

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2025

☐ **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)

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

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

Title of each class	Trading Symbol(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 May 13, 2025, was 27,249,462.

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 (“US”), 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, uncertainty regarding tariffs, 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, ir.bioaffinitytech.com, www.cypathlung.com and 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.

FORM 10-Q
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PART I
FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

bioAffinity Technologies, Inc.
Consolidated Balance Sheets

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 444,706	\$ 1,105,291
Accounts and other receivables, net	963,744	1,139,204
Inventory	38,782	27,608
Prepaid expenses and other current assets	416,550	422,995
Total current assets	1,863,782	2,695,098
Non-current assets:		
Property and equipment, net	382,409	375,385
Operating lease right-of-use asset, net	431,746	463,011
Finance lease right-of-use asset, net	684,629	780,872
Goodwill	1,404,486	1,404,486
Intangible assets, net	760,556	775,139
Other assets	19,675	19,676
Total assets	<u>\$ 5,547,283</u>	<u>\$ 6,513,667</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,381,578	\$ 987,311
Accrued expenses	1,370,735	1,398,722
Unearned revenue	24,404	24,404
Operating lease liability, current portion	130,342	127,498
Finance lease liability, current portion	403,584	395,301
Notes payable, current portion	104,766	171,669
Total current liabilities	3,415,409	3,104,905
Non-current liabilities		
Operating lease liability, net of current portion	308,415	342,098
Finance lease liability, net of current portion	335,899	444,448
Notes payable, net of current portion	48,156	20,180
Total liabilities	4,107,879	3,911,631
Commitments and contingencies (See Note 11)		
Stockholders' equity:		
Preferred stock, no shares issued or outstanding at March 31, 2025, and December 31, 2024, respectively	—	—
Common stock, par value \$0.007 per share; 100,000,000 shares authorized; 18,255,825 and 15,576,674 shares issued and outstanding as of March 31, 2025, and December 31, 2024, respectively	124,777	106,593
Additional paid-in capital	57,619,354	56,139,753
Accumulated deficit	(56,304,727)	(53,644,310)
Total stockholders' equity	1,439,404	2,602,036
Total liabilities, and stockholders' equity	<u>\$ 5,547,283</u>	<u>\$ 6,513,667</u>

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

bioAffinity Technologies, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended March 31,	
	2025	2024
Net Revenue	\$ 1,853,597	\$ 2,406,391
Operating expenses:		
Direct costs and expenses	1,367,860	1,573,441
Research and development	367,386	393,639
Clinical development	138,353	48,960
Selling, general and administrative	2,452,549	2,185,944
Depreciation and amortization	154,588	149,637
Total operating expenses	4,480,736	4,351,621
Loss from operations	(2,627,139)	(1,945,230)
Other income (expense):		
Interest income	542	6,127
Interest expense	(15,485)	(23,550)
Other income	2	4,510
Other expense	(9,642)	—
Total other expense	(24,583)	(12,913)
Net loss before provision for income taxes	(2,651,722)	(1,958,143)
Income tax expense	(8,695)	(3,672)
Net loss	\$ (2,660,417)	\$ (1,961,815)
Net loss per common share, basic and diluted	\$ (0.16)	\$ (0.20)
Weighted average common shares outstanding, basic and diluted	16,257,456	9,915,426

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

bioAffinity Technologies, Inc.
Unaudited Consolidated Statements of Changes in Stockholders' Equity

	For the Three Months Ended March 31, 2025						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at December 31, 2024	—	\$ —	15,227,619	\$ 106,593	\$ 56,139,753	\$ (53,644,310)	\$ 2,602,036
Stock-based compensation expense	—	—	159,259	1,115	325,501	—	326,616
Exercise of stock warrants	—	—	2,438,473	17,069	1,501,398	—	1,518,467
Offering costs	—	—	—	—	(347,298)	—	(347,298)
Net loss	—	—	—	—	—	(2,660,417)	(2,660,417)
Balance at March 31, 2025 (unaudited)	—	\$ —	17,825,351	\$ 124,777	\$ 57,619,354	\$ (56,304,727)	\$ 1,439,404
	For the Three Months Ended March 31, 2024						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at December 31, 2023	—	\$ —	9,394,610	\$ 65,762	\$ 49,393,972	\$ (44,604,479)	\$ 4,855,255
Stock-based compensation expense	—	—	157,033	1,099	282,613	—	283,712
Exercise of stock options	—	—	68,848	454	74,445	—	74,899
Sale of common stock	—	—	1,600,000	11,200	2,488,800	—	2,500,000
Offering costs	—	—	—	—	(495,000)	—	(495,000)
Net loss	—	—	—	—	—	(1,961,815)	(1,961,815)
Balance at March 31, 2024 (unaudited)	—	\$ —	11,220,551	\$ 78,515	\$ 51,744,830	\$ (46,566,294)	\$ 5,257,051

