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

(Mark One)

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

For the quarterly period ended June 30, 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 Section 13(a) of the Exchange Act. ☐

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

The number of shares of the issuer's common stock outstanding as of August 13, 2025, was 28,468,612.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, and capital requirements;
- the success, cost, and timing of our clinical trials;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our diagnostic tests or therapeutic product candidates;
- our dependence on third parties, including the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our diagnostic tests or therapeutic product candidates;
- the potential that the results of our pre-clinical and clinical trials indicate our current diagnostic tests or any future diagnostic tests or therapeutic product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property (“IP”) protection for our current diagnostic test or future diagnostic tests and therapeutic product candidates;
- our ability to protect our IP rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our IP rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their IP rights and that we may incur substantial costs and be required to devote substantial time defending against such claims;
- the success of competing therapies, diagnostic tests, and therapeutic products that are or will become available;
- our ability to expand our organization to accommodate potential growth and to retain and attract key personnel;
- our potential to incur substantial costs resulting from product liability lawsuits against us and the potential for such lawsuits to cause us to limit the commercialization of our diagnostic tests and therapeutic product candidates;
- market acceptance of our diagnostic test and diagnostic tests in development and therapeutic product candidates, the size and growth of the potential markets for our current diagnostic test, diagnostic tests in development, and therapeutic product candidates, and any future diagnostic tests and therapeutic product candidates we may seek to develop, and our ability to serve those markets;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- compliance with government regulations, including environmental, health, and safety regulations, and liabilities thereunder;
- the impact of a health epidemic on our business, our clinical trials, our research programs, healthcare systems, or the global economy as a whole;
- general instability of economic and political conditions in the United States, including inflationary pressures, increased interest rates, economic slowdown or recession, and escalating geopolitical tensions;

- anticipated uses of net proceeds from our financings;
- the increased expenses associated with being a public company; and
- other factors discussed elsewhere in this Quarterly Report.

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

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

Website and Social Media Disclosure

We use our websites (www.bioaffinitytech.com, 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
TABLE OF CONTENTS

PART I	
FINANCIAL INFORMATION	
ITEM 1 -	5
Condensed Consolidated Financial Statements (unaudited)	
Condensed Consolidated Balance Sheets at June 30, 2025 (unaudited) and December 31, 2024	5
Unaudited Condensed Consolidated Statements of Operations for the Three and Six Months ended June 30, 2025 and 2024	6
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Three and Six Months ended June 30, 2025 and 2024	7
Unaudited Condensed Consolidated Statements of Cash Flows for the Six Months ended June 30, 2025 and 2024	8
Notes to Unaudited Condensed Consolidated Financial Statements	9
ITEM 2 -	20
Management's Discussion and Analysis of Financial Condition and Results of Operations	
ITEM 3 -	28
Quantitative and Qualitative Disclosures about Market Risk	
ITEM 4 -	28
Controls and Procedures	
PART II	
OTHER INFORMATION	
ITEM 1 -	29
Legal Proceedings	
ITEM 1A -	29
Risk Factors	
ITEM 2 -	31
Unregistered Sales of Equity Securities and Use of Proceeds	
ITEM 3 -	31
Defaults Upon Senior Securities	
ITEM 4 -	31
Mine Safety Disclosure	
ITEM 5 -	31
Other Information	
ITEM 6 -	32
Exhibits	
Signatures	33

PART I
FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 802,835	\$ 1,105,291
Accounts and other receivables, net	421,869	1,139,204
Inventory	43,971	27,608
Prepaid expenses and other current assets	400,151	422,995
Total current assets	1,668,826	2,695,098
Non-current assets:		
Property and equipment, net	351,368	375,385
Operating lease right-of-use asset, net	399,879	463,011
Finance lease right-of-use asset, net	167,730	780,872
Goodwill	1,404,486	1,404,486
Intangible assets, net	745,972	775,139
Other assets	12,814	19,676
Total assets	<u>\$ 4,751,075</u>	<u>\$ 6,513,667</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 1,169,837	\$ 987,311
Accrued expenses	1,048,034	1,398,722
Unearned revenue	24,404	24,404
Operating lease liability, current portion	133,239	127,498
Finance lease liability, current portion	179,844	395,301
Notes payable, current portion	32,946	171,669
Total current liabilities	2,588,304	3,104,905
Non-current liabilities:		
Operating lease liability, net of current portion	274,074	342,098
Finance lease liability, net of current portion	3,942	444,448
Notes payable, net of current portion	45,952	20,180
Warrant liability	3,974,911	—
Total liabilities	6,887,183	3,911,631
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at June 30, 2025, and December 31, 2024	—	—
Common stock, par value \$0.007 per share; 100,000,000 shares authorized; 28,459,541 and 15,576,674 issued and outstanding at June 30, 2025, and December 31, 2024, respectively	197,236	106,593
Additional paid-in capital	58,032,170	56,139,753
Accumulated deficit	(60,365,514)	(53,644,310)
Total stockholders' equity (deficit)	(2,136,108)	2,602,036
Total liabilities and stockholders' equity (deficit)	<u>\$ 4,751,075</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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net revenue	\$ 1,269,483	\$ 2,397,652	\$ 3,123,080	\$ 4,804,043
Operating expenses:				
Direct costs and expenses	1,016,602	1,407,710	2,384,462	2,981,151
Research and development	311,372	402,433	678,758	796,072
Clinical development	129,279	51,462	267,632	100,422
Selling, general and administrative	2,214,561	2,472,775	4,667,110	4,658,719
Depreciation and amortization	113,229	151,070	267,817	300,707
Total operating expenses	<u>3,785,043</u>	<u>4,485,450</u>	<u>8,265,779</u>	<u>8,837,071</u>
Loss from operations	(2,515,560)	(2,087,798)	(5,142,699)	(4,033,028)
Other income (expense):				
Interest income	2,025	5,186	2,567	11,313
Interest expense	(10,460)	(22,249)	(25,945)	(45,799)
Other income	38,053	1	38,055	4,511
Other expense	(483,043)	—	(492,685)	—
Change in fair value of warrants issued	(1,062,818)	—	(1,062,818)	—
Total other income (expense), net	<u>(1,516,243)</u>	<u>(17,062)</u>	<u>(1,540,826)</u>	<u>(29,975)</u>
Net loss before provision for income tax expense	(4,031,803)	(2,104,860)	(6,683,525)	(4,063,003)
Income tax expense	28,984	5,419	37,679	9,091
Net loss	<u>\$ (4,060,787)</u>	<u>\$ (2,110,279)</u>	<u>\$ (6,721,204)</u>	<u>\$ (4,072,094)</u>
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.19)	\$ (0.20)	\$ (0.38)
Weighted average common shares outstanding	24,021,546	11,389,308	20,148,211	10,655,483

