

**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 September 30, 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)

**3300 Nacogdoches Road, Suite 216, San Antonio, Texas**  
(Address of principal executive offices)

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

**78217**  
(Zip Code)

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

**22211 W. Interstate, Suite 1206, San Antonio Texas, 78257**  
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

Large accelerated filer ☐  
Non-accelerated filer ☒

Accelerated filer ☐  
Smaller reporting company ☒  
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Sec 13(a) of the Exchange Act. ☐

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

The number of shares of the issuer's common stock outstanding as of November 12, 2024, was 15,584,635.

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® 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 financings;
- 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>September 30, 2024</u>	<u>December 31, 2023</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 756,580	\$ 2,821,570
Accounts and other receivables, net	1,327,168	811,674
Inventory	25,363	18,484
Prepaid expenses and other current assets	440,027	321,017
Total current assets	2,549,138	3,972,745
Non-current assets:		
Property and equipment, net	418,190	458,633
Operating lease right-of-use asset, net	493,687	370,312
Finance lease right-of-use asset, net	877,115	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	789,722	833,472
Other assets	19,676	16,060
Total assets	<u>\$ 6,552,014</u>	<u>\$ 8,221,552</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 782,937	\$ 604,789
Accrued expenses	904,252	1,149,811
Unearned revenue	24,404	33,058
Operating lease liability, current portion	124,710	94,708
Finance lease liability, current portion	387,780	365,463
Notes payable, current portion	267,081	—
Total current liabilities	2,491,164	2,247,829
Non-current liabilities:		
Finance lease liability, net of current portion	543,007	835,467
Operating lease liability, net of current portion	375,139	283,001
Notes payable, net of current portion	21,679	—
Total liabilities	3,430,989	3,366,297
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at September 30, 2024, and December 31, 2023	—	—
Common stock, par value \$0.007 per share; 100,000,000 shares authorized; 13,424,648 and 9,394,610 issued and outstanding at September 30, 2024, and December 31, 2023, respectively	90,064	65,762
Additional paid-in capital	53,708,374	49,393,972
Accumulated deficit	(50,677,413)	(44,604,479)
Total stockholders' equity	3,121,025	4,855,255
Total liabilities and stockholders' equity	<u>\$ 6,552,014</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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Net Revenue</b>	\$ 2,350,386	\$ 298,484	\$ 7,154,429	\$ 319,143
<b>Operating expenses:</b>				
Direct costs and expenses	1,440,158	74,704	4,421,309	76,025
Research and development	274,497	330,376	1,070,569	1,035,118
Clinical development	93,705	106,422	194,127	161,310
Selling, general and administrative	2,364,592	2,023,917	7,023,311	4,576,708
Depreciation and amortization	151,298	57,569	452,005	100,805
<b>Total operating expenses</b>	<b>4,324,250</b>	<b>2,592,988</b>	<b>13,161,321</b>	<b>5,949,966</b>
<b>Loss from operations</b>	<b>(1,973,864)</b>	<b>(2,294,504)</b>	<b>(6,006,892)</b>	<b>(5,630,823)</b>
Other income (expense):				
Interest income	2,228	27,193	13,541	109,971
Interest expense	(21,631)	(8,785)	(67,430)	(11,801)
Other income	9,683	4,606	9,683	4,606
Other expense	(14,697)	(17,100)	(10,186)	(17,100)
<b>Total other income (expense)</b>	<b>(24,417)</b>	<b>5,914</b>	<b>(54,392)</b>	<b>85,676</b>
<b>Net loss before provision for income tax expense</b>	<b>(1,998,281)</b>	<b>(2,288,590)</b>	<b>(6,061,284)</b>	<b>(5,545,147)</b>
Income tax expense	2,559	2,294	11,650	18,700
<b>Net loss</b>	<b>\$ (2,000,840)</b>	<b>\$ (2,290,884)</b>	<b>\$ (6,072,934)</b>	<b>\$ (5,563,847)</b>
Net loss per common share, basic and diluted	\$ (0.16)	\$ (0.26)	\$ (0.54)	\$ (0.65)
Weighted average common shares outstanding	12,391,867	8,696,554	11,237,324	8,551,154

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

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

	For the Nine Months Ended September 30, 2024							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	—	\$ —	9,394,610	\$ 65,762	\$ 49,393,972	\$ (44,604,479)	\$ 4,855,255	
Stock-based compensation expense	—	—	379,962	2,661	752,933	—	755,594	
Exercise of stock options	—	—	208,031	454	74,445	—	74,899	
Exercise of stock warrants	—	—	1,066,763	7,467	1,335,910	—	1,343,377	
Sale of Common Stock	—	—	1,960,000	13,720	2,936,280	—	2,950,000	
Offering costs	—	—	—	—	(785,167)	—	(785,167)	
Net loss	—	—	—	—	—	(6,072,934)	(6,072,934)	
Balance at September 30, 2024 (unaudited)	—	\$ —	13,009,366	\$ 90,064	\$ 53,708,374	\$ (50,677,413)	\$ 3,121,025	
	For the Three Months Ended September 30, 2024							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at June 30, 2024 (unaudited)	—	\$ —	11,487,046	\$ 79,407	\$ 52,030,280	\$ (48,676,573)	\$ 3,433,114	
Stock-based compensation expense	—	—	95,605	670	185,017	—	185,687	
Exercise of stock warrants	—	—	1,066,715	7,467	1,335,763	—	1,343,230	
Sale of Common Stock	—	—	360,000	2,520	447,480	—	450,000	
Offering costs	—	—	—	—	(290,167)	—	(290,167)	
Net loss	—	—	—	—	—	(2,000,840)	(2,000,840)	
Balance at September 30, 2024 (unaudited)	—	\$ —	13,009,366	\$ 90,064	\$ 53,708,374	\$ (50,677,413)	\$ 3,121,025	
	For the Nine Months Ended September 30, 2023							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	—	\$ —	8,381,324	\$ 58,669	\$ 47,652,242	\$ (36,667,468)	\$ 11,043,443	
Stock-based compensation expense	—	—	270,587	1,911	512,402	—	514,313	
Stock issued for acquisition	—	—	564,972	3,955	996,045	—	1,000,000	
Net loss	—	—	—	—	—	(5,563,847)	(5,563,847)	
Balance at September 30, 2023 (unaudited)	—	\$ —	9,216,883	\$ 64,535	\$ 49,160,689	\$ (42,231,315)	\$ 6,993,909	
	For the Three Months Ended September 30, 2023							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at June 30,	—	\$ —	8,555,365	\$ 59,887	\$ 47,978,892	\$ (39,940,431)	\$ 8,098,348	