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

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (2,660,417)	\$ (1,961,815)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	154,588	149,637
Stock-based compensation expense	326,616	283,712
Changes in operating assets and liabilities:		
Accounts and other receivables	175,460	(311,935)
Inventory	(11,174)	8,997
Prepaid expenses and other assets	6,446	(23,883)
Accounts payable	394,267	(220,796)
Accrued expenses	(27,987)	(266,492)
Unearned revenue	—	(2,884)
Operating lease right-of-use asset	426	(516)
Net cash used in operating activities	(1,641,775)	(2,345,975)
Cash flows from investing activities		
Purchase of property and equipment	(50,786)	(41,387)
Net cash used in investing activities	(50,786)	(41,387)
Cash flows from financing activities		
Proceeds from issuance of Common Stock from direct offering, net of underwriting discounts, commissions, and offering expenses of \$495,000 in 2024	—	2,005,000
Proceeds from exercised stock options	—	74,899
Proceeds from exercise of warrants, net of underwriting discounts, commissions, and offering expenses of \$243,145	1,171,169	—
Payment on loans payable	(38,927)	—
Proceeds from loans payable	—	27,723
Principal repayments on finance leases	(100,266)	(88,665)
Net cash provided by financing activities	1,031,976	2,018,957
Net decrease in cash and cash equivalents	(660,585)	(368,405)
Cash and cash equivalents at beginning of period	1,105,291	2,821,570
Cash and cash equivalents at end of period	\$ 444,706	\$ 2,453,165
Supplemental disclosures of cash flow information:		
Interest expense paid in cash	\$ 542	\$ 23,550
Income taxes paid in cash	8,695	3,672

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 lung cancer at early stage and other diseases of the lung. bioAffinity Technologies’ proprietary platform uses flow cytometry and automated data analysis built by machine learning, a form of artificial intelligence (“AI”), to preferentially target cancer cell populations and other cell populations indicative of a diseased state. 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”). The Company also conducted and intends to seek strategic partners to advance therapeutic discoveries that could in the future result in broad-spectrum cancer treatments. Research and optimization of the Company’s proprietary platform technologies are conducted in laboratories at PPLS and laboratory space leased at The University of Texas at San Antonio.

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, PPLS, as a Texas limited liability company, to acquire the assets of Village Oaks Pathology Services, P.A. (“Village Oaks”), a Texas professional association d/b/a Precision Pathology Services, 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, 2024, 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, 2025, 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, 2024, filed with the SEC on March 31, 2025 (the “2024 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 \$56.3 million at March 31, 2025. The Company’s cash and cash equivalents at March 31, 2025, were approximately \$0.4 million. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at March 31, 2025, management concludes that there is substantial doubt about the Company’s ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying unaudited condensed consolidated financial statements. On May 7, 2025, the Company completed a public offering of its common stock pursuant to which the Company raised an additional \$3.25 million in cash in gross proceeds, see *Note 15. Subsequent Events*. However, the Company 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 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 financial statements in conformity with GAAP in the U.S. 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.

Principles of Consolidation

The Company’s 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 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.

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 \$28,206 and \$11,920 for the three months ended March 31, 2025 and 2024, 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 March 31, 2025 and 2024, respectively, as they would be anti-dilutive:

	As of March 31,	
	2025	2024
Shares underlying options outstanding	304,125	618,847
Shares underlying warrants outstanding	12,873,602	8,838,717
Shares underlying unvested restricted stock	430,474	297,862
	<u>13,608,201</u>	<u>9,755,426</u>

Revenue Recognition

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

Post-acquisition of PPLS, 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. 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.

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. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation.

	For the Three Months Ended March 31,	
	2025	2024
Patient service fees ¹	\$ 1,570,382	\$ 2,149,049
Histology service fees	263,754	237,972
Medical director fees	16,588	16,058
Department of Defense observational studies	—	2,885
Other revenues	2,873	427
Total net revenue	<u>\$ 1,853,597</u>	<u>\$ 2,406,391</u>

¹ Patient services fees include direct billing for CyPath[®] Lung diagnostic test of approximately \$169,000 and \$45,000 for the three months ended March 31, 2025 and 2024, respectively.

Property and Equipment

In accordance with ASC 360-10, *Accounting for the Impairment of Long-Lived Assets*, the Company periodically reviews the carrying value of its long-lived assets, such as property, equipment, and definite-lived intangible assets, to test whether current events or circumstances indicate that such carrying value may not be recoverable. When evaluating assets for potential impairment, the Company compares the carrying value of the asset to its estimated undiscounted future cash flows. If an asset's carrying value exceeds such estimated cash flows (undiscounted and with interest charges), the Company records an impairment charge for the difference. The Company did not record any impairment for the three months ended March 31, 2025, or for the fiscal year ended December 31, 2024.

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

The Company's acquisition of PPLS on September 18, 2023, identified goodwill and intangible assets. Goodwill represents the purchase price in excess of fair values assigned to the underlying identifiable net assets of the acquired business. The Company tests goodwill for impairment annually, therefore, does not record amortization. The intangible assets and their respective useful lives are as follows: trade names and trademarks (18 years) and customer relationships (14 years). Intangible assets, net of accumulated amortization, are summarized as follows as of March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Cost		
Goodwill	\$ 1,404,486	\$ 1,404,486
Trade names and trademarks	150,000	150,000
Customer relationships	700,000	700,000
	<u>2,254,486</u>	<u>2,254,486</u>
Accumulated amortization		
Trade names and trademarks	(12,777)	(10,694)
Customer relationships	(76,667)	(64,167)
	<u>(89,444)</u>	<u>(74,861)</u>
Intangible assets, net	<u>\$ 2,165,042</u>	<u>\$ 2,179,625</u>

The Company incurred amortization of intangible assets of \$14,583 for each of the three months ended March 31, 2025 and 2024.

