

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

(Mark One)

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

For the quarterly period ended September 30, 2023

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

For the transition period from _____ to _____.

COMMISSION FILE NUMBER: 001-41463

bioAffinity Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

78257
(Zip Code)

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

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

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

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

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

The number of shares of the issuer's common stock outstanding as of November 8, 2023, was 9,502,243.

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;
- our ability to successfully integrate our newly acquired laboratory services business;
- our ability to successfully operate the clinical pathology laboratory and generate significant profit or revenue from such business operation;
- 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 and 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 ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems, or the global economy as a whole;
- general instability of economic and political conditions in the United States, including inflationary pressures, increased interest rates, economic slowdown or recession, and escalating geopolitical tensions;

- compliance with government regulations, including environmental, health, and safety regulations, and liabilities thereunder;
- 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, the evolving nature of the COVID-19 endemic and the emergence of new viral variants, and any consequent worsening of the global business and economic environment. New factors emerge from time to time, and it is not possible for us to predict all such factors. Should one or more of the risks or uncertainties described in this Quarterly Report or any other filing with the Securities and Exchange Commission (the “SEC”) occur or should the assumptions underlying the forward-looking statements we make herein and therein prove incorrect, our actual results and plans could differ materially from those expressed in any forward-looking statements. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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

Website and Social Media Disclosure

We use our websites (www.bioaffinitytech.com, ir.bioaffinitytech.com and www.precisionpath.us/) and at times our corporate X account (@bioAffinity), LinkedIn account (www.linkedin.com/company/bioaffinitytechnologies) and Facebook account (<https://www.facebook.com/bioaffinitytechnologies>) to distribute company information. Information contained on or that can be accessed through our websites and social media channels is not, however, incorporated by reference in this Quarterly Report. Investors should not consider any such information to be part of this Quarterly Report.

bioAffinity Technologies, Inc.

FORM 10-Q
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PART I
FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,509,236	\$ 11,413,759
Accounts and other receivables, net	1,108,414	10,489
Inventory	9,908	5,540
Prepaid expenses and other current assets	382,651	531,899
Total current assets	<u>6,010,209</u>	<u>11,961,687</u>
Non-current assets:		
Property and equipment, net	512,152	214,438
Operating lease right-of-use asset, net	392,347	—
Finance lease right-to-use, net	1,262,087	—
Goodwill	1,148,553	—
Intangible assets, net	848,056	—
Other assets	16,060	6,000
Total assets	<u>\$ 10,189,464</u>	<u>\$ 12,182,125</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 827,407	\$ 345,042
Accrued expenses	643,786	541,894
Unearned revenue	38,250	—
Operating lease liability, current portion	90,863	—
Finance lease liability, current portion	358,282	—
Loan payable	—	251,746
Total current liabilities	<u>1,958,588</u>	<u>1,138,682</u>
Non-current liabilities:		
Finance lease liability, net of current portion	929,570	—
Operating lease liability, net of current portion	307,397	—
Total liabilities	<u>3,195,555</u>	<u>1,138,682</u>
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; no shares issued or outstanding at September 30, 2023, and December 31, 2022	—	—
Common stock, par value \$0.007 per share; 25,000,000 and 14,285,714 shares authorized; 9,216,883 and 8,381,324 issued and outstanding at September 30, 2023 and at December 31, 2022, respectively.	64,535	58,669
Additional paid-in capital	49,160,689	47,652,242
Accumulated deficit	(42,231,315)	(36,667,468)
Total stockholders' equity	<u>6,993,909</u>	<u>11,043,443</u>
Total liabilities and stockholders' equity	<u>\$ 10,189,464</u>	<u>\$ 12,182,125</u>