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 Six Months Ended June 30, 2025						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance at December 31, 2024	—	\$ —	15,227,619	\$ 106,593	\$ 56,139,753	\$ (53,644,310)	\$ 2,602,036
Stock-based compensation expense	—	—	294,068	2,059	536,164	—	538,223
Sale of common stock, net	—	—	7,784,904	54,494	187,834	—	242,328
Exercise of stock warrants	—	—	4,870,010	34,090	1,524,486	—	1,558,576
Offering costs	—	—	—	—	(356,067)	—	(356,067)
Net loss	—	—	—	—	—	(6,721,204)	(6,721,204)
Balance at June 30, 2025 (unaudited)	—	\$ —	28,176,601	\$ 197,236	\$ 58,032,170	\$ (60,365,514)	\$ (2,136,108)
	For the Three Months Ended June 30, 2025						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance at March 31, 2025 (unaudited)	—	\$ —	17,825,351	\$ 124,777	\$ 57,619,354	\$ (56,304,727)	\$ 1,439,404
Stock-based compensation expense	—	—	134,809	944	210,663	—	211,607
Sale of common stock	—	—	7,784,904	54,494	187,834	—	242,328
Exercise of stock warrants	—	—	2,431,537	17,021	23,087	—	40,108
Offering costs	—	—	—	—	(8,768)	—	(8,768)
Net loss	—	—	—	—	—	(4,060,787)	(4,060,787)
Balance at June 30, 2025 (unaudited)	—	\$ —	28,176,601	\$ 197,236	\$ 58,032,170	\$ (60,365,514)	\$ (2,136,108)
	For the Six Months Ended June 30, 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	—	—	284,357	1,991	567,916	—	569,907
Exercise of stock options	—	—	208,031	454	74,445	—	74,899
Exercise of stock warrants	—	—	48	—	147	—	147
Sale of common stock	—	—	1,600,000	11,200	2,488,800	—	2,500,000
Offering costs	—	—	—	—	(495,000)	—	(495,000)
Net loss	—	—	—	—	—	(4,072,094)	(4,072,094)
Balance at June 30, 2024 (unaudited)	—	\$ —	11,487,046	\$ 79,407	\$ 52,030,280	\$ (48,676,573)	\$ 3,433,114
	For the Three Months Ended June 30, 2024						
	Preferred Stock		Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at March 31, 2024	—	\$ —	11,216,491	\$ 78,515	\$ 51,744,830	\$ (46,566,294)	\$ 5,257,051
Stock-based compensation expense	—	—	127,324	892	285,303	—	286,195
Exercise of stock options	—	—	143,183	—	—	—	—
Exercise of stock warrants	—	—	48	—	147	—	147
Net loss	—	—	—	—	—	(2,110,279)	(2,110,279)

	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Balance at June 30, 2024 (unaudited)	<u> — </u>	<u>\$ — </u>	<u> 11,487,046 </u>	<u> \$ 79,407 </u>	<u> \$ 52,030,280 </u>	<u> \$ (48,676,573) </u>	<u> \$ 3,433,114 </u>

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

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

	Six Months Ended June 30,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (6,721,204)	\$ (4,072,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	267,817	300,707
Stock-based compensation expense	538,223	569,907
Fair value adjustment on warrants	1,062,818	—
Changes in operating assets and liabilities:		
Accounts and other receivables	717,335	(783,952)
Inventory	(16,363)	(11,284)
Prepaid expenses and other assets	29,706	63,676
Accounts payable	182,526	243,313
Accrued expenses	(350,688)	(180,718)
Unearned revenue	—	(6,923)
Operating lease right-of-use asset	849	(1,032)
Net cash used in operating activities	(4,288,981)	(3,878,400)
Cash flows from investing activities		
Purchase of property and equipment	(64,213)	(69,672)
Net cash used in investing activities	(64,213)	(69,672)
Cash flows from financing activities		
Proceeds from issuance of Common Stock from direct offering, net of underwriting discounts, commissions, and offering expenses of \$112,922 in 2025 and \$495,000 in 2024	2,798,354	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	1,558,576	147
Payment on loans payable	(112,951)	—
Proceeds from loans payable	—	26,872
Principal repayments on finance leases	(193,241)	(179,105)
Net cash provided by financing activities	4,050,738	1,927,813
Net decrease in cash and cash equivalents	(302,456)	(2,020,259)
Cash and cash equivalents at beginning of period	1,105,291	2,821,570
Cash and cash equivalents at end of period	\$ 802,835	\$ 801,311
Supplemental disclosures of cash flow information:		
Interest expense paid in cash	\$ 2,567	\$ 45,799
Income taxes paid in cash	37,679	9,091

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 is developing its flow cytometry platform to address the need to identify patients who can benefit from new and emerging therapies for asthma and Chronic Obstructive Pulmonary Disease (COPD) with noninvasive precision diagnostic tests. Research also is advancing the Company’s therapeutic discoveries that could in the future result in broad-spectrum cancer treatments, beginning with treatment delivered topically for squamous cell skin cancer. Commercial operations and product development 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 \$60.4 million at June 30, 2025. The Company’s cash and cash equivalents at June 30, 2025, were approximately \$0.8 million. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at June 30, 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. In May 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. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that the Company’s current cash resources are sufficient to continue operations through August 2025. 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 \$171,822 and \$131,125 for the six months ended June 30, 2025 and 2024, respectively, and \$143,616 and \$119,205 for the three months ended June 30, 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 June 30, 2025 and 2024, as they would be anti-dilutive:

	As of June 30,	
	2025	2024
Shares underlying options outstanding	304,125	337,810
Shares underlying warrants outstanding	28,193,118	8,838,669
Shares underlying unvested restricted stock	282,940	246,044
	<u>28,780,183</u>	<u>9,422,523</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 six months ended June 30,	
	2025	2024
Patient service fees ¹	\$ 2,512,449	\$ 4,209,955
Histology service fees	572,358	530,053
Medical director fees	33,897	33,193
Department of Defense observational studies	—	6,923
Other revenues	4,376	23,919
Total net revenue	<u>\$ 3,123,080</u>	<u>\$ 4,804,043</u>

¹ Patient services fees include direct billing for CyPath[®] Lung diagnostic test of approximately \$323,000 and \$199,000 for the six months ended June 30, 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 and six months ended June 30, 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 and, 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 June 30, 2025, and December 31, 2024:

	June 30, 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	(14,861)	(10,694)
Customer relationships	(89,167)	(64,167)
	<u>(104,028)</u>	<u>(74,861)</u>
Intangible assets, net	<u>\$ 2,150,458</u>	<u>\$ 2,179,625</u>

The Company incurred amortization of intangible assets of \$29,167 for each of the six months ended June 30, 2025 and 2024, and \$14,583 for each of the three months ended June 30, 2025 and 2024.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (“ASU 2024-03”), which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company's annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this pronouncement on its related disclosures.

Segment Information

The Company is organized into 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 and therapeutic discoveries. 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.