Recent Accounting Pronouncements

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

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[®] Lung from bioAffinity Technologies.

	As of March 31,	
	2025	2024
Net revenues:		
Diagnostic R&D	\$ —	\$ 2,885
Laboratory services	1,853,597	2,403,506
Total net revenues	<u>1,853,597</u>	<u>2,406,391</u>
Operating expenses:		
Diagnostic R&D	(505,739)	(442,599)
Laboratory services	(2,267,656)	(2,736,999)
General corporate activities	(1,707,341)	(1,172,023)
Total operating loss	<u>(2,627,139)</u>	<u>(1,945,230)</u>
Non-operating income (expense), net	(24,583)	(12,913)
Net loss before income taxes	<u>(2,651,722)</u>	<u>(1,958,143)</u>
Income tax expense	(8,695)	(3,672)
Net loss	<u>\$ (2,660,417)</u>	<u>\$ (1,961,815)</u>

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 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[®] 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:

	March 31, 2025	December 31, 2024
Patient service fees	\$ 744,859	\$ 915,488
Histology service fees	189,904	190,648
Medical director fees	11,600	5,194
Other receivables	17,381	27,874
Total accounts and other receivables, net	<u>\$ 963,744</u>	<u>\$ 1,139,204</u>

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

	March 31, 2025	December 31, 2024
Prepaid insurance	\$ 160,756	\$ 248,364
Legal and professional	15,787	27,448
Other	240,007	147,183
Total prepaid expenses and other current assets	<u>\$ 416,550</u>	<u>\$ 422,995</u>

Note 5. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	March 31, 2025	December 31, 2024
Lab equipment	\$ 679,995	\$ 662,747
Computers and software	81,433	81,433
Leasehold improvements	19,353	19,353
Vehicles	181,640	148,103
	962,421	911,636
Less: accumulated depreciation and amortization	(580,012)	(536,251)
Total property and equipment, net	\$ 382,409	\$ 375,385

Depreciation expense was \$43,763 and \$38,811 for the three months ended March 31, 2025 and 2024, respectively.

Note 6. ACCRUED EXPENSES

Accrued expenses are summarized below:

	March 31, 2025	December 31, 2024
Compensation	\$ 932,208	\$ 1,079,839
Legal and professional	107,064	98,477
Clinical	287,258	160,371
Other	44,205	60,035
Total accrued expenses	\$ 1,370,735	\$ 1,398,722

Note 7. UNEARNED REVENUE

The Company engaged in an observational study of CyPath[®] Lung with the U.S. Department of Defense (“DOD”). A total of 70 CyPath[®] Lung units were ordered and shipped. However, in compliance with FASB ASC 606, the performance obligation was complete for only 40 units as of March 31, 2025. The performance obligation is deemed complete after samples have been collected, processed, and analyzed and results communicated to patients. The unearned revenue balance amounted to \$24,404 as of March 31, 2025, and December 31, 2024.

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 three levels of the hierarchy and the related inputs are as follows:

Level	Inputs
1	Unadjusted quoted prices in active markets for identical assets and liabilities; Unadjusted quoted prices in active markets for similar assets and liabilities.
2	Unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active; or inputs other than quoted prices that are observable for the asset or liability.
3	Unobservable inputs for the asset or liability.

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 note 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 2.3 to 5.4 years as of March 31, 2025. The Company has finance leases consisting of office and lab equipment with remaining lease terms ranging from approximately 1.1 to 2.8 years as of March 31, 2025, 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 sheets. There are no material residual guarantees associated with any of the Company’s leases, and there are no significant restrictions or covenants included in the Company’s lease agreements. Certain leases include variable payments related to common area maintenance and property taxes, which are billed by the landlord, as is customary with these types of charges for office space. The Company has not entered into any lease arrangements with related parties, and the Company is not the sublessor in any arrangement.

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

The components of lease expense, which are included in selling, general and administrative expense and depreciation and amortization for the three months ended March 31, 2025 and 2024, are as follows:

Components of lease expense:	2025	2024
Amortization of right-of-use assets - finance lease	\$ 96,243	\$ 96,243
Interest on lease liabilities - finance lease	13,081	23,550
Operating lease cost	29,793	29,915
Total lease cost	<u>\$ 139,117</u>	<u>\$ 149,708</u>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	\$ 100,266	\$ 88,665
Operating cash flows from operating leases	29,197	30,431
Operating leases:	March 31, 2025	December 31, 2024
Operating lease right-of-use, assets	\$ 431,746	\$ 463,011
Operating lease liability, current	\$ 130,342	\$ 127,498
Operating lease liability, non-current	\$ 308,415	\$ 342,098
Total operating lease liabilities	<u>\$ 438,757</u>	<u>\$ 469,596</u>
Finance leases:	March 31, 2025	December 31, 2024
Finance lease right-of-use asset, gross	\$ 1,294,168	\$ 1,294,168
Accumulated amortization	(609,539)	(513,296)
Finance lease right-of-use asset, net	<u>\$ 684,629</u>	<u>\$ 780,872</u>
Finance lease liability, current portion	\$ 403,584	\$ 395,301
Finance lease liability, long-term	335,899	444,448
Total finance lease liabilities	<u>\$ 739,483</u>	<u>\$ 839,749</u>
Weighted-average remaining lease term:	March 31, 2025	December 31, 2024
Operating leases (in years)	3.60	4.21
Finance leases (in years)	2.28	2.39
Weighted-average discount rate:	March 31, 2025	December 31, 2024
Operating leases	7.38%	7.41%
Finance leases	8.04%	8.03%