2023 (unaudited)								
Stock-based compensation expense	—	—	96,546	693	185,752	—	186,445	
Stock issued for acquisition	—	—	564,972	3,955	996,045	—	1,000,000	
Net loss	—	—	—	—	—	(2,290,884)	(2,290,884)	
Balance at September 30, 2023 (unaudited)	—	\$ —	9,216,883	\$ 64,535	\$ 49,160,689	\$ (42,231,315)	\$ 6,993,909	

*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>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (6,072,934)	\$ (5,563,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	452,005	100,805
Stock-based compensation expense	755,594	514,313
Changes in operating assets and liabilities:		
Accounts and other receivables	(515,494)	71,840
Inventory	(6,879)	(4,368)
Prepaid expenses and other assets	(122,626)	152,768
Accounts payable	178,148	406,836
Accrued expenses	(245,559)	(144,013)
Unearned revenue	(8,654)	38,250
Operating lease right-of-use asset	(1,235)	5,913
<b>Net cash used in operating activities</b>	<b>(5,587,634)</b>	<b>(4,421,503)</b>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(79,082)	(36,344)
Acquisition of subsidiary, net cash acquired	—	(2,186,497)
<b>Net cash used in by investing activities</b>	<b>(79,082)</b>	<b>(2,222,841)</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 \$785,167	2,164,833	—
Proceeds from exercised stock options	74,899	—
Proceeds from exercise of warrants	1,343,377	—
Payment on loans payable	—	(251,746)
Proceeds from loans payable	288,760	—
Principal repayments on finance leases	(270,143)	(8,433)
<b>Net cash provided by (used in) financing activities</b>	<b>3,601,726</b>	<b>(260,179)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(2,064,990)</b>	<b>(6,904,523)</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>\$ 756,580</b>	<b>\$ 4,509,236</b>
<b>Supplemental disclosures of cash flow information:</b>		
Interest expense paid in cash	\$ 13,541	\$ 11,801
Income taxes paid in cash	11,650	18,700

*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® Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. CyPath® 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® 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 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 ending 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”).

***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 approximately \$50.7 million at September 30, 2024. The Company’s cash and cash equivalents at September 30, 2024, were approximately \$0.8 million. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at September 30, 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, on October 21, 2024, the Company consummated a registered direct offering and concurrent private placement offering, pursuant to which the Company raised an additional \$2.3 million in cash, see *Note 15. Subsequent Events*. However, 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. Furthermore, an alternative source of funding to the sale of additional equity or debt securities is the exercise 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® 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 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 of 1988 ("CLIA"). The primary reason for the acquisition was 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.

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

Cash	\$	2,500,000
Common Stock		1,000,000
Total purchase consideration	\$	3,500,000
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	\$	3,500,000

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 November 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 and expensed approximately \$811,000 in acquisition costs.

For prior year comparative purposes, the pro-forma statement of operations as if combined on January 1, 2023, would result in net revenues of \$5,639,186, net loss of \$(6,244,179) and loss per share of \$(0.73) for the nine months ended September 30, 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 \$232,396 and \$42,947 for the nine months ended September 30, 2024 and 2023, respectively, and \$101,271 and \$15,206 for the three months ended September 30, 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 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, unvested restricted stock, 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 September 30, 2024 and 2023, as they would be anti-dilutive:

	As of September 30,	
	2024	2023
Shares underlying options outstanding	337,810	683,695
Shares underlying warrants outstanding	9,573,898	4,649,952
Shares underlying unvested restricted stock	415,282	133,414
	<u>10,326,990</u>	<u>5,467,061</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 85% of the Company's consolidated net revenues for the nine months ended September 30, 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 nine months ended September 30,	
	2024	2023
Patient service fees <sup>1</sup>	\$ 6,259,806	\$ 248,654
Histology service fees	811,914	31,854
Medical director fees	50,136	2,393
Department of Defense observational studies	8,654	14,250
Other revenues <sup>2</sup>	23,919	21,992
Total net revenue	<u>\$ 7,154,429</u>	<u>\$ 319,143</u>

<sup>1</sup> Patient services fees include direct billing for CyPath<sup>®</sup> Lung diagnostic test of approximately \$332,000 and \$24,000 for the nine months ended September 30, 2024 and 2023.

<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 and nine months ended September 30, 2024, or for the 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, and goodwill are summarized as follows as of September 30, 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	(8,611)	141,389
Customer relationships	9/18/2023	14 years	700,000	(51,667)	648,333
<b>Total intangible assets, net</b>			<b>\$ 2,254,486</b>	<b>\$ (60,278)</b>	<b>\$ 2,194,208</b>

The Company incurred amortization of intangible assets of \$43,750 and \$1,943 for the nine months ended September 30, 2024 and 2023, respectively, and \$14,583 and \$1,943 for the three months ended September 30, 2024 and 2023, respectively.

## Recent Accounting Pronouncements

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

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 five steps to ASC 280 to evaluate what, if any, segment reporting would be beneficial for shareholders. These five steps included: 1) evaluate operating segments for aggregation, 2) perform quantitative threshold tests, 3) evaluate remaining operating segments for aggregation, 4) ensure that 75% of revenue is reported, and 5) consider practical limit. Based on the analysis above against those five 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 Technologies.

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net revenue:				
Diagnostic R&D	\$ 1,731	\$ 14,250	\$ 8,654	\$ 14,250
Laboratory services <sup>1</sup>	2,348,655	284,234	7,145,775	304,893
Total net revenue	2,350,386	298,484	7,154,429	319,143
Operating expenses:				
Diagnostic R&D	(368,202)	(436,799)	(1,264,696)	(1,196,428)
Laboratory services	(2,150,825)	(307,172)	(7,423,109)	(308,493)
General corporate activities	(1,805,223)	(1,849,017)	(4,473,516)	(4,445,045)
Total operating loss	(1,973,864)	(2,294,504)	(6,006,892)	(5,630,823)
Non-operating income (expense), net	(24,417)	5,914	(54,392)	85,676
Net loss before income tax expense	(1,998,281)	(2,288,590)	(6,061,284)	(5,545,147)
Income tax expense	(2,559)	(2,294)	(11,650)	(18,700)
Net loss	\$ (2,000,840)	\$ (2,290,884)	\$ (6,072,934)	\$ (5,563,847)

<sup>1</sup>The majority of the increase versus the prior year is from the acquisition of the clinical pathology laboratory on September 18, 2023.