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Net revenue:				
Diagnostic R&D	\$ —	\$ 4,038	\$ —	\$ 6,923
Laboratory services ¹	1,269,483	2,393,614	3,123,080	4,797,120
Total net revenue	<u>1,269,483</u>	<u>2,397,652</u>	<u>3,123,080</u>	<u>4,804,043</u>
Operating expenses:				
Diagnostic R&D	(440,651)	(453,895)	(946,390)	(896,494)
Laboratory services	(1,646,471)	(2,535,285)	(3,914,127)	(5,272,284)
General corporate activities	(1,697,921)	(1,496,270)	(3,405,262)	(2,668,293)
Total operating loss	<u>(2,515,560)</u>	<u>(2,087,798)</u>	<u>(5,142,699)</u>	<u>(4,033,028)</u>
Non-operating income (expense), net	(1,516,243)	(17,062)	(1,540,826)	(29,975)
Net loss before income tax expense	<u>(4,031,803)</u>	<u>(2,104,860)</u>	<u>(6,683,525)</u>	<u>(4,063,003)</u>
Income tax expense	(28,984)	(5,419)	(37,679)	(9,091)
Net loss	<u>\$ (4,060,787)</u>	<u>\$ (2,110,279)</u>	<u>\$ (6,721,204)</u>	<u>\$ (4,072,094)</u>

¹ The majority of the decrease versus the prior year is primarily due to discontinuing certain unprofitable pathology services to focus on CyPath[®] Lung and other high-margin services.

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 Centers for Medicare & Medicaid Services ("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 our wholly owned subsidiary PPLS, a clinical pathology laboratory accredited by the College of American Pathologists ("CAP") and certified under the Clinical Laboratory Improvement Amendments ("CLIA").

Note 3. ACCOUNTS AND OTHER RECEIVABLES, NET

The following is a summary of accounts receivables and other receivables:

	June 30, 2025	December 31, 2024
Patient service fees	\$ 237,586	\$ 915,488
Histology service fees	148,871	190,648
Medical director fees	15,896	5,194
Other receivables	19,516	27,874
Total accounts and other receivables, net	<u>\$ 421,869</u>	<u>\$ 1,139,204</u>

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

	June 30, 2025	December 31, 2024
Prepaid insurance	\$ 141,183	\$ 248,364
Legal and professional	28,323	27,448
Other	230,645	147,183
Total prepaid expenses and other current assets	<u>\$ 400,151</u>	<u>\$ 422,995</u>

Note 5. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	June 30, 2025	December 31, 2024
Lab equipment	\$ 679,995	\$ 662,747
Computers and software	81,433	81,433
Leasehold improvements	32,781	19,353
Vehicles	181,640	148,103
	975,849	911,636
Accumulated depreciation	(624,481)	(536,251)
Total property and equipment, net	\$ 351,368	\$ 375,385

Depreciation expense was \$88,231 and \$79,054 for the six months ended June 30, 2025 and 2024, respectively, and \$44,468 and \$40,243 for the three months ended June 30, 2025 and 2024, respectively.

Note 6. ACCRUED EXPENSES

Accrued expenses are summarized below:

	June 30, 2025	December 31, 2024
Compensation	\$ 776,065	\$ 1,079,839
Legal and professional	45,832	98,477
Clinical	113,547	160,371
Other	112,590	60,035
Total accrued expenses	\$ 1,048,034	\$ 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 June 30, 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 June 30, 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.

Warrants

The Company issued liability classified warrants in connection with the issuance of the May 2025 warrants. The warrants were liability classified as a result of certain terms in the May 2025 warrant agreement and is reflected as a liability in the condensed consolidated balance sheets. The Company uses a Black Scholes model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized in “Change in fair value of warrants issued” for each reporting period in the condensed consolidated income statement. Refer to Note 14 for additional details of the warrants.

The following tables present liabilities measured and recorded at fair value on the Company’s consolidated balance sheet as of June 30, 2025, the Company notes there were no liabilities as of December 31, 2024.

	June 30, 2025			
	Total	Level 1	Level 2	Level 3
Liability classified warrants	\$ 3,974,911	\$ —	\$ —	\$ 3,974,911
Total	\$ 3,974,911	\$ —	\$ —	\$ 3,974,911

The Company initially recorded a warrant liability of \$2.9 million as a result of the May 2025 public offering. The Company remeasured the warrants as of June 30, 2025 and recognized a \$1.1 million change in the fair value of the warrants.

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. On April 1, 2025, the company terminated one of the finance leases related to lab equipment due to the Company's targeted strategic actions announced in March, 2025. 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 2.8 to 5.2 years as of June 30, 2025. The Company has finance leases consisting of lab equipment with remaining lease terms ranging from approximately 0.8 to 1.58 years as of June 30, 2024, for which the Company has determined that it will use the equipment for a major part of its remaining economic life.

The lease agreements generally do not provide an implicit borrowing rate. Therefore, the Company used a benchmark approach as of the date of inception of the leases to derive an appropriate incremental borrowing rate to discount remaining lease payments. The Company benchmarked itself against other companies of similar credit ratings and comparable quality and derived imputed interest rates ranging from 6.41% to 8.07% for the lease term lengths.

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

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

The components of lease expense, which are included in selling, general and administrative expense and depreciation and amortization for the three and six months ended June 30, 2025 and 2024, are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Amortization of right-of-use asset - finance lease	\$ 54,177	\$ 224,567	\$ 150,420	\$ 320,810
Interest on lease liabilities - finance lease	7,410	22,235	20,491	45,785
Operating lease cost	39,764	29,916	79,529	59,831
Total lease cost	<u>\$ 101,351</u>	<u>\$ 276,718</u>	<u>\$ 250,440</u>	<u>\$ 426,426</u>

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

Operating cash flows from finance leases	\$ (92,975)	\$ (90,440)	\$ (193,241)	\$ (179,105)
Operating cash flows from operating leases	(31,443)	(23,434)	(56,238)	(46,402)

Operating leases:	June 30, 2025	December 31, 2024
Operating lease right-of-use, assets	\$ 399,879	\$ 463,011
Operating lease liability, current	\$ 133,239	\$ 127,498
Operating lease liability, non-current	274,074	342,098
Total operating lease liabilities	<u>\$ 407,313</u>	<u>\$ 469,596</u>
Finance leases:	June 30, 2025	December 31, 2024
Finance lease right-of-use asset, gross	\$ 565,030	\$ 1,294,168
Accumulated amortization	(397,300)	(513,296)
Finance lease right-of-use asset, net	\$ 167,730	\$ 780,872
Finance lease liability, current portion	\$ 179,844	\$ 395,301
Finance lease liability, long-term	3,942	444,448
Total finance lease liabilities	<u>\$ 183,786</u>	<u>\$ 839,749</u>
Weighted-average remaining lease term:	June 30, 2025	December 31, 2024
Operating leases (in years)	3.83	4.21
Finance leases (in years)	0.88	2.39
Weighted-average discount rate:	June 30, 2025	December 31, 2024
Operating leases	7.36%	7.41%
Finance leases	7.85%	8.03%

Future minimum lease payments under non-cancellable lease as of June 30, 2025, are as follows:

	Operating Leases	Finance Leases
Remaining for 2025	\$ 79,156	\$ 122,767
2026	159,282	67,425
2027	110,063	—
2028	40,616	—
2029	42,252	—
2030 and thereafter	28,919	—
Total undiscounted cash flows	460,288	190,192
Less discounting	(52,975)	(6,406)
Present value of lease liabilities	<u>\$ 407,313</u>	<u>\$ 183,786</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 June 30, 2025, was \$31,876. The current portion of the balance of this loan as of June 30, 2025 was \$4,330.