Future minimum lease payments under non-cancellable lease as of March 31, 2025, are as follows:

	Operating Leases	Finance Leases
Remaining for 2025	\$ 118,497	\$ 336,379
2026	159,282	270,395
2027	110,063	202,970
2028	40,616	—
2029	42,252	—
2030 and thereafter	28,919	—
Total undiscounted cash flows	499,629	809,744
Less discounting	(60,872)	(70,261)
Present value of lease liabilities	<u>\$ 438,757</u>	<u>\$ 739,483</u>

Note 10. NOTES PAYABLE***Vehicles Notes Payable***

On January 10, 2025, the Company entered into a second Finance Agreement to purchase a 2024 Toyota Corolla for \$33,517 with a maturity date of January 18, 2031. The loan bears fixed interest at a rate of 11.65% per annum, with monthly payments of \$651, which is comprised of principal and interest. This loan is collateralized by the underlying vehicle. The balance of this loan as of March 31, 2025, was \$32,882. The current portion of the balance of this loan as of March 31, 2025 was \$4,247.

On March 18, 2024, the Company entered into a Finance Agreement to purchase a 2024 Toyota Corolla for \$33,620 with a maturity date of February 18, 2030. The loan bears fixed interest at a rate of 5.99% per annum, with monthly payments of \$467, which is comprised of principal and interest. This loan is collateralized by the underlying vehicle. The balance of this loan as of March 31, 2025, and December 31, 2024, was \$23,815 and \$24,849, respectively. The current portion of the balance of this loan as of March 31, 2025, and December 31, 2024, was \$4,294 and \$5,603, respectively.

Directors and Officers Insurance Policy – 2024

In September 2024, the Company obtained short-term financing of approximately \$260,000 with 11 monthly payments of approximately \$24,000 and interest at a 6.7% fixed annual rate for director and officer insurance policies. The current portion of the balance of this loan as of March 31, 2025, and December 31, 2024, was \$96,225 and \$167,000, 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 18,255,825 shares of Common Stock, of which 430,474 are unvested restricted stock awards as of March 31, 2025, and 15,576,674 shares of Common Stock, of which 349,057 are unvested restricted stock awards as of December 31, 2024.

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 March 31,	
	2025	2024
Research and development	\$ 21,250	\$ 21,882
General and administrative	305,366	260,731
Total stock-based compensation expense	<u>\$ 326,616</u>	<u>\$ 282,613</u>

The following table summarizes stock option activity under the 2014 Plan and 2024 Plan:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2024	304,125	\$ 6.95	4.45	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding at March 31, 2025	<u>304,125</u>	<u>\$ 6.95</u>	<u>4.20</u>	<u>—</u>
Vested and exercisable at March 31, 2025	<u>304,125</u>	<u>\$ 6.95</u>	<u>4.20</u>	<u>—</u>

As of March 31, 2025, there was no unrecognized compensation cost related to non-vested stock options.

The following table summarizes restricted stock award activity under the 2014 Plan and 2024 Plan:

	Number of restricted stock awards (RSA)	Weighted- average grant price	FMV on grant date	As of March 31, 2025	
				Vested number of RSA	Unvested number of RSA
Balance at December 31, 2024	1,326,861	\$ 1.99	\$ 2,636,259	1,072,838	254,023
Granted	253,398	0.84	212,875	66,658	186,740
Forfeited	(10,289)	0.81	(8,334)	—	(10,289)
Balance at March 31, 2025	1,569,970	\$ 2.24	\$ 2,840,800	1,139,496	430,474

During the three months ended March 31, 2025, the Company issued restricted stock awards (“RSAs”) for an aggregate of 243,109 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 March 31, 2025, 92,601 shares vested from RSAs granted prior to January 1, 2025, and 66,658 shares vested from RSAs granted during the three months ended March 31, 2025.

Note 14. WARRANTS

The Company’s outstanding Common Stock warrants are equity classified. As of March 31, 2025, and December 31, 2024, the Company had 12,873,602 and 12,298,124 warrants outstanding to purchase one share of the Company’s Common Stock for each warrant at a weighted average exercise price of \$2.74 and expire at various dates through February 2030. During the three months ended March 31, 2025, a total number of 2,438,473 warrants were exercised into an equivalent number of shares of Common Stock as compared to no warrants being exercised during the three months ended March 31, 2024. The proceeds of the exercised warrants for the three months ended March 31, 2025, was \$1,414,314, compared to no proceeds during the three months ended March 31, 2024.