### **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 laboratory operations, preclinical studies, compensation, and consulting costs.

### **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 United States ("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 ("LDT") 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 receivables and other receivables:

	September 30, 2024	December 31, 2023
Patient service fees	\$ 1,119,933	\$ 657,717
Histology service fees	151,548	121,301
Medical director fees	6,494	3,103
Other receivables <sup>1</sup>	49,193	29,553
Total accounts and other receivables, net	<u>\$ 1,327,168</u>	<u>\$ 811,674</u>

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

Prepaid expenses and other current assets are summarized below:

	September 30, 2024	December 31, 2023
Prepaid insurance	\$ 275,706	\$ 171,855
Legal and professional	10,148	24,476
Other	154,173	124,686
Total prepaid expenses and other current assets	<u>\$ 440,027</u>	<u>\$ 321,017</u>

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

Property and equipment are summarized below:

	September 30, 2024	December 31, 2023
Lab equipment	\$ 662,747	\$ 647,214
Computers and software	81,433	68,682
Leasehold improvements	19,353	9,941
Vehicles	148,103	105,919
	911,636	831,756
Accumulated depreciation	(493,446)	(373,123)
Total property and equipment, net	\$ 418,190	\$ 458,633

Depreciation expense was \$119,526 and \$66,780 for the nine months ended September 30, 2024 and 2023, respectively, and \$40,472 and \$45,095 for the three months ended September 30, 2024 and 2023, respectively.

**Note 6. ACCRUED EXPENSES**

Accrued expenses are summarized below:

	September 30, 2024	December 31, 2023
Compensation	\$ 659,294	\$ 857,037
Legal and professional	66,361	257,926
Clinical	135,286	15,350
Other	43,311	19,498
Total accrued expenses	\$ 904,252	\$ 1,149,811

**Note 7. UNEARNED REVENUE**

The Company engaged in an observational study of CyPath<sup>®</sup> Lung with the U.S. Department of Defense (“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 40 units as of September 30, 2024. The performance obligation is deemed complete after samples have been collected, processed, analyzed, and results communicated to patients. The unearned revenue balance amounted to \$24,404 and \$33,058 as of September 30, 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. Additionally, the Company entered into another operating lease on September 1, 2024 with regard to office space. The Company has operating leases consisting of office space with remaining lease terms ranging from 3.1 to 5.9 years as of September 30, 2024. The Company has finance leases consisting of office and lab equipment with remaining lease terms ranging from approximately 1.5 to 3.3 years as of September 30, 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 the date of inception of the leases 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 7.43% 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 and nine months ended September 30, 2024 and 2023, are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Amortization of right-of-use asset - finance lease	\$ 96,243	\$ 32,081	\$ 288,729	\$ 32,081
Interest on lease liabilities - finance lease	21,533	8,634	67,318	8,634
Operating lease cost	33,198	9,972	93,029	9,972
Total lease cost	\$ 150,974	\$ 50,687	\$ 449,076	\$ 50,687

Cash paid for amounts included in the measurement of lease liabilities:

Operating cash flows from finance leases	\$ (91,038)	\$ —	\$ (270,143)	\$ (8,433)
Operating cash flows from operating leases	(203)	—	(1,235)	—

Supplemental balance sheet information relating to leases was as follows as of September 30, 2024, and December 31, 2023:

<b>Operating leases:</b>	September 30, 2024	December 31, 2023
Operating lease right-of-use asset	\$ 493,687	\$ 370,312
Operating lease liability, current	\$ 124,710	\$ 94,708
Operating lease liability, long-term	\$ 375,139	\$ 283,001
<b>Finance leases:</b>	September 30, 2024	December 31, 2023
Finance lease right-of-use asset, gross	\$ 1,294,168	\$ 1,294,168
Accumulated amortization	(417,053)	(128,324)
Finance lease right-of-use asset, net	\$ 877,115	\$ 1,165,844
Finance lease liability, current portion	\$ 387,780	\$ 365,463
Finance lease liability, long-term	543,007	835,467
Total finance lease liabilities	\$ 930,787	\$ 1,200,930
<b>Weighted-average remaining lease term:</b>	September 30, 2024	December 31, 2023
Operating leases (in years)	4.17	3.58
Finance leases (in years)	2.60	3.25
<b>Weighted-average discount rate:</b>	September 30, 2024	December 31, 2023
Operating leases	7.43%	8.07%
Finance leases	8.02%	8.01%

Future minimum lease payments under non-cancellable lease as of September 30, 2024, are as follows:

	Operating Leases	Finance Leases
Remaining for 2024	\$ 39,341	\$ 112,126
2025	157,837	448,505
2026	159,282	270,395
2027	110,063	202,970
2028 and thereafter	111,788	—
Total undiscounted cash flows	578,311	1,033,996
Less discounting	(78,462)	(103,209)
Present value of lease liabilities	\$ 499,849	\$ 930,787



**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 September 30, 2024, and December 31, 2023, was \$25,868 and \$0, respectively. The current portion of the balance of this loan as of September 30, 2024, and December 31, 2023, was \$4,189 and \$0, respectively.

***Directors and Officers Insurance Policy – 2024***

In September 2024, the Company obtained short-term financing of approximately \$0.26 million with 11 monthly payments of approximately \$24,000 and interest at a 6.7% fixed annual rate for director and officer insurance policies. The balance of this loan is \$262,892 as of September 30, 2024. The current portion of the balance of this loan as of September 30, 2024, and December 31, 2023, was \$262,892 and \$0, respectively.

**Note 11. COMMITMENTS AND CONTINGENCIES*****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 100,000,000 shares of Common Stock, \$0.007 par value per share. On June 4, 2024, the Company received stockholder approval to increase the number of authorized shares of Common Stock from 25,000,000 shares to 100,000,000 shares, and on June 5, 2024, the Company filed an amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the increase. The Company has issued 13,424,648 shares of Common Stock, of which 415,282 are unvested restricted stock awards as of September 30, 2024, and 9,505,255 shares of Common Stock, of which 110,645 are unvested restricted stock awards as of December 31, 2023.