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 June 30, 2025, and December 31, 2024, was \$22,765 and \$24,849, respectively. The current portion of the balance of this loan as of June 30, 2025, and December 31, 2024, was \$4,359 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 June 30, 2025, and December 31, 2024, was \$24,257 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 28,459,541 shares of Common Stock, of which 282,940 are unvested restricted stock awards as of June 30, 2025, and 15,576,674 shares of Common Stock, of which 349,057 are unvested restricted stock awards as of December 31, 2024.

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 and accompanying warrant of \$0.32 per share. Each pre-funded warrant and accompanying warrant was sold at a combined public offering price of \$0.313 (See Note 14 – Warrants). In connection with this offering, the Company paid a cash fee equal to 8.0% of the aggregate gross proceeds, expenses up to \$120,000 and issued 304,687 warrants with substantially the same terms as the warrants issued as part of the public offering, except the warrants do not have an anti-dilution adjustment.

On May 22, 2025, the Company entered into an At-The-Market Issuance Sales Agreement (the “ATM Agreement”) with WallachBeth Capital LLC (“WallachBeth”), as sales agent providing for the sale of our common stock from time to time in an “at the market offering” program. The aggregate market value of the shares of Common Stock eligible for sale is currently \$5,801,000. The ATM Agreement provides that WallachBeth will receive 3.0% of the gross sales price sold under the ATM Agreement. From May 22, 2025 through June 30, 2025, the Company did not sell any shares through the ATM Agreement.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	\$ (8,334)	\$ 35,345	\$ 12,916	\$ 57,227
General and administrative	219,941	251,949	525,307	512,680
	<u>\$ 211,607</u>	<u>\$ 287,294</u>	<u>\$ 538,223</u>	<u>\$ 569,907</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 June 30, 2025	<u>304,125</u>	<u>\$ 6.95</u>	<u>3.90</u>	<u>—</u>
Vested and exercisable at June 30, 2025	<u>304,125</u>	<u>\$ 6.95</u>	<u>3.90</u>	<u>—</u>

As of June 30, 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 June 30, 2025	
				Vested number of RSA	Unvested number of RSA
Balance at December 31, 2024	1,326,861	\$ 1.99	\$ 2,636,259	1,215,592	171,671
Granted	258,398	0.81	208,559	121,408	136,990
Forfeited	(25,721)	0.81	(20,834)	—	(25,721)
Balance at June 30, 2025	<u>1,559,538</u>	<u>\$ 1.81</u>	<u>\$ 2,823,984</u>	<u>1,139,496</u>	<u>282,940</u>

During the three months ended June 30, 2025, the Company issued restricted stock awards (“RSAs”) for 5,000 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 six months ended June 30, 2025, 172,660 shares vested from RSAs granted prior to January 1, 2025, and 121,408 shares vested from RSAs granted during the six months ended June 30, 2025.

Note 14. WARRANTS

The Company's outstanding Common Stock warrants are a combination of equity and liability classified. As of June 30, 2025, and December 31, 2024, the Company had 28,193,118 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 \$1.44 and expire at various dates through May 2030. During the six months ended June 30, 2025, a total number of 4,870,010 warrants were exercised into an equivalent number of shares of Common Stock as compared to 48 warrants being exercised during the six months ended June 30, 2024. The proceeds of the exercised warrants for the six months ended June 30, 2025 were approximately \$2.4 million, compared to proceeds of \$294 during the six months ended June 30, 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"). 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.

On May 7, 2025 the Company completed a public offering (the "Offering") of 7,784,904 shares of our Common Stock, pre-funded warrants to purchase 2,371,346 shares of our Common Stock, together with warrants to initially purchase up to 15,234,375 shares of Common Stock (the "May 2025 Warrants"). Each share and accompanying warrant was sold at a combined public offering price of \$0.32 per share, and each pre-funded warrant and accompanying warrant was sold at a combined public offering price of \$0.313 per share.

The May 2025 Warrants have an initial exercise price of \$0.352 per share, and are exercisable for a term of five years on a date that is five years after the later of receiving the shareholder The number of shares of our Common Stock issuable upon exercise of the May 2025 Warrant Shares is subject to the following adjustments: (i) a 30% increase in the number of shares of Common Stock that would be issuable upon exercise of the May 2025 Warrants if a reverse stock split is effected prior to the expiration of the May 2025 Warrants (the "Reverse Stock Split Adjustment"), and (ii) subject to Warrant Stockholder Approval (as defined below), a decrease of the exercise price of the May 2025 Warrants, if in a subsequent offering of the Company's securities the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering is less than the exercise price immediately prior to such subsequent offering, to an exercise price that is equal to the lowest of the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering (subject to a floor of \$0.10 per share) and an increase in the number of shares of Common Stock underlying the May 2025 Warrants upon such exercise price reset so that the reset exercise price multiplied by the increased number of shares equals the aggregate proceeds that would have resulted from the full exercise of the May 2025 Warrants immediately prior to the reset (the "Anti-Dilution Adjustment"). The May 2025 Warrants will be immediately exercisable, except that the issuance of shares of Common Stock upon exercise of the May 2025 Warrants pursuant to the Anti-Dilution Adjustment will be subject to the filing of an amendment to the Company's certificate of incorporation, as amended (the "Certificate of Incorporation"), with the Secretary of State of the State of Delaware to increase the Company's authorized number of shares of Common Stock to 350,000,000 shares (the "Certificate of Amendment") and the date of stockholder approval of the Anti-Dilution Adjustment (collectively, the "Warrant Stockholder Approval"). The May 2025 Warrants will expire on the five-year anniversary of the later of the date that the Company files a Current Report on Form 8-K giving public notice of the Warrant Stockholder Approval (the "Stockholder Approval Notice Date") and the effective date of the filing of the Certificate of Amendment.

The Company agreed not to consummate a subsequent offering of its securities at a price less than the exercise price of the May 2025 Warrants immediately prior to such subsequent offering (a "Dilutive Issuance") until the earlier of (i) eight months from the closing date of the Offering; and (ii) later of: (a) the filing of a registration statement registering certain shares of Common Stock issuable as a result of the Anti-Dilution Adjustment; (b) the Stockholder Approval Notice Date; and (c) the effective date of the filing of the Certificate of Amendment. Based on an initial exercise price of \$0.352 per share (equal to 110% of the combined offering price per Share and accompanying May 2025 Warrant), if a reverse stock split is effected an additional 4,570,312 shares of Common Stock (on a pre-reverse stock split basis which number shall be adjusted based on the reverse stock split ratio) will be issuable upon exercise of the May 2025 Warrants and then, subject to obtaining Warrant Stockholder Approval, if a Dilutive Issuance is consummated, an additional 49,907,811 shares of Common Stock (on a pre-reverse stock split basis which number shall be adjusted based on the reverse stock split ratio) would be issuable upon exercise of the May 2025 Warrants.