On February 25, 2025, the Company entered into a warrant inducement agreement (the “February Inducement Agreement”) with certain holders (the “Holders”) of the Company’s warrants to purchase shares of the Company’s common stock, issued in a private placement offering that closed on October 21, 2024 (the “October Warrants”), and a private placement offering that closed on August 5, 2024 (the “August Warrants” and, together with the October Warrants, collectively, the “Existing Warrants”). Pursuant to the February Inducement Agreement, the Holders of the Existing Warrants agreed to exercise for cash (i) October Warrants to purchase an aggregate of up to 1,136,391 shares of Common Stock (the “October Warrant Shares”), at the reduced exercise price of \$0.58 per share and August Warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock (the “August Warrant Shares” and, together with the October Warrant Shares, the “Existing Warrant Shares”), at the reduced exercise price of \$0.58 per share. The transactions contemplated by the Inducement Agreement (the “Warrant Inducement”) were consummated on February 26, 2025.

In consideration of the Holders’ immediate exercise of the Existing Warrants in accordance with the February Inducement Agreement, the Company issued unregistered Common Stock Purchase Warrants (the “New Warrants”) to purchase an aggregate of up to 2,926,166 shares of Common Stock (the “New Warrant Shares”) to the Holders of the Existing Warrants, with an exercise price of \$0.85.

In addition, designees of the placement agent for the Offering were granted warrants to purchase an aggregate of up to 87,785 shares of Common Stock, with an exercise price of \$0.85.

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	\$ 0.85
Fair market closing price per share of Common Stock	\$ 0.58
Volatility	83%
Expected term (years)	5
Risk-free interest rate	4.12%
Dividend yield	0%

The fair value of the New Warrants using the assumptions above was \$601,752 for the warrants, \$104,153 for the change in fair value related to the change in exercise price, and \$31,422 for the placement agent warrants. The fair value of the above warrants was recorded in Additional paid-in capital.

As of March 31, 2025, 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	(725,580)	1,601,255
IPO non-tradeable	3,015,464	3.06	(311,006)	2,704,458
Direct offering March 8, 2024	1,600,000	1.64	(1,066,667)	533,333
Placement agent direct offering March 8, 2024	32,000	1.64	—	32,000
Inducement/direct offering August 5, 2024	1,752,082	1.50	(1,302,082)	450,000
Placement agent direct offering August 5, 2024	49,862	1.50	—	49,862
Direct offering October 21, 2024	2,662,782	1.50	(1,136,391)	1,526,391
Placement agent direct offering October 21, 2024	61,448	1.50	—	61,448
Warrant inducement February 25, 2025	2,926,166	0.85	—	2,926,166
Placement agent warrant inducement February 25, 2025	87,785	0.85	—	87,785
Balance at March 31, 2025	17,415,328	\$ 2.74	(4,541,726)	12,873,602

Note 15. SUBSEQUENT EVENTS

On May 7, 2025, the Company completed a public offering of securities for gross proceeds to the Company of \$3.25 million, before deducting placement agent fees and other estimated expenses payable by the company. The offering consisted of 10,156,250 shares of our Common Stock, of which 2,371,346 were pre-funded warrants, together with warrants to initially purchase up to 15,234,375 shares of Common Stock, at a combined offering price for each share of common stock (or pre-funded warrant) and accompanying warrant of \$0.32 per share. The warrants have an exercise price of \$0.352 per share and certain provisions that allow for additional shares to be issued in the event of a reverse split of the Company's common stock. Additionally, the warrants include an anti-dilution adjustment which is subject to stockholders approval. In connection with this offering, the Company issued 304,687 warrants with substantially the same terms as the warrants issued as part of the public offering, except they will not have an anti-dilution adjustment.

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, 2024, included in the 2024 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 2024 Form 10-K.

Data as of and for the three months ended March 31, 2025 and 2024, 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 three months ended March 31, 2025, to the comparable period in 2024.
- *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

We develop noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung using flow cytometry and automated analysis developed by machine learning, a form of AI. One of our diagnostic tests analyzes cell populations, including cancer and cancer-related cells, that are indicative of a specific diseased state.

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

Commercial laboratory services, including CyPath[®] Lung, are performed at our wholly owned subsidiary PPLS which we acquired by purchasing the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services, that included the CAP-accredited and CLIA-certified commercial laboratory it owned. We now own and operate the clinical anatomic and clinical pathology laboratory. CyPath[®] Lung is offered for sale to physicians by PPLS.

Through our wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC, we have conducted research that has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells. We expect to present our findings at conferences and publish our research in the near future. We intend to seek strategic partners to develop our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future.

Research and optimization of our platform technologies are conducted in laboratories at our wholly owned subsidiary PPLS and leased laboratory space at The University of Texas at San Antonio.

Current Year Financial Highlights

Key financial results for the three months quarter ended March 31, 2025, include:

- Consolidated revenue decreased approximately 23% to \$1.9 million as compared to \$2.4 million for the three months ended March 31, 2024, primarily as a result of the Company's targeted strategic actions to discontinue certain unprofitable pathology services, reduce costs through operational efficiency and drive sales growth for CyPath[®] Lung.
- CyPath[®] Lung testing revenue increased approximately 275% to \$169,000 as compared to \$45,000 for the three months ended March 31, 2024, due to an increase in total test results delivered of approximately 200 for the current quarter.
- The Company raised approximately \$1.4 million in gross proceeds from equity transactions to fund operating activities.