**Note 13. STOCK-BASED COMPENSATION**

The Company granted options and restricted stock awards under its 2014 Equity Incentive Plan (the “2014 Plan”). Under the 2014 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 2014 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 Plan expired according to the respective 10-year term of the 2014 Plan in March 2024. A new 2024 Incentive Compensation Plan (the “2024 Plan”) was approved 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 statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 30,605	\$ 10,304	\$ 87,832	\$ 32,193
General and administrative	155,082	74,941	667,762	482,120
	<u>\$ 185,687</u>	<u>\$ 85,245</u>	<u>\$ 755,594</u>	<u>\$ 514,313</u>

The following table summarizes stock option activity under the 2014 and 2024 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	(208,031)	1.16		
Forfeited	(137,854)	1.16		
Outstanding at September 30, 2024	<u>337,810</u>	<u>\$ 6.88</u>	<u>5.08</u>	<u>—</u>
Vested and exercisable at September 30, 2024	<u>337,810</u>	<u>\$ 6.88</u>	<u>5.08</u>	<u>—</u>

As of September 30, 2024, there was no unrecognized compensation cost related to non-vested stock options.

During the nine months ended September 30, 2024, 208,031 options were exercised at an exercise price of \$1.155, of which 143,183 options were from a cashless exercise, and 137,854 options were forfeited due to a cashless exercise.

The following table summarizes restricted stock award activity under the 2014 and 2024 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	488,611	\$ 2.27	\$ 1,109,391	448,011	40,600
Granted	750,224	1.88	1,407,613	362,273	374,682
Forfeited	(13,269)	1.57	(20,832)	—	—
Balance at September 30, 2024	1,225,566	\$ 2.04	\$ 2,496,172	810,284	415,282

During the three months ended September 30, 2024, the Company issued restricted stock awards (“RSAs”) for 330,468 shares of Common Stock to employees, non-employees, and the board of directors. The shares vest in equal monthly installments over terms of immediately and up to three years, subject to the employees and non-employees providing continuous service through the vesting date. During the three months ended September 30, 2024, 106 shares vested from RSAs granted prior to January 1, 2024, and 95,499 shares vested from RSAs granted during the nine months ended September 30, 2024.

#### Note 14. WARRANTS

The Company’s outstanding Common Stock warrants are equity classified. As of September 30, 2024, and December 31, 2023, the Company had 9,574,018 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 \$3.37 and expire at various dates through March 2029. During the nine months ended September 30, 2024, excluding the August offering, a total number of 25,096 warrants were exercised into an equivalent number shares of Common Stock as compared to no warrants being exercised during the nine months ended September 30, 2023. The proceeds of the exercised warrants for the nine months ended September 30, 2024, excluding the August offering, was \$41,294, compared to no proceeds during the nine months ended September 30, 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.

On August 5, 2024, the Company entered into warrant exercise agreements with three existing accredited investors to exercise certain outstanding warrants to purchase an aggregate of 1,041,667 of the Company’s shares of Common Stock (the “Existing Warrants”). The exercising holders received in a private placement new unregistered warrants (the “New Warrants”) to purchase up to an aggregate of 1,302,082 shares of Common Stock with an exercise price of \$1.50 per share, which are initially exercisable on the date that stockholder approval of the exercise of the New Warrants is obtained and will expire five years from the date of such approval. In connection with the exercise of the Existing Warrants, the Company agreed to reduce the exercise price of the Existing Warrants from \$1.64 to \$1.25 per share. The exercise of the Existing Warrants and the issuance of the New Warrants occurred on August 5, 2024.

On August 5, 2024, the Company also entered into a securities purchase agreement (the “Purchase Agreement”) with an institutional investor (the “Purchaser”), pursuant to which the Company issued to the Purchaser, (1) in a registered direct offering, 360,000 shares of Common Stock, and (2) in a concurrent private placement, warrants (the “Private Warrants”) to purchase an aggregate of 450,000 shares of Common Stock (the “Private Warrant Shares”), with an exercise price of \$1.50 (collectively, the “Offering”).

In addition, designees of the placement agent for the Offering were granted warrants to purchase an aggregate of up to 49,862 shares of Common Stock, with an exercise price of \$1.50.

The following table summarizes the calculated aggregate fair values for the warrant derivative liability using the Black-Scholes method based on the following assumptions for the Offering:

Exercise price per share of warrant	\$ 1.50
Fair market closing price per share of Common Stock	\$ 1.65
Volatility	135%
Expected term (years)	5
Risk-free interest rate	3.62%
Dividend yield	0%

The fair value of the New Warrants and the Private Warrant Shares using the assumptions above was \$912,446 for the warrants, \$28,758 for the change in fair value related to the change in exercise price, and \$72,912 for the placement agent warrants. The fair value of the above warrants were recorded in Additional paid-in capital.

As of September 30, 2024, and prior to the Offering, 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 3,269,791 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	2,326,835	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	(1,066,763)	533,237
Placement agent direct offering March 8, 2024	32,000	1.64	—	32,000
Inducement/direct offering August 5, 2024	1,752,082	1.50	—	1,752,082
Placement agent direct offering August 5, 2024	49,862	1.50	—	49,862
Balance at September 30, 2024	11,677,147	\$ 3.53	(2,103,249)	9,573,898

## Note 15. SUBSEQUENT EVENTS

On October 9, 2024, the Company announced that CyPath<sup>®</sup> Lung, its noninvasive test to detect early-stage lung cancer, will be added to the U.S. Federal Supply Schedule, a procurement system that provides the Veterans Health Administration (the “VHA”) and the Military Health System streamlined access to state-of-the-art healthcare products and services. The VHA, part of the U.S. Department of Veterans Affairs (“VA”), serves 9.1 million Veterans each year and is the largest integrated health care system in the country, providing care at 1,380 health care facilities, including 170 medical centers and 1,193 outpatient sites. Approximately 8,000 Veterans are diagnosed and treated for lung cancer annually, according to the VA. Veterans are at higher risk for lung cancer due to older age, smoking and environmental exposure during and after military service. The VA promotes annual lung cancer screening for high-risk individuals, which could result in a revenue stream from sales of CyPath<sup>®</sup> Lung through the Federal Supply Schedule.

