">Amendment to Michael Dougherty Offer Letter (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 31, 2024)</a>
10.3	<a href="#">Form of Securities Purchase Agreement, dated as of March 6, 2024, by and among the Company and the investors parties thereto (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 March 8, 2024)</a>
10.4	<a href="#">Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)</a>
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, 2024, 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, 2024, 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: May 15, 2024

By: /s/ Michael Dougherty

Michael Dougherty

Vice President and Chief Financial Officer

Date: May 15, 2024

**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 March 31, 2024**

I, Maria Zannes, certify that:

1. I have reviewed this quarterly 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: May 15, 2024

*/s/ Maria Zannes*

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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 March 31, 2024**

I, Michael Dougherty, certify that:

1. I have reviewed this quarterly 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: May 15, 2024

*/s/ Michael Dougherty*

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

**Certification of Chief Executive Officer and Chief Financial Officer 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, 2024, 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, 2024 (the last date of the period covered by the Report).

*/s/ Maria Zannes*

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Maria Zannes  
President and Chief Executive Officer  
(Principal Executive Officer)  
Date: May 15, 2024

*/s/ Michael Dougherty*

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Michael Dougherty  
Vice President and Chief Financial Officer  
(Principal Financial Officer)  
Date: May 15, 2024

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