The exercise price of the May 2025 Warrants and number of shares of Common Stock issuable upon exercise thereof will also adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events.

The pre-funded warrants may be exercised on a cashless basis at any time at an exercise price of \$0.007 per share. The May 2025 Warrants may be exercised on a cashless basis if at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the May 2025 Warrant Shares to the holder, provided however that those purchasers who do not enter into the Purchase Agreement and do not provide the Company with information required for registration of the resale of shares of Common Stock shall not have any of their shares issuable as a result of an Anti-Dilution Adjustment included in the registration statement the Company will file covering shares issuable as a result of an Anti-Dilution Adjustment and will not be able to effect a cashless exercise with respect to such shares.

As of June 30, 2025, all pre-funded warrants had been exercised and the Company received proceeds \$12,855 and issued 2,361,224 shares. In addition, designees of the placement agent for the Offering were issued warrants to purchase an aggregate of up to 304,687 shares of Common Stock, with an exercise price of \$0.352 per share and are exercisable for five years.

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	\$	0.352
Fair market closing price per share of Common Stock	\$	0.21
Volatility		152%
Expected term (years)		5
Risk-free interest rate		3.87%
Dividend yield		0%

The fair value of the above warrants was recorded as a warrant liability for the Offering, with the residual proceeds recorded in additional paid-in capital. The fair value of the Offering using the assumptions above was approximately \$2.9 million for the warrant liability and approximately \$0.2 million to equity.

During the six months ended June 30, 2025, 70,313 warrants were exercised resulting in reclassification to additional paid-in capital in the amount of approximately \$46,000. Due to fair value changes since the transaction through June 30, 2025, the Company recorded a loss on the remeasurement of its warrant liabilities of approximately \$1.0 million.

As of June 30, 2025, there were tradeable warrants to purchase up to an aggregate of 1,601,255 shares of Common Stock outstanding and non-tradeable warrants to purchase an aggregate of up to 2,704,458 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
Warrant inducement February 25, 2025	2,926,166	0.85	—	2,926,166
Public offering May 7, 2025	15,234,375	0.35	(70,313)	15,164,062
Placement agent offering May 7, 2025	304,687	0.35	—	304,687
Balance at June 30, 2025	<u>32,805,157</u>	<u>\$ 1.44</u>	<u>(4,612,039)</u>	<u>28,193,118</u>

Note 15. SUBSEQUENT EVENTS

On May 22, 2025, the Company initiated an ATM Agreement under a prospectus supplement for aggregate sales proceeds of up to \$5.8 million. In July 2025, the Company has sold an aggregate of 8,371 shares for gross proceeds of approximately \$3,000, and paid cash commissions of approximately \$100 to WallachBeth.

On July 4, 2025, the “One Big Beautiful Bill Act” was signed into law, which includes significant changes to federal tax law and other regulatory provisions that may impact the Company. We are currently evaluating the provisions of the new law and the potential effects on our financial position, results of operations, and cash flows.

On July 22, 2025, the Company held its 2025 Annual Meeting of Stockholders (the “2025 Annual Meeting”). At the 2025 Annual Meeting, the Company’s stockholders approved each of the following proposals: (i) the election of Maria Zannes, Steven Girgenti, Robert Anderson, Peter Knight, Gary Rubin, Roby Joyce, MD and Jamie Platt, PhD to the Company’s board of directors to serve until the 2026 Annual Meeting of Stockholders and until such director’s successor has been duly elected and qualified; (ii) the ratification of the appointment of WithumSmith+Brown, PC as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2025; (iii) an amendment to the Company’s Certificate of Incorporation to effect a reverse stock split, at the discretion of the Company’s board of directors, within a range of 1-for-2 to 1-for-100; (iv) the issuance of up to an aggregate of 2,926,166 shares of our Common Stock upon the exercise of our Common Stock purchase warrants issued in connection with our private placement offering that closed on February 26, 2025, that may be equal to or exceed 20% of our Common Stock outstanding before such offering, pursuant to Nasdaq listing rules; (v) an amendment to the Company’s Certificate of Incorporation, as amended, at the discretion of the Board, to increase the authorized number of shares of the Company’s Common Stock, from 100,000,000 to 350,000,000; (vi) the Anti-Dilution Adjustment provision of the May 2025 Warrants; and (vii) the adjournment proposal.

On August 7, 2025, the Company received notice from Nasdaq noting the Company’s bid price for its common stock closed at less than \$1 per share over the previous 30 consecutive business days as of February 7, 2025, and has not regained compliance according to Listing Rule 5550(a)(2). In addition, the Company did not comply with the continued listing requirement of a minimum of \$2.5 million in stockholders’ equity set forth in Listing Rule 5550(b)(1). As of August 14, 2025 the Company requested a hearing appeal on the determination. Such request will stay any further action by Nasdaq and will allow the Company’s ordinary shares to continue to trade on Nasdaq under the symbol “BIAF” at least pending the issuance of the Panel’s decision and the expiration of any extension the Panel may grant to the Company following the appeal.

On August 13, 2025, the Company entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell, in a private placement, (i) 990 shares of the Company’s newly designated Series B Convertible Preferred Stock, with a par value \$0.001 per share and stated value of \$1,000 per share, for gross proceeds to the Company of \$990,000, initially convertible into 4,304,343 shares of the Company’s Common Stock, par value \$0.007 per share at an initial conversion price of \$0.23 per share and (ii) warrants to purchase up to 6,714,780 shares of the Company’s Common Stock at an exercise price of \$0.352 per share of Common Stock.

On August 13, 2025, the Company entered into a warrant inducement agreement with the holder of a warrant to purchase 450,000 shares of Common Stock originally issued on August 5, 2024, with a current exercise price of \$1.25 per share and a warrant to purchase 650,000 shares of Common Stock originally issued on October 21, 2024 with a current exercise price of \$1.50 per share, pursuant to which the Holder agreed to exercise in cash the Existing Warrants at a reduced exercise price of \$0.23 per share, for gross proceeds to the Company of \$253,000. As an inducement to such exercise, the Company agreed to issue to the holder unregistered warrants (the “New Warrants”) to purchase up to 1,430,000 shares of the Company’s Common Stock. The New Warrants, which have an exercise price of \$0.352 per share and will not become exercisable until the Company’s stockholders approve the issuance of shares of Common Stock.

As a result of the foregoing transactions on August 13, 2025, the Company will issue approximately 8.0 million additional warrants to the participants in the May 2025 public offering.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 as may be amended, supplemented or superseded from time to time by other reports we file with the SEC. All amounts in this report are in U.S. dollars, unless otherwise noted.