On October 21, 2024, we issued (i) in a registered direct offering, 2,048,294 shares (the “Shares”) of our Common Stock, par value \$0.007 per share (the “Common Stock”), and (ii) in a concurrent private placement, common warrants (the “Common Warrants”) to purchase an aggregate of 2,662,782 shares of Common Stock (the “Common Warrant Shares”), with an exercise price of \$1.50, pursuant to a securities purchase agreement, dated October 18, 2024 (the “Purchase Agreement”) with institutional investors (the “Purchasers”). Such registered direct offering and concurrent private placement are collectively referred to as the “Offerings.” We received aggregate gross proceeds from the Offerings of approximately \$2,662,782, before deducting placement agent fees and other offering expenses payable by us. The Shares were being offered pursuant to a shelf registration statement on Form S-3 (File No. 333-275608), which was declared effective by the SEC on November 27, 2023 (as amended from time to time, the “Registration Statement”). The Common Warrants and the Common Warrant Shares were issued in a concurrent private placement and have not been registered under the Securities Act of 1933, as amended (the “Securities Act”) and were instead offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. The Common Warrants will be exercisable commencing on the effective date of stockholder approval, as may be required by the applicable rules and regulations of The Nasdaq Stock Market LLC (“Nasdaq”), for the exercise of the Common Warrants and issuance of the Common Warrant Shares issuable upon exercise of the Common Warrants (the “Stockholder Approval”) and will expire on the fifth anniversary of the date of Stockholder Approval (the “Stockholder Approval Date”). WallachBeth Capital, LLC acted as the exclusive placement agent (the “Placement Agent”) on a “reasonable best efforts” basis, in connection with the Offerings pursuant to that a placement agency agreement, dated October 18, 2024 (the “Placement Agency Agreement”), by and between us and the Placement Agent and received a cash fee of 8.0% of the aggregate gross proceeds paid to us for the securities sold in the Offerings and reimbursement of certain out-of-pocket expenses up to a maximum of \$75,000, as well as warrants (“Placement Agent Warrants”) to purchase an aggregate of 61,448 shares of Common Stock (the “Placement Agent Warrant Shares”), which is equal to approximately 3.0% of the number of Shares issued in the registered direct offering, at an exercise price per share equal to \$1.50.

Pursuant to the Purchase Agreement, we agreed to file a resale registration statement on Form S-1 (the “Resale Registration Statement”) to register the resale of the Common Warrant Shares as soon as practicable (and in any event within 45 calendar days following the date of the Purchase Agreement), and to use commercially reasonable efforts to have the Resale Registration Statement declared effective by the Commission and to keep such registration statement effective at all times until the Purchasers no longer owns any Common Warrants or Common Warrant Shares. The Company intends to register the Common Warrant Shares and the Placement Agent Warrant Shares on the Resale Registration Statement.

On October 30, 2024, the Company announced that the Japan Patent Office had issued a Certificate of Grant of Patent to bioAffinity Technologies for the method of predicting the likelihood of lung cancer used by the CyPath<sup>®</sup> Lung diagnostic test for early-stage lung cancer. The Japanese patent, titled “System and Method for Determining the State of Health of the Lungs,” is an important addition to bioAffinity Technologies’ patent portfolio, which includes 17 awarded U.S. and foreign patents and 30 pending patent applications related to its diagnostic platform and cancer treatment therapeutics. The Japanese patent is the first awarded for the CyPath<sup>®</sup> Lung flow cytometry test as a stand-alone assay for the detection of lung cancer.

## **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 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"). 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 and nine months ended September 30, 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 nine months and three months ended September 30, 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 have developed a proprietary noninvasive diagnostic test 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 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 August 5, 2024, the Company entered into warrant exercise agreements with three existing accredited investors to exercise certain outstanding warrants to purchase an aggregate of 1,041,667 of the Company's shares of Common Stock (the "Existing Warrants"). The exercising holders received in a private placement new unregistered warrants (the "New Warrants") to purchase up to an aggregate of 1,302,082 shares of Common Stock with an exercise price of \$1.50 per share and are initially exercisable on the date that stockholder approval of the exercise of the New Warrants is obtained and will expire five years from the date of such approval. In connection with the exercise of the Existing Warrants, the Company agreed to reduce the exercise price of the Existing Warrants from \$1.64 to \$1.25 per share. The exercise of the Existing Warrants and the issuance of the New Warrants occurred on August 5, 2024. On the same day, the Company also entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor (the "Purchaser"), pursuant to which the Company issued to the Purchaser, (1) in a registered direct offering, 360,000 shares of Common Stock, and (2) in a concurrent private placement, warrants (the "Private Warrants") to purchase an aggregate of 450,000 shares of Common Stock (the "Private Warrant Shares"), with an exercise price of \$1.50 (collectively, the "Offering"). In addition, the placement agent was granted warrants to purchase 49,862 shares of Common Stock, with an exercise price of \$1.50.

On August 23, 2024, bioAffinity Technologies announced J. Michael Edwards, who oversaw the Company's Initial Public Offering ("IPO") as the Company's Chief Financial Officer ("CFO"), would replace Michael Dougherty who resigned his position to move to the Pacific Northwest where he accepted a CFO position in the energy industry. Mr. Edwards has more than three decades of experience in financial management and business strategy. Previously, he was CFO of CytoBioscience Inc., which develops and manufactures instruments for disease analysis and treatment, and OncoVista Innovative Therapies, Inc., a biopharmaceutical company that develops targeted anticancer therapies by utilizing tumor-associated biomarkers. Earlier in his career, Mr. Edwards held finance positions at BioNumerik Pharmaceuticals, Inc. and Ilex Oncology, Inc. He is a certified public accountant who began his career at PricewaterhouseCoopers LLP. Edwards earned his MBA from The University of Texas McCombs School of Business in Austin.

On September 18, 2024, the Company announced publication in a peer-reviewed journal of an economic study concluding that adding CyPath® Lung to the standard of care for Medicare patients with a positive lung cancer screening could have saved an average of \$2,773 per patient for total cost savings of \$379 million in 2022. The study found that adding CyPath® Lung to the standard of care for private-payer patients could save an average of \$6,460 per patient and estimated total healthcare savings of \$895 million if all individuals screened in 2022 were covered by private insurance. The peer-reviewed study, published in the Journal of Health Economics and Outcomes Research, attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications. Michael J. Morris, M.D., Brooke Army Medical Center (BAMC) pulmonology and critical care physician and Assistant Dean of Research at San Antonio Uniformed Services Health Education Consortium, and Sheila A. Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital and Assistant Professor at the University of Texas Health Science Center at San Antonio, were first and second authors on the study. Economists John E. Schneider, Ph.D., and Maggie L. Do Valle, Master of Public Health, of Avalon Health Economics also contributed to the study.

On October 21, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with institutional investors (the "Purchasers"), pursuant to which the Company agreed to issue to the Purchasers, (i) in a registered direct offering, 2,048,294 shares (the "Shares") of Common Stock, and (ii) in a concurrent private placement, common warrants to purchase an aggregate of 2,662,782 shares of Common Stock, with an exercise price of \$1.50.