Recent Developments

On May 8, 2025, the Company released “CyPath[®] Lung In Practice” authored by Gordon Downie, MD, PhD, Director of the Titus Regional Hospital Lung Nodule Clinic and Interventional Pulmonology, in which he presented his experience and approach to using CyPath[®] Lung in medical practice, including four case studies in which CyPath[®] Lung proved clinically determinative. Dr. Downie opined that “adding CyPath[®] Lung to our algorithm has accelerated diagnosis, helped guide difficult clinical discussions, and prevented unnecessary invasive procedures.”

On May 7, 2025, the Company completed a public offering of securities for gross proceeds to the Company of \$3.25 million, before deducting agent fees and other estimated expenses payable by the company. The offering consisted of 10,156,250 shares of our Common Stock, of which 2,371,346 were pre-funded warrants, together with warrants to purchase up to 15,234,375 shares of Common Stock, at a combined offering price for each share of common stock (or pre-funded warrant) and accompanying warrant of \$0.32 per share. The warrants have an exercise price of \$0.352 per share and have certain provisions that allow for additional shares to be issued in the event of a reverse split of the Company’s common stock. Additionally, the warrants include an anti-dilution adjustment which is subject to stockholders approval.

On April 1, 2025, the Company increased the list price of CyPath[®] Lung to \$2,900 from \$1,900 after evaluating reimbursement provisions in agreements executed with private insurance carriers to take best advantage of payment terms.

On March 7, 2025, we announced targeted strategic actions to improve financial performance and accelerate the commercial growth of CyPath[®] Lung, taking steps to deliver up to \$3 to \$4 million in annual cost savings at its subsidiary Precision Pathology Laboratory Services (PPLS), while increasing resources to expand CyPath[®] Lung sales in high-potential national markets. Specifically, cost savings are a result of labor cost reductions, operational efficiency enhancements, and discontinuing certain unprofitable pathology services to focus on high-margin services such as CyPath[®] Lung.

On February 26, 2025, we entered into a warrant inducement agreement with certain holders of existing warrants, such holders exercised for cash a total of 2,438,473 warrants originally issued in August 2024 and October 2024, at the reduced exercise price of \$0.58 per share, for aggregate gross proceeds of approximately \$1.4 million, before deducting advisory fees and other expenses payable by it. In consideration of the immediate exercise of the October Warrants and August Warrants, the Company issued unregistered common warrants to purchase an aggregate of up to 2,926,166 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the warrants) at an exercise price of \$0.85 per share, which warrants are not exercisable until our stockholders approve such exercise.

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 and public sales of our equity (“IPO”). As of March 31, 2025, we had cash and cash equivalents of \$0.4 million. As of May 13, 2025, after the 2025 equity financing, we had cash and cash equivalents of \$2.3 million, which we expect will not support our operations through August 2025. We have incurred significant losses and negative cash flows from operations since inception and expect to continue to incur losses and negative cash flows for the foreseeable future. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at March 31, 2025, 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.

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 the Company and Village Oaks. In the second quarter of 2022, prior to the acquisition, we started to recognize revenue as part of a limited beta market testing program of the CyPath[®] Lung test. We have never been profitable, and as of March 31, 2025, we had a working capital deficit of approximately \$1.6 million and an accumulated deficit of approximately \$56.3 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and advance our diagnostic tests through clinical trials.

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

Results of Operations

Three Months Ended March 31, 2025, Compared to Three Months Ended March 31, 2024

Net loss for the three months ended March 31, 2025, was approximately \$2.7 million, compared to a net loss of approximately \$2.0 million for the three months ended March 31, 2024.

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. 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.

	For the Three Months Ended March 31,	
	2025	2024
Patient service fees ¹	\$ 1,570,382	\$ 2,149,049
Histology service fees	263,754	237,972
Medical director fees	16,588	16,058
Department of Defense observational studies	—	2,885
Other revenues	2,873	427
Total net revenue	<u>\$ 1,853,597</u>	<u>\$ 2,406,391</u>

¹ Patient services fees include direct billing for CyPath[®] Lung diagnostic test of approximately \$169,000 and \$45,000 for the three months ended March 31, 2025 and 2024, respectively.

Net revenue totaled approximately \$1.9 million and \$2.4 million for the three months ended March 31, 2025 and 2024, respectively. The decrease is attributable to discontinuing certain unprofitable pathology services to focus on high-margin services such as our diagnostic test, CyPath[®] Lung.

Operating Expenses

	Three Months Ended March 31,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Operating expenses:				
Direct costs and expenses	\$ 1,367,860	\$ 1,573,441	\$ (205,581)	(13)%
Research and development	367,386	393,639	(26,253)	(7)%
Clinical development	138,353	48,960	89,393	183%
Selling, general and administrative	2,452,549	2,185,944	266,605	12%
Depreciation and amortization	154,588	149,637	4,951	3%
Total operating expenses	<u>\$ 4,480,736</u>	<u>\$ 4,351,621</u>	<u>\$ 129,115</u>	<u>3%</u>

Operating expenses totaled approximately \$4.5 million and \$4.4 million for the three months ended March 31, 2025 and 2024, 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 \$1.6 million during the three months ended March 31, 2025 and 2024, respectively. The decrease of approximately \$206,000, or 13%, for 2025 compared to 2024 was primarily attributable to the targeted strategic actions which occurred in March 2025, aimed at streamlining operations and reducing costs related to our lab operations.