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 screening in accordance with guidelines. 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 own and operate the clinical anatomic and clinical pathology laboratory. CyPath[®] Lung is offered for sale to physicians by PPLS.

We continue to advance development our flow cytometry+AI platform for diagnostic tests targeted at Chronic Obstructive Pulmonary Disease (COPD) and asthma. Diagnostics under development are designed to detect specific receptors in sputum that determine the effectiveness of new and emerging therapies for asthma and COPD that have proved to effectively treat some but not all patients.

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 continue to advance research and development for use of this technology for topical treatment of squamous cell skin cancer. We expect to present our findings at conferences and publish our research in peer-reviewed journals 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 six months ended June 30, 2025, include:

- CyPath[®] Lung testing revenue increased approximately 62% to \$323,000 as compared to \$199,000 for the six months ended June 30, 2024, due to an increase in total test results delivered of 169 for the six months ended June 30, 2025.
- Consolidated revenue decreased approximately 35% to \$3.1 million as compared to \$4.8 million for the six months ended June 30, 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.
- The Company raised approximately \$3.25 million in gross proceeds from equity transactions in the current quarter to fund operating activities.

Recent Developments

Record CyPath® Lung Sales

On August 13, 2025, the Company announced that the number of completed CyPath® Lung tests in July represented a 72% increase over the previous monthly average for the first six months of 2025. The upward trend reflects back-to-back record monthly sales in June and July. The Company reaffirmed its forecast of 3X year-over-year revenues for CyPath® Lung.

Patient Case Studies

Detection at Stage 1A followed by treatment offers a 95% 10-year survival rate as compared to the current overall 5-year survival rate of 26%. and the patient's prognosis, according to a NEJM study. Physicians have reported numerous patient case studies in which CyPath® Lung was the critical clinical decision maker including instances in which cancer was detected in Stage 1A when existing treatments can be curative. On July 29, 2025, the Company released details of a case study in which Stage 1A invasive mucinous adenocarcinoma was detected by CyPath® Lung after imaging and a competitive serum test were indeterminate.

On July 23, 2025, the Company announced that CyPath® Lung identified a Stage 1A neuroendocrine tumor in the patient's lung after PET scan, bronchoscopies and a serum tumor marker test suggested the pulmonary nodule was non-cancerous inflammation.

On July 9, 2025, the Company released details of a complex clinical case in which CyPath® Lung identified Stage 1A adenocarcinoma lung cancer in a patient whose PET imaging and risk model probability indicated a low risk of malignancy. In each case, use of our test was the determining factor that led to a biopsy and treatment.

These most recent case studies follow release on May 8, 2025, of the report "CyPath® Lung in Practice" authored by Gordon Downie, MD, PhD, then Director of the Titus Regional Hospital Lung Nodule Clinic and Interventional Pulmonology, in which he reported on case studies including an 85-year-old patient who averted biopsy after CyPath® Lung was negative for cancer, persuading the patient to wait for three months when a new CT showed the nodules had disappeared. The paper also reported on a patient who was previously treated for lung cancer and had a small nodule in the opposing lung. The CyPath® Lung was positive for cancer and a biopsy confirmed a second primary lung cancer for which the patient is being treated. In a third case study, CyPath® Lung helped identify a hidden recurrence of breast cancer after a routine CT detected a small pulmonary nodule.

Appointment of Chief Medical Officer

On June 15, 2025, Dr. Gordon Downie was appointed Chief Medical Officer. Dr. Downie brings more than three decades of experience in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology to the role. He has authored more than 30 peer-reviewed publications, many centered on innovation in bronchoscopy, early lung cancer diagnosis and medical device development. He has worked extensively in both academic medicine and private practice, led FDA-approved research programs, and served in national leadership roles with the American College of Chest Physicians in the areas of interventional pulmonology, lung cancer, and medical ethics.

Patent Awards

On June 24, 2025, the Company announced that the China National Intellectual Property Administration (CNIPA) has issued a notification of patent grant for the company's novel composition and method for selectively killing cancer by targeting the CD320 and LRP2 receptors on the cell membrane. The Company reported that research and development of this broad-spectrum therapeutic approach will be applied first to topical application for treatment of skin cancers.

On July 22, 2025, the Company announced its patent related to a method to detect lung disease through flow cytometry analysis of sputum has been allowed by the Canadian Patent Office. The Canadian patent protects the use of defined antibodies and the porphyrin TCPP to label cell populations in sputum and the use of flow cytometry to determine the presence of lung cancer cells in the sputum.

On July 15, 2025, the Company announced it received notification of allowance from the China National Intellectual Property Administration (CNIPA) for a patent application related to methods of predicting the likelihood of lung cancer using flow cytometry. The newly allowed Chinese patent protects the use of defined antibodies and the porphyrin TCPP to label cell populations in sputum and the use of flow cytometry to determine the presence of lung cancer cells in the sputum.

On May 28, 2025, the Company announced the U.S. Patent and Trademark Office (USPTO) issued a new patent covering a novel composition and method for selectively killing cancer by targeting the CD320 and LRP2 receptors on the cell membrane. Company research and development of this broad-spectrum therapeutic approach will be applied first to topical application for treatment of skin cancers.

Recent Financings

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 stockholder approval.

On August 13, 2025, the Company entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell, in a private placement, (i) 990 shares of the Company's newly designated Series B Convertible Preferred Stock, with a par value \$0.001 per share and stated value of \$1,000 per share, for gross proceeds to the Company of \$990,000, initially convertible into 4,304,343 shares of the Company's Common Stock, par value \$0.007 per share at an initial conversion price of \$0.23 per share and (ii) warrants to purchase up to 6,714,780 shares of the Company's Common Stock at an exercise price of \$0.352 per share of Common Stock.

On August 13, 2025, the Company entered into a warrant inducement agreement with the holder of a warrant to purchase 450,000 shares of Common Stock originally issued on August 5, 2024, with a current exercise price of \$1.25 per share and a warrant to purchase 650,000 shares of Common Stock originally issued on October 21, 2024 with a current exercise price of \$1.50 per share, pursuant to which the Holder agreed to exercise in cash the Existing Warrants at a reduced exercise price of \$0.23 per share, for gross proceeds to the Company of \$253,000. As an inducement to such exercise, the Company agreed to issue to the holder unregistered warrants (the "New Warrants") to purchase up to 1,430,000 shares of the Company's Common Stock. The New Warrants, which have an exercise price of \$0.352 per share and will not become exercisable until the Company's stockholders approve the issuance of shares of Common Stock.

As a result of the foregoing transactions on August 13, 2025, the Company will issue approximately 8.0 million additional warrants to the participants in the May 2025 public offering.