On October 30, 2024, the Company announced that the Japan Patent Office had issued a Certificate of Grant of Patent to bioAffinity Technologies for the method of predicting the likelihood of lung cancer used by the CyPath® Lung diagnostic test for early-stage lung cancer. The Japanese patent, titled "System and Method for Determining the State of Health of the Lungs," is an important addition to bioAffinity Technologies' patent portfolio, which includes 17 awarded U.S. and foreign patents and 30 pending patent applications related to its diagnostic platform and cancer treatment therapeutics. The Japanese patent is the first awarded for the CyPath® Lung flow cytometry test as a stand-alone assay for the detection of lung cancer.

On November 1, 2024, William Bauta, Ph.D., was named Chief Science Officer for bioAffinity Technologies. Dr. Bauta joined bioAffinity Technologies in 2016 as Senior Vice President of Research and Development and has been responsible for multiple Company inventions for which patents have been awarded or patent applications pending that support bioAffinity Technologies' diagnostic and therapeutic advancements, including CyPath® Lung. Before coming to bioAffinity Technologies, Dr. Bauta was Associate Director of science at Genzyme Corporation and held a similar position at Ilex Products, Inc., where he was responsible for the discovery, development and FDA approval of multiple therapeutics. In addition to bioAffinity Technologies patents on which he is a named inventor, he holds several additional healthcare-related patents and has published in more than a dozen scientific journals, including the journal Science. Dr. Bauta received his Ph.D. from the University of Chicago where he received fellowships from the National Science Foundation and the American Chemical Society. His post-doctoral studies were at the University of Texas at Austin under a National Institutes of Health fellowship. Dr. Bauta succeeds Vivienne I. Rebel, M.D., Ph.D. who retired from her position on October 31, 2024 as Executive Vice President and Chief Science and Medical Officer for bioAffinity Technologies. Dr. Rebel is a stem cell biologist whose academic research focused on understanding the molecular events that regulate blood-forming stem cells in bone marrow and prohibit them from developing into cancer. She joined the Company in 2016 and led the research and development of the Company's first commercial product, CyPath® Lung, for the early detection of lung cancer.

### ***Financial***

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our diagnostic test, CyPath® Lung. As a result, since our inception in 2014, we have funded our operations principally through private sales of our equity and our initial public offering. As of September 30, 2024, we had cash and cash equivalents of \$0.8 million. As of November 12, 2024, after the October 2024 Offerings, we had cash and cash equivalents of \$2.0 million, which we expect will not support our operations beyond March 2025.

Prior to acquisition of the clinical pathology laboratory by PPLS, Village Oaks, under the trade name Precision Pathology Services, had licensed and developed CyPath® Lung as a laboratory developed test ("LDT") for sale to physicians. The license agreement provided that revenues from the sale would be split evenly between us 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® Lung test. We have never been profitable, and as of September 30, 2024, we had total working capital of approximately \$58,000 and an accumulated deficit of approximately \$50.7 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 expect revenue to increase due to the acquisition of the clinical pathology laboratory (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 September 30, 2024, Compared to Three Months Ended September 30, 2023

Net loss for the three months ended September 30, 2024, was approximately \$2.0 million, compared to a net loss of approximately \$2.3 million for the three months ended September 30, 2023.

#### Revenue

Since acquisition of the clinical pathology laboratory on September 19, 2023, additional revenue streams have been consolidated. 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 our diagnostic test, CyPath<sup>®</sup> Lung, (2) clinical flow cytometry services provided to Village Oaks related to our CyPath<sup>®</sup> Lung test, and (3) CyPath<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 September 30,	
	2024	2023
Patient service fees <sup>1</sup>	\$ 2,049,851	\$ 248,654
Histology service fees	281,861	31,854
Medical director fees	16,943	2,393
Department of Defense observational studies	1,731	14,250
Other revenues <sup>2</sup>	—	1,333
Total net revenue	<u>\$ 2,350,386</u>	<u>\$ 298,484</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.

#### Operating Expenses

	Three Months Ended September 30,		Change in 2024 Versus 2023	
	2024	2023	\$	%
Operating expenses:				
Direct costs and expenses	\$ 1,440,158	\$ 74,704	\$ 1,365,454	1,828%
Research and development	274,497	330,376	(55,879)	(17)%
Clinical development	93,705	106,422	(12,717)	(12)%
Selling, general and administrative	2,364,592	2,023,917	340,675	17%
Depreciation and amortization	151,298	57,569	93,729	163%
Total operating expenses	<u>\$ 4,324,250</u>	<u>\$ 2,592,988</u>	<u>\$ 1,731,262</u>	<u>67%</u>

Operating expenses totaled approximately \$4.3 million and \$2.6 million during the three months ended September 30, 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 \$1.4 million and \$74,704 during the three months ended September 30, 2024 and 2023, respectively. The increase of approximately \$1.4 million for 2024 compared to 2023 was primarily attributable to the laboratory operations of the newly acquired clinical pathology laboratory in September 2023.

### **Research and Development Expenses**

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

Research and development expenses totaled \$274,497 and \$330,376 for the three months ended September 30, 2024 and 2023, respectively. The decrease of approximately \$56,000, or 17%, for the three months ended September 30, 2024, compared to the same period in 2023 was primarily due to the acquisition of PPLS in September 2023 due to acquiring new personnel and related costs for the laboratory supplies and reagents in 2023. Additionally, equipment costs increased in 2023 as we purchased capital equipment to support research and development efforts.

### **Clinical Development**

Clinical development expenses totaled \$93,705 and \$106,422 for the three months ended September 30, 2024 and 2023, respectively. The decrease of approximately \$12,000, or 12%, for the three months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to an increase in professional fees in 2023, including consulting fees, related to evaluating the clinical strategy for our pivotal clinical trial designed to confirm the sensitivity and specificity of CyPath<sup>®</sup> Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate pulmonary nodules between 6mm and 30mm in size which often present a challenge in diagnosis.

### **Selling, General and Administrative**

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

Selling, general and administrative expenses totaled approximately \$2.4 million and \$2.0 million for the three months ended September 30, 2024 and 2023, respectively. The increase of approximately \$0.4 million, or 17%, for the three months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to acquired general and administrative costs from PPLS and an increase in employee compensation related to administrative and sales due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath<sup>®</sup> Lung.

### **Depreciation and Amortization**

Depreciation and amortization expenses totaled \$151,298 and \$57,569 for the three months ended September 30, 2024 and 2023, respectively. The increase of approximately \$93,729, or 163%, for the three months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to depreciation on the assets from the acquisition of PPLS in September 2023.