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

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Net Revenue	\$ 298,484	\$ 1,150	\$ 319,143	\$ 2,457
Cost of sales	74,704	146	76,025	292
Gross profit	223,780	1,004	243,118	2,165
Operating expenses:				
Research and development	330,376	319,744	1,035,118	949,388
Clinical development	106,422	60,941	161,310	141,684
Selling, general and administrative	2,023,917	595,702	4,576,708	1,295,558
Depreciation and amortization	57,569	773	100,805	2,852
Total operating expenses	2,518,284	977,160	5,873,941	2,389,482
Loss from operations	(2,294,504)	(976,156)	(5,630,823)	(2,387,317)
Other income (expense):				
Interest income	27,193	7,414	109,971	8,261
Interest expense	(8,785)	(896,502)	(11,801)	(2,443,350)
Other income	4,606	—	4,606	—
Other expense	(17,100)	—	(17,100)	—
Gain on extinguishment of debt	—	—	—	212,258
Fair value adjustments on convertible notes payable	—	(3,053,914)	—	(1,866,922)
Net loss before provision for income taxes	(2,288,590)	(4,919,158)	(5,545,147)	(6,477,070)
Income tax expense	(2,294)	(300)	(18,700)	(2,460)
Net loss	<u>\$ (2,290,884)</u>	<u>\$ (4,919,458)</u>	<u>\$ (5,563,847)</u>	<u>\$ (6,479,530)</u>
Net loss per common share, basic and diluted	\$ (0.26)	\$ (1.17)	\$ (0.65)	\$ (2.03)
Weighted average common shares outstanding, basic and diluted	8,696,554	4,203,781	8,551,154	3,194,765

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

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity (Deficit)

	For the Nine Months Ended September 30, 2023							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	—	\$ —	8,381,324	\$ 58,669	\$ 47,652,242	\$ (36,667,468)	\$ 11,043,443	
Stock-based compensation expense	—	—	270,587	1,911	512,402	—	514,313	
Stock issued for acquisition	—	—	564,972	3,955	996,045	—	1,000,000	
Net loss	—	—	—	—	—	(5,563,847)	(5,563,847)	
Balance at September 30, 2023 (unaudited)	—	\$ —	9,216,883	\$ 64,535	\$ 49,160,689	\$ (42,231,315)	\$ 6,993,909	
	For the Three Months Ended September 30, 2023							
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity	
	Shares	Amount	Shares	Amount				
Balance at June 30, 2023	—	\$ —	8,555,365	\$ 59,887	\$ 47,978,892	\$ (39,940,431)	\$ 8,098,348	
Stock-based compensation expense	—	—	96,546	693	185,752	—	186,445	
Stock issued for acquisition	—	—	564,972	3,955	996,045	—	1,000,000	
Net loss	—	—	—	—	—	(2,290,884)	(2,290,884)	
Balance at September 30, 2023 (unaudited)	—	\$ —	9,216,883	\$ 64,535	\$ 49,160,689	\$ (42,231,315)	\$ 6,993,909	
	For the Nine Months Ended September 30, 2022							
	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit	
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	756,558	\$ 4,044,318	2,677,140	\$ 18,740	\$ 12,703,896	\$ (28,513,355)	\$ (15,790,719)	
Stock-based compensation expense	—	—	18,154	127	211,618	—	211,745	
Beneficial conversion feature for bridge notes	—	—	—	—	348,219	—	348,219	
Return of capital from stock split	—	—	—	—	(185)	—	(185)	
Debt discount for warrants issued	—	—	—	—	383,696	—	383,696	
Common stock issued upon initial public offering, net of underwriters' commission and offering costs of \$1.8 million	—	—	1,282,600	8,978	6,018,436	—	6,027,414	
Common stock issued on conversion of convertible preferred stock	(756,558)	(4,044,318)	756,558	5,296	4,039,022	—	4,044,318	
Common stock issued on conversion of notes payable	—	—	2,533,964	17,738	16,047,594	—	16,065,332	
Exercise of warrants	—	—	1,036,486	7,255	7,706,055	—	7,713,310	
Exercise of stock options	—	—	64,848	454	74,446	—	74,900	

Net loss	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(6,479,530)</u>	<u>(6,479,530)</u>
Balance at September 30, 2022 (unaudited)	<u>—</u>	<u>\$ —</u>	<u>8,369,750</u>	<u>\$ 58,588</u>	<u>\$ 47,532,797</u>	<u>\$ (34,992,885)</u>	<u>\$ 12,598,500</u>