Research and Development Expenses

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

Research and development expenses totaled approximately \$367,000 and \$394,000 for the three months ended March 31, 2025 and 2024, respectively. The decrease of \$26,000, or 7%, for the three months ended March 31, 2025, compared to the same period in 2024 was primarily attributable to a decrease in compensation costs and benefits and lab supplies.

Clinical Development

Clinical development expenses totaled approximately \$138,000 and \$49,000 for the three months ended March 31, 2025 and 2024, respectively. The increase of \$89,000, or 183%, for the three months ended March 31, 2025, compared to the same period in 2024 was primarily attributable to an increase in professional fees in 2025 related to managing our clinical strategy for our pivotal clinical trial.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately \$2.4 million and \$2.2 million for the three months ended March 31, 2025 and 2024, respectively. The increase of approximately 267,000, or 12%, for the three months ended March 31, 2025, compared to the same period in 2024 was primarily attributable an increase in employee compensation related to administrative and sales due to additional personnel and support services to support the growth of sales of our diagnostic test, CyPath[®] Lung.

Depreciation and Amortization

Depreciation and amortization expenses totaled \$154,588 and \$149,637 for the three months ended March 31, 2025 and 2024, respectively. The depreciation and amortization remained relatively consistent compared to the prior year period as the assets have remained consistent.

Other Income (Expense)

	Three Months Ended March 31,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Interest (expense) income, net	\$ (14,493)	\$ (17,423)	\$ 2,480	(14)%
Other income (expense), net	(9,640)	4,510	(14,150)	(314)%
Total other (expense) income	<u>\$ (24,583)</u>	<u>\$ (12,913)</u>	<u>\$ (11,670)</u>	90%

Interest income (expense)

Interest expense of approximately \$14,000 and \$17,000 for the three months ended March 31, 2025 and 2024, respectively, increased in the current year due to the interest recognized related to the financing lease for laboratory equipment compared to the same period in the prior year, partially offset by a decrease in interest income earned on cash balances.

Other income (expense)

Other income (expense), net totaled (\$9,640) and \$4,510 for the three months ended March 31, 2025 and 2024, respectively. The decrease in the other income (expense) of \$14,150 is primarily attributable to property taxes.

Liquidity, Capital Resources, and Going Concern

To date, we have funded our operations primarily through our IPO, exercise of stock options and warrants, and the sale of our securities, resulting in gross proceeds of approximately \$46.0 million. We have evaluated whether there are conditions and events that raise substantial doubt about our ability to continue as a going concern for at least one year after the date the condensed consolidated financial statements are issued.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic test or therapeutic products to generate revenue. For the three months ended March 31, 2025 and 2024, we had net losses of \$2.7 million and \$2.0 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$56.3 million as of March 31, 2025. Despite our recent financing in May 2025 in which we raised gross proceeds of \$3.25 million, and our financing in February 2025, in which we raised gross proceeds of approximately \$1.4 million, we believe our current cash and anticipated revenue from operations will be sufficient to support our operations through August 2025. Based on our current expected level of operating expenditures, current expected levels of revenue, and the cash and cash equivalents on hand at March 31, 2025, of \$0.4 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:

		Three Months Ended March 31,	
		2025	2024
Cash and cash equivalents at beginning of period	\$	1,105,291	\$ 2,821,570
Net cash used in operating activities		(1,641,775)	(2,345,975)
Net cash used in investing activities		(50,786)	(41,387)
Net cash provided by financing activities		1,031,976	2,018,957
Cash and cash equivalents at end of period	\$	444,706	\$ 2,453,165

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$1.6 million and \$2.3 million for the three months ended March 31, 2025 and 2024, respectively. The decrease of approximately \$0.7 million in cash used by operations during the three months ended March 31, 2025, compared to the same period in 2024 was primarily attributable to an increase of approximately \$660,000 in our loss from operations, a decrease in patient accounts receivables of approximately \$487,000, offset by an increase in accounts payable and accrued expenses of approximately \$863,000.

Net Cash Used in Investing Activities

We used approximately \$51,000 for the three months ended March 31, 2025, in investing activities related primarily to the purchase of computer and laboratory equipment, compared to \$41,000 used in investing activities for the three months ended March 31, 2024.

Net Cash Provided by Financing Activities

Cash provided by financing activities was approximately \$1.0 million compared to cash provided by financing activities of approximately \$2.0 million for the three months ended March 31, 2025 and 2024, respectively. The change is primarily attributable to the net proceeds from our financing in February 2025, in which we raised gross proceeds of approximately \$1.4 million, compared to our March 2024 financing, in which we raised gross proceeds of \$2.5 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. 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. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation.