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

Other income (expense), net totaled (\$24,417) and \$5,914 for the three months ended September 30, 2024 and 2023, respectively. The decrease in the other income of \$30,331 is mostly attributable to a reduction in interest income of \$24,965 which is due to a lower cash balance in a money market savings account and an increase in interest expense of \$12,846 related to equipment finance leases from the acquired PPLS laboratory as compared to the same period last year.

### **Nine Months Ended September 30, 2024, Compared to Nine Months Ended September 30, 2023**

Net loss for the nine months ended September 30, 2024, was approximately \$6.1 million, compared to a net loss of approximately \$5.6 million for the nine months ended September 30, 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 our diagnostic test, CyPath<sup>®</sup> Lung, (2) clinical flow cytometry services provided to Village Oaks related to our CyPath<sup>®</sup> Lung test, and (3) CyPath<sup>®</sup> Lung tests purchased by the DOD for an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath<sup>®</sup> 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<sup>®</sup> 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 nine months ended September 30,	
	2024	2023
Patient service fees <sup>1</sup>	\$ 6,259,806	\$ 248,654
Histology service fees	811,914	31,854
Medical director fees	50,136	2,393
Department of Defense observational studies	8,654	14,250
Other revenues <sup>2</sup>	23,919	21,992
Total net revenue	<u>\$ 7,154,429</u>	<u>\$ 319,143</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.



## Operating Expenses

	Nine Months Ended September 30,		Change in 2024 Versus 2023	
	2024	2023	\$	%
Operating expenses:				
Direct costs and expenses	\$ 4,421,309	\$ 76,025	\$ 4,345,284	5,716%
Research and development	1,070,569	1,035,118	35,451	3%
Clinical development	194,127	161,310	32,817	20%
Selling, general and administrative	7,023,311	4,576,708	2,446,603	53%
Depreciation and amortization	452,005	100,805	351,200	348%
Total operating expenses	<u>\$ 13,161,321</u>	<u>\$ 5,949,966</u>	<u>\$ 7,211,355</u>	<u>121%</u>

Operating expenses totaled approximately \$13.5 million and \$6.0 million during the nine months ended September 30, 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 \$4,421,309 and \$76,025 during the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$4.3 million for 2024 compared to 2023 was primarily attributable an entire quarter of laboratory operations for PPLS compared to a partial quarter in 2023 from the acquisition of PPLS in September 2023.

### Research and Development Expenses

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

Research and development expenses totaled \$1.1 million and \$1.0 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$35,000, or 3%, for the nine months ended September 30, 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 laboratory supplies and reagents.

### Clinical Development

Clinical development expenses totaled \$194,127 and \$161,310 for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$32,000, or 20%, for the nine months ended September 30, 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, and other professional services, and general operating expenses.

Selling, general and administrative expenses totaled approximately \$7.0 million and \$4.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$2.4 million, or 53%, for the nine months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to acquired general and administrative costs from PPLS and an increase in employee compensation related to administrative and sales due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath<sup>®</sup> Lung.

### Depreciation and Amortization

Depreciation and amortization expenses totaled \$452,005 and \$100,805 for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$351,000, or 348%, for the nine months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to depreciation on the assets from the acquisition of PPLS in September 2023.

### Other Income (Expense)

Other income (expense), net totaled (\$54,392) and \$85,676 for the nine-month period ended September 30, 2024 and 2023, respectively. The decrease in other income of approximately \$140,000 is mostly attributable to a reduction in interest income of \$96,430 which is due to a lower cash balance in a money market savings account and an increase in interest expense of \$55,629 related to equipment finance leases from the acquired PPLS laboratory as compared to the same period last year.

## 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 \$38.5 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 nine months ended September 30, 2024 and 2023, we had net losses of \$6.1 million and \$5.6 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$50.7 million as of September 30, 2024. Despite our recent financing in October 2024, pursuant to which we raised gross proceeds of approximately \$2.3 million, we believe our current cash and anticipated revenue from operations will not be sufficient to support our operations beyond March 2025. Based on our current expected level of operating expenditures, current expected levels of revenue, and the cash and cash equivalents on hand at September 30, 2024, of \$0.8 million, management concludes that there is substantial doubt about our 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 contained in this Quarterly Report. 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:

	Nine Months Ended September 30,	
	2024	2023
Cash and cash equivalents at beginning of period	\$ 2,821,570	\$ 11,413,759
Net cash used in operating activities	(5,587,634)	(4,421,503)
Net cash used in investing activities	(79,082)	(2,222,841)
Net cash provided by (used in) financing activities	3,601,726	(260,179)
Cash and cash equivalents at end of period	<u>\$ 756,580</u>	<u>\$ 4,509,236</u>

### Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$5.6 million and \$4.4 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$1.1 million in cash used by operations during the nine months ended September 30, 2024, compared to the same period in 2023 was primarily attributable to an increase of approximately \$852,000 in our loss from operations and an increase in patient accounts receivables of approximately \$587,000 due to a 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 and deposits, as anticipated.

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

We used approximately \$80,000 for the nine months ended September 30, 2024, in investing activities related primarily to the purchase of computer and laboratory equipment, compared to approximately \$2.2 million used in investing activities for the nine months ended September 30, 2023. We used approximately \$2.2 million of cash in the prior year related primarily to the Acquisition of the clinical pathology laboratory, which occurred on September 18, 2023.

#### *Net Cash Provided by (Used In) Financing Activities*

Cash provided in financing activities was approximately \$3.6 million compared to cash used in financing activities of approximately \$260,000 for the nine months ended September 30, 2024 and 2023, respectively. The change in proceeds from prior year was primarily related to net proceeds from the equity transactions in the current year for \$3.6 million.

#### ***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 collection of net proceeds. 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 PPLS’ acquisition of the clinical pathology laboratory and control of Village Oaks, our board-certified pathologists provide anatomic and clinical pathology services for patients and other customers. Our other customer types include contract research organizations (“CROs”), hospitals, and independent laboratories. We enter into contracts with our customers for these services. The majority of our 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, we separately contract with third-party payers (insurance companies and governmental payers), 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 payers, and uncollectible balances from individual payers. To estimate these allowances of credit losses, we assess 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. We have 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 and 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 September 30, 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 September 30, 2024. Based on their assessment, they have concluded that, as of September 30, 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 September 30, 2024, the period covered by this Quarterly Report, that could materially affect, or are reasonably likely to materially affect, our internal control over 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.**

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, 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. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2023 Form 10-K.