Nasdaq Compliance

On August 7, 2025, the Company received notice from Nasdaq noting the Company's bid price for its common stock closed at less than \$1 per share over the previous 30 consecutive business days as of February 7, 2025, and has not regained compliance according to Listing Rule 5550(a)(2). In addition, the Company did not comply with the continued listing requirement of a minimum of \$2.5 million in stockholders' equity set forth in Listing Rule 5550(b)(1). As of August 14, 2025 the Company requested a hearing appeal on the determination. Such request will stay any further action by Nasdaq and will allow the Company's ordinary shares to continue to trade on Nasdaq under the symbol "BIAF" at least pending the issuance of the Panel's decision and the expiration of any extension the Panel may grant to the Company following the appeal.

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. As of June 30, 2025, we had cash and cash equivalents of \$0.8 million. As of August 14, 2025, after the 2025 equity financing, we had cash and cash equivalents of \$0.3 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 June 30, 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 June 30, 2025, we had a working capital deficit of approximately \$0.9 million and an accumulated deficit of approximately \$60.4 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 June 30, 2025, Compared to Three Months Ended June 30, 2024

Net loss for the three months ended June 30, 2025, was approximately \$4.1 million, compared to a net loss of approximately \$2.1 million for the three months ended June 30, 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 June 30,	
	2025	2024
Patient service fees ¹	\$ 942,067	\$ 2,060,906
Histology service fees	308,604	292,081
Medical director fees	17,309	17,135
Department of Defense observational studies	—	4,038
Other revenues	1,503	23,492
Total net revenue	<u>\$ 1,269,483</u>	<u>\$ 2,397,652</u>

¹ Patient services fees include direct billing for CyPath[®] Lung diagnostic tests as well as anatomical tests and pathology services unrelated to CyPath[®] Lung including services discontinued due to unprofitability.

Consolidated revenue decreased approximately \$1.1 million, or 35%, to \$1.3 million for the three months ended June 30, 2025, as compared to \$2.4 million for the three months ended June 30, 2024, primarily as a result of the Company's targeted strategic actions to discontinue certain unprofitable pathology services, and drive sales growth for CyPath[®] Lung. CyPath[®] Lung testing revenue decreased approximately \$9,000, or 5%, to \$153,000 for the three months ended June 30, 2025, compared to \$162,000 for the three months ended June 30, 2024, as a result of a total of 197 test results delivered for the three months ended June 30, 2025, compared to 168 tests for the three months ended June 30, 2024. During the second quarter of the prior year, the Company was estimating CyPath[®] Lung revenue using limited collection data due to the early stages of collections on the test. However, during the current year the Company is using recent timely collection data to estimate revenue on historical collections. Therefore, the Company recognizes a decrease in revenue compared to the prior year with an increase in tests.

Operating Expenses

	Three Months Ended June 30,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Operating expenses:				
Direct costs and expenses	\$ 1,016,602	\$ 1,407,710	\$ (391,108)	(28)%
Research and development	311,372	402,433	(91,061)	(23)%
Clinical development	129,279	51,462	77,817	151%
Selling, general and administrative	2,214,561	2,472,775	(258,214)	(10)%
Depreciation and amortization	113,229	151,070	(37,841)	(25)%
Total operating expenses	<u>\$ 3,785,043</u>	<u>\$ 4,485,450</u>	<u>\$ (700,407)</u>	<u>(16)%</u>

Operating expenses totaled approximately \$3.8 million and \$4.5 million during the three months ended June 30, 2025 and 2024, respectively. The decrease 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 \$1.0 million and \$1.4 million during the three months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$0.3 million 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 \$311,000 and \$402,000 for the three months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$91,000, or 23%, for the three months ended June 30, 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 \$129,000 and \$51,000 for the three months ended June 30, 2025 and 2024, respectively. The increase of approximately \$77,000, or 151%, for the three months ended June 30, 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 \$2.2 million and \$2.5 million for the three months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$0.3 million, or 10%, for the three months ended June 30, 2025, compared to the same period in 2024 was primarily attributable a decrease in general and administrative costs related to lab operations as a result of our targeted strategic actions which occurred in March 2025, aimed at streamlining operations and reducing costs. These decreases were partially offset by an increase in employee compensation related to the addition of additional personnel and support services to support sales of our diagnostic test, CyPath[®] Lung.

Depreciation and Amortization

Depreciation and amortization expenses totaled approximately \$113,000 and \$151,000 for the three months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$38,000, or 25%, for the three months ended June 30, 2025, compared to the same period in 2024 was primarily attributable to the termination of a financing lease in April 2025 due to the Company's targeted strategic actions announced in March, 2025.

Other Income (Expense)

	Three Months Ended June 30,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Interest (expense) income, net	\$ (8,435)	\$ (17,063)	\$ 8,623	(14)%
Other income (expense), net	(444,990)	1	(444,991)	—)%
Gain (loss) on remeasurement of warrant liabilities	(1,062,818)	—	(1,062,818)	—%
Total other (expense) income	<u>\$ (1,516,243)</u>	<u>\$ (17,062)</u>	<u>\$ (1,499,181)</u>	<u>8787%</u>

Total other income (expense), net totaled (\$1.5 million) and approximately (\$17,000) for the three months ended June 30, 2025 and 2024, respectively. The increase in the total other expenses of approximately \$1.5 million is mostly attributable to the remeasurement of warrant liability and offering costs related to the May public offering.

Six Months Ended June 30, 2025, Compared to Six Months Ended June 30, 2024

Net loss for the six months ended June 30, 2025, was approximately \$6.7 million, compared to a net loss of approximately \$4.1 million for the six months ended June 30, 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 Six Months Ended June 30,	
	2025	2024
Patient service fees ¹	\$ 2,512,449	\$ 4,209,955
Histology service fees	572,358	530,053
Medical director fees	33,897	33,193
Department of Defense observational studies	—	6,923
Other revenues	4,376	23,919
Total net revenue	<u>\$ 3,123,080</u>	<u>\$ 4,804,043</u>

¹ Patient services fees include direct billing for CyPath[®] Lung diagnostic tests and anatomical testing and pathology services wholly unrelated to CyPath[®] Lung including those services discontinued due to unprofitability.

Consolidated revenue decreased approximately \$1.7 million, or 35%, to \$3.1 million for the six months ended June 30, 2025, as compared to \$4.8 million for the three months ended June 30, 2024, primarily as a result of the Company's targeted strategic actions to discontinue certain unprofitable pathology services, and drive sales growth for CyPath[®] Lung. CyPath[®] Lung testing revenue increased approximately \$116,000, or 56%, to \$323,000 for the six months ended June 30, 2025, compared to \$207,000 for the six months ended June 30, 2024, as a result of a total of 390 test results delivered for the three months ended June 30, 2025, compared to 221 tests for the six months ended June 30, 2024.

Operating Expenses

	Six Months Ended June 30,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Operating expenses:				
Direct costs and expenses	\$ 2,384,462	\$ 2,981,151	\$ (596,689)	(20)%
Research and development	678,758	796,072	(117,314)	(15)%
Clinical development	267,632	100,422	167,210	167%
Selling, general and administrative	4,667,110	4,658,719	8,391	0%
Depreciation and amortization	267,817	300,707	(32,890)	%
Total operating expenses	<u>\$ 8,265,779</u>	<u>\$ 8,837,071</u>	<u>\$ (571,292)</u>	<u>(6)%</u>

Operating expenses totaled approximately \$8.3 million and \$8.8 million during the six months ended June 30, 2025 and 2024, respectively. The decrease 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 approximately \$2.4 million and \$3.0 million during the six months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$0.6 million 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 laboratory operations, preclinical and clinical studies, compensation, and consulting costs.