Patient Fee Receivables and Considerations for Credit Losses

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

Discount Rate for Finance Leased Equipment

We follow ASC 842, *Leases*. In February 2016, the FASB issued Topic ASC 842, under which a lessee is required to recognize most leases on its balance sheet. We have elected to apply a third-party valuation incremental 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 March 31, 2025, the end of the period covered by this Quarterly Report, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our “disclosure controls and procedures,” as defined in Rule 13a-15(e) under the Exchange Act. The Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our disclosure controls and procedures as of March 31, 2025. Based on their assessment, they have concluded that as of March 31, 2025, our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) over financial reporting during the three months ended March 31, 2025, 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 2024 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 2024 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2024 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.

Prior to 2022, we had not generated any revenue. During the three months ended March 31, 2025, we generated revenue of approximately \$1.9 million, and \$9.4 million during the year ended December 31, 2024.

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[®] 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[®] Lung as a Class II in vitro diagnostic;
- Work with our partners to develop and commercialize our first diagnostic test, CyPath[®] Lung, as a CE-marked test in accordance with the In Vitro Diagnostic Regulation (“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 our value 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 our value could also cause you to lose all or part of your investment.

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

As of March 31, 2025, we had an accumulated deficit of \$56.3 million and \$0.4 million cash on hand. As of May 13, 2025, our cash and cash equivalents were \$2.3 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 August 2025. Based on our current expected level of operating expenditures, current expected levels of revenue, and the cash and cash equivalents on hand at March 31, 2025, of \$0.4 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. 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, 2024, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2024, 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 \$13.7 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.

Risks Related to Ownership of Our Common Stock and Warrants

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.

The shares of our Common Stock are listed for trading on The Nasdaq Capital Market under the symbol “BIAF” and our Tradeable Warrants are listed under the symbol “BIAFW.” On February 7, 2025, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”) notifying us that for the preceding 30 consecutive business days (December 23, 2024, through February 6, 2025), our Common Stock did not maintain a minimum closing bid price of \$1.00 (“Minimum Bid Price Requirement”) per share as required by Nasdaq Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of our Common Stock, and the Common Stock will continue to trade on The Nasdaq Capital Market under the symbol “BIAF.” In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days, or until August 6, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance may be achieved without further action if the closing bid price of our Common Stock is at or above \$1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case Nasdaq will notify us if it determines we are in compliance and the matter will be closed; however, Nasdaq may require the closing bid price to equal or to exceed the \$1.00 minimum bid price requirement for more than 10 consecutive business days before determining that a company complies.

If, however, we do not achieve compliance with the Minimum Bid Price Requirement by August 6, 2025, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. We intend to actively monitor the bid price of our Common Stock and will consider available options to regain compliance with the Nasdaq listing requirements.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, the stockholder’s equity requirement, or the minimum closing bid price requirement, The Nasdaq Capital Market may take steps to de-list our Common Stock or Tradeable Warrants. As reported in this Quarterly Report on Form 10-Q, our stockholders’ equity of approximately \$1.4 million is below the Nasdaq required stockholders’ equity of \$2.5 million. As a result, we will be unable to request an additional 180 day period within which to comply with the Minimum Bid Price Requirement. Such a de-listing or even notification of failure to comply with such requirements would likely have a negative effect on the price of our Common Stock and Tradeable Warrants and would impair the ability to sell or purchase our Common Stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with The Nasdaq Capital Market’s listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price, improve the liquidity of our Common Stock, prevent our Common Stock from dropping below The Nasdaq Capital Market minimum bid price requirement, or prevent future non-compliance with The Nasdaq Capital Market’s listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Because our Common Stock is listed on The Nasdaq Capital Market, it is a covered security. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from The Nasdaq Capital Market, our Common Stock would cease to be recognized as a covered security and we would be subject to regulation in each state in which we offer our securities.

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 26% 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 March 31, 2025, in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

During the three months ended March 31, 2025, 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	<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>
3.2	<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>
3.3	<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>
3.4	<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>
3.5	<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>
3.6	<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>
3.7	<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>
3.8	<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>
3.9	<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>
4.1	<u>Form of New 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 February 27, 2025)</u>
4.2	<u>Form of Advisor 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 February 27, 2025)</u>
10.1	<u>Amendment No. 2 to Employment Agreement with Maria Zannes (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 14, 2025)</u>
10.2	<u>Form of Warrant Inducement Agreement (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 February 27, 2025)</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002</u>
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended 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 March 31, 2024, formatted in Inline XBRL
101.INS	Inline XBRL Instance Document *
101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *

* Filed herewith.

† Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOAFFINITY TECHNOLOGIES, INC.

(Registrant)

By: /s/ Maria Zannes

Maria Zannes

Chief Executive Officer, President, Founder, and Director

Date: May 15, 2025

By: /s/ J. Michael Edwards

J. Michael Edwards

Vice President and Chief Financial Officer

Date: May 15, 2025

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended March 31, 2025

I, Maria Zannes, certify that:

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

Date: May 15, 2025

/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 March 31, 2025

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: May 15, 2025

/s/ J. Michael Edwards

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

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

In connection with the Quarterly Report on Form 10-Q of bioAffinity Technologies, Inc., a Delaware Corporation (“Company”), for the period ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (“Report”), each of the undersigned officers of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer’s knowledge:

- 1) the Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of March 31, 2025 (the last date of the period covered by the Report).

/s/ Maria Zannes

Maria Zannes

President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

/s/ J. Michael Edwards

J. Michael Edwards

Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: May 15, 2025