#### **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 nine months ended September 30, 2024, and September 30, 2023, we generated revenue of approximately \$7.2 million and \$319,143, respectively. During the nine months ended September 30, 2024, we generated \$6.3 million from laboratory patient services (of which approximately \$332,000 related to our first diagnostic test, CyPath<sup>®</sup> Lung), approximately \$812,000 from histology laboratory tests, approximately \$50,000 from medical director fees, and approximately \$9,000 in connection with CyPath<sup>®</sup> Lung tests purchased by the DOD 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), approximately \$273,000 from histology laboratory tests, approximately \$19,000 from medical director fees, and approximately \$19,000 in connection with CyPath<sup>®</sup> Lung tests purchased by the DOD 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 European Union (“EU”);
- Synthesize, test, and attract licensing partners for drug conjugates, siRNAs, and other therapeutics (and methods for their use) developed by the Company;
- 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 September 30, 2024, we had an accumulated deficit of \$50.7 million. As of November 12, 2024, our cash and cash equivalents were \$2.0 million. Despite our recent financings, we will 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 March 2025. 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.

***We are unable to precisely estimate when we will begin to generate significant profit from revenue, if ever, from PPLS’ services, the amount of profit or revenue that will be generated, or the expenses that will be incurred.***

We do not expect to immediately derive profit from revenue from PPLS’ services. Since its acquisition in September 2023, we have generated \$9.6 million in revenue from PPLS. Once we begin to generate such profit, there is no guarantee that it will be sufficient to realize the expected financial benefits of the acquisition. In addition, since we have limited experience operating a clinical laboratory, we may not accurately estimate the expenses we will incur.

***Our failure to file a registration statement to register the shares of Common Stock issuable upon exercise of the warrants issued in October 2024, or to timely hold a stockholders meeting to obtain stockholder approval of the issuance of shares of Common Stock upon the exercise of the warrants issued in October 2024, will result in a breach of the terms of certain agreements.***

Pursuant to the terms of certain agreements that we entered into with certain purchasers in October 2024, we are obligated to file a registration statement to register the shares of Common Stock issuable upon exercise of the warrants issued to such purchasers within 45 days of the date of such agreement and to use commercially reasonable efforts to keep the registration statement effective at all times while the purchasers own any warrants or shares of Common Stock issuable upon exercise of the warrants. We are also obligated to hold a stockholders' meeting 90 days after the closing date and, if approval is not obtained at the shareholders meeting, every six months thereafter seeking approval of the exercise of the warrants issued to the purchasers. Additionally, we are obligated to use commercially reasonable efforts to keep the registration statements that we filed to register the shares of Common Stock issuable upon exercise of warrants that we issued in March 2024 and August 2024 effective at all times for so long as the purchasers of such warrants own any such warrants or shares of Common Stock issuable upon exercise thereof. The failure to take any of these actions will constitute a default under the operative agreement.

***Our management collectively owns a substantial percentage of our Common Stock.***

Based on the provisions for determining beneficial ownership in accordance with Rule 13d-3 and Item 403 of Regulation S-K under the Exchange Act, our officers and directors own or exercise control of approximately 46.13% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

- the composition of our Board and, through it, any determination with respect to our business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;
- our acquisition or disposition of assets; and
- our corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring, or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our Common Stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

## **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 September 30, 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 September 30, 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**

3.1	<a href="#"><u>Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (Incorporated by reference as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-41463) filed with the SEC on April 1, 2024)</u></a>
3.2	<a href="#"><u>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)</u></a>
3.3	<a href="#"><u>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)</u></a>
3.4	<a href="#"><u>Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u></a>
3.5	<a href="#"><u>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 Annual Report on Form 10-K (File No. 001-41463) filed with the SEC on April 1, 2024)</u></a>
3.6	<a href="#"><u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u></a>
3.7	<a href="#"><u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)</u></a>
3.8	<a href="#"><u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 5, 2024 (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 5, 2024)</u></a>
3.9	<a href="#"><u>Amendment to Amended and Restated By-Laws of bioAffinity Technologies Inc., dated October 17, 2024 (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 October 21, 2024)</u></a>
4.1	<a href="#"><u>Form of Purchase Warrant (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 August 5, 2024)</u></a>
4.2	<a href="#"><u>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 August 5, 2024)</u></a>
4.3	<a href="#"><u>Form of Common Warrant (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 October 21, 2024)</u></a>
4.4	<a href="#"><u>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 October 21, 2024)</u></a>
10.1	<a href="#"><u>Form of Securities Purchase Agreement, dated as of August 2, 2024, by and among the Company and the investor listed on the signature page 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 August 5, 2024)</u></a>
10.2	<a href="#"><u>Form of Warrant Inducement Agreement (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 August 5, 2024)</u></a>
10.3	<a href="#"><u>Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)</u></a>
10.4†	<a href="#"><u>Consulting Agreement, dated August 21, 2024, by and between bioAffinity Technologies, Inc. and Michael Edwards (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 August 23, 2024)</u></a>
10.5†	<a href="#"><u>Employment Agreement between bioAffinity Technologies, Inc. and Michael Edwards, dated as of October 9, 2024 (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 October 10, 2024)</u></a>
10.6	<a href="#"><u>Form of Securities Purchase Agreement, dated as of October 18, 2024, by and between the Company and the purchasers listed on the signature pages 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 October 21, 2024)</u></a>
10.7	<a href="#"><u>Form of Support Agreement (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 October 21, 2024)</u></a>
31.1*	<a href="#"><u>Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u></a>
31.2*	<a href="#"><u>Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u></a>
32.1*	<a href="#"><u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002</u></a>
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 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 September 30, 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: November 14, 2024

By: /s/ J. Michael Edwards

J. Michael Edwards

Vice President and Chief Financial Officer

Date: November 14, 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 September 30, 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: November 14, 2024

/s/ Maria Zannes

Maria Zannes  
President and Chief Executive Officer  
(Principal Executive Officer)

**Certification of the Chief Financial Officer**  
**Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,**  
**as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**  
**For the Quarterly Period Ended September 30, 2024**

I, J. Michael Edwards, 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: November 14, 2024

*/s/ J. Michael Edwards*

J. Michael Edwards  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

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**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 September 30, 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 September 30, 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: November 14, 2024

*/s/ J. Michael Edwards*

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J. Michael Edwards  
Vice President and Chief Financial Officer  
(Principal Financial Officer)  
Date: November 14, 2024

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