Research and development expenses totaled \$0.7 million and \$0.8 million for the six months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$0.1 million, or 15%, for the six months ended June 30, 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 \$0.3 million and \$0.1 million for the six months ended June 30, 2025 and 2024, respectively. The increase of approximately \$0.2 million, or 16%, for the six months ended June 30, 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 and tax, and other professional services, and general operating expenses.

Selling, general and administrative expenses totaled approximately \$4.7 million for each of the six months ended June 30, 2025 and 2024, respectively. Our selling, general and administrative costs stayed level as a result of decreases in aimed at streamlining operations and reducing costs in our lab operations, offset by increases in employee compensation related to the addition of additional personnel and support services to support sales of our diagnostic test, CyPath[®] Lung.

Depreciation and Amortization

Depreciation and amortization expenses totaled approximately \$268,000 and \$300,00 for the six months ended June 30, 2025 and 2024, respectively. The decrease of approximately \$33,000, or 11%, for the six months ended June 30, 2025, compared to the same period in 2024 was primarily attributable to the termination of a financing lease in April 2025 due to the Company's targeted strategic actions announced in March 2025.

	Six Months Ended June 30,		Change in 2025 Versus 2024	
	2025	2024	\$	%
Interest (expense) income, net	\$ (23,378)	\$ (34,486)	\$ 11,108	(32)%
Other income (expense), net	(454,630)	4,511	(459,141)	(10,178)%
Gain (loss) on remeasurement of warrant liabilities	(1,062,818)	—	(1,062,818)	—%
Total other (expense) income	<u>\$ (1,540,826)</u>	<u>\$ (29,975)</u>	<u>\$ (1,510,851)</u>	<u>5,040%</u>

Other Income (Expense)

Total other income (expense), net totaled (\$1.5 million) and approximately \$(30,000) for the six months ended June 30, 2025 and 2024, respectively. The increase in the total other expenses of approximately \$1.5 million is mostly attributable the remeasurement of warrant liability and offering costs related to the May public offering.

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 six months ended June 30, 2025 and 2024, we had net losses of \$6.7 million and \$4.1 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$60.4 million as of June 30, 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 not 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 June 30, 2025, of \$0.8 million, management concludes that there is substantial doubt about our ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying unaudited condensed consolidated financial statements contained in this Quarterly Report. We need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or through exercised outstanding warrants to support our future operations unless our revenue increases significantly. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. There can be no assurance that we will be successful in accomplishing these objectives.

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

Summary Statements of Cash Flows

The following information reflects cash flows for the periods presented:

	Six Months Ended June 30,	
	2025	2024
Cash and cash equivalents at beginning of period	\$ 1,105,291	\$ 2,821,570
Net cash used in operating activities	(4,288,981)	(3,878,400)
Net cash used in investing activities	(64,213)	(69,672)
Net cash provided by financing activities	4,050,738	1,927,813
Cash and cash equivalents at end of period	<u>\$ 802,835</u>	<u>\$ 801,311</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$4.3 million and \$3.9 million for the six months ended June 30, 2025 and 2024, respectively. The increase of approximately \$0.4 million in cash used by operations during the six months ended June 30, 2025, compared to the same period in 2024 was primarily attributable to an increase of \$2.6 million in our loss from operations, a decrease in accrued expenses by \$0.2 million offset by a decrease in accounts receivable by \$1.5 million compared to the prior year, and a fair value adjustment to the warrant liability by \$1.1 million related to the May 2025 warrant agreement.

Net Cash Used in Investing Activities

We used approximately \$64,000 for the six months ended June 30, 2025, in investing activities related primarily to purchase of computer and lab equipment, compared to approximately \$70,000 used in investing activities for the six months ended June 30, 2024.

Net Cash Provided by Financing Activities

Cash provided in financing activities was approximately \$4.1 million compared to cash provided by financing activities of approximately \$1.9 million for the six months ended June 30, 2025 and 2024, respectively. The change in proceeds from prior year was primarily related to net proceeds from the equity transactions of \$4.4 million offset by payments for loans and finance leases of \$0.3 million, compared to the prior year of equity transactions of \$2.1 offset by payments for loans and finance leases of \$0.2 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-cancellable 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. 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 June 30, 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 June 30, 2025. Based on their assessment, they have concluded that as of June 30, 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 June 30, 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 six months ended June 30, 2025, we generated revenue of approximately \$3.1 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 of new diagnostic and therapeutic products;

- Expand commercialization of CyPath[®] Lung as an LDT under the CAP/CLIA guidelines and regulations administered by CMS and CAP and/or, if and when we obtain clearance from FDA for our CyPath[®] Lung test, to expand sales in accordance with FDA rules and regulations.
- Develop and commercialize CyPath[®] Lung as a CE-marked test in accordance with the In Vitro Diagnostic Regulation (“IVDR”) of the European Union (“EU”);
- Conduct research studies resulting in scientific results required to successfully develop therapeutic products based on our discoveries that the knockdown of certain cell receptors results in cancer death without harm to healthy tissue;
- 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 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 June 30, 2025, we had an accumulated deficit of \$60.4 million and \$0.8 million cash on hand. As of August 14, 2025, our cash and cash equivalents were \$0.3 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 September 2025. Based on our current expected level of operating expenditures, current expected levels of revenue, and the cash and cash equivalents on hand at June 30, 2025, of \$0.8 million, management concludes that there is substantial doubt about our ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying unaudited condensed consolidated financial statements contained in this Quarterly Report. 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.

Since its acquisition in September 2023, we have generated \$16.8 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 \$(2.1) 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 46.13% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended June 30, 2025, none of the Company’s directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement.”

ITEM 6. EXHIBITS.

Exhibit No.	Title of Document
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002
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
104*	Cover Page Interactive Data File – the cover page from the Registrant’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 is formatted in Inline XBRL

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

BIOAFFINITY TECHNOLOGIES, INC.

Date: August 14, 2025

By: /s/ Maria Zannes

Maria Zannes

Chief Executive Officer, President, Founder, and Director
(Principal Executive Officer)

Date: August 14, 2025

By: /s/ J. Michael Edwards

J. Michael Edwards

Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended June 30, 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: August 14, 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 June 30, 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: August 14, 2025

/s/ J. Michael Edwards

J. Michael Edwards
Vice President and Chief Financial Officer
(Principal Financial and Accounting 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 June 30, 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 June 30, 2025 (the last date of the period covered by the Report).

Date: August 14, 2025

/s/ Maria Zannes

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

Date: August 14, 2025

/s/ J. Michael Edwards

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