For the Three Months Ended September 30, 2022

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at June 30, 2022	756,558	\$ 4,044,318	2,694,459	\$ 18,861	\$ 13,268,237	\$ (30,073,427)	\$ (16,786,329)
Stock-based compensation expense	—	—	835	6	79,007	—	79,013
Beneficial conversion feature for bridge notes	—	—	—	—	134,277	—	134,277
Debt discount for warrants issued	—	—	—	—	165,723	—	165,723
Common stock issued upon initial public offering, net of underwriters' commission and offering costs of \$1.8 million	—	—	1,282,600	8,978	6,018,436	—	6,027,414
Common stock issued on conversion of convertible preferred stock	(756,558)	(4,044,318)	756,558	5,296	4,039,022	—	4,044,318
Common stock issued on conversion of notes payable	—	—	2,533,964	17,738	16,047,594	—	16,065,332
Exercise of warrants	—	—	1,036,486	7,255	7,706,055	—	7,713,310
Exercise of stock options	—	—	64,848	454	74,446	—	74,900
Net loss	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(4,919,458)</u>	<u>(4,919,458)</u>
Balance at September 30, 2022 (unaudited)	<u>—</u>	<u>\$ —</u>	<u>8,369,750</u>	<u>\$ 58,588</u>	<u>\$ 47,532,797</u>	<u>\$ (34,992,885)</u>	<u>\$ 12,598,500</u>

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

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (5,563,847)	\$ (6,479,530)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	100,805	2,852
Accretion of debt issuance costs	—	1,972,948
Fair value adjustments on convertible notes payable	—	1,866,922
Stock-based compensation expense	514,313	211,745
Gain on extinguishment of debt	—	(212,258)
Changes in operating assets and liabilities:		
Accounts and other receivables	71,840	(8,400)
Inventory	(4,368)	(5,715)
Prepaid expenses and other assets	152,768	(502,177)
Accounts payable	406,836	(80,725)
Accrued expenses	(144,013)	(1,524)
Accrued interest	—	465,653
Unearned revenue	38,250	—
Operating lease right-of-use asset	5,913	—
Net cash used in operating activities	(4,421,503)	(2,770,209)
Cash flows from investing activities		
Purchase of property and equipment	(36,344)	—
Acquisition of subsidiary, net cash acquired	(2,186,497)	—
Net cash used in investing activities	(2,222,841)	—
Cash flows from financing activities		
Proceeds from issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses of approximately \$1.8 million	—	6,027,414
Exercise of warrants	—	7,713,310
Exercise of stock options	—	74,900
Proceeds from loans payable	—	555,148
Payment on loans payable	(251,746)	(31,612)
Principle repayments on finance leases	(8,433)	—
Proceeds from issuance of convertible notes payable	—	724,000
Repayment of convertible loan payable	—	(100,000)
Payment of debt issuance costs	—	(55,651)
Net cash (used in) provided by financing activities	(260,179)	14,907,509
Net (decrease)/increase in cash and cash equivalents	(6,904,523)	12,137,300
Cash and cash equivalents at beginning of period	11,413,759	1,360,638
Cash and cash equivalents at end of period	\$ 4,509,236	\$ 13,497,938
Supplemental disclosures of cash flow information:		
Interest expense paid in cash	\$ 11,801	\$ 2,459
Income taxes paid in cash	18,700	3,945
Noncash investing and financing activities:		
Common stock issuance for acquisition of subsidiary	1,000,000	—
Conversion of convertible preferred stock into common stock	—	4,044,318
Conversion of convertible notes payable into common stock	—	16,065,332
Fair value of warrants issued to placement agents	—	383,696
Beneficial conversion feature for bridge notes	—	348,219

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

bioAffinity Technologies, Inc.
Notes To Condensed Consolidated Financial Statements
(unaudited)

Note 1. NATURE OF OPERATIONS, ORGANIZATION, AND BASIS OF PRESENTATION

Description of Business

bioAffinity Technologies, Inc., a Delaware corporation (the “Company,” or “bioAffinity Technologies”), addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung. The Company also is conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. bioAffinity Technologies develops proprietary noninvasive diagnostic tests using technology that preferentially targets cancer cells and 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”). Research and optimization of the Company’s proprietary platform for *in vitro* diagnostics and technologies are conducted in laboratories at The University of Texas at San Antonio and PPLS. The Company is developing its platform technologies so that in the future they will be able to detect, monitor, and treat diseases of the lung and other cancers.

Organization

The Company was formed on March 26, 2014, as a Delaware corporation with its corporate offices located in San Antonio, Texas. On June 15, 2016, the Company formed a wholly owned subsidiary, OncoSelect® Therapeutics, LLC, as a Delaware limited liability company. On August 14, 2023, the Company formed a wholly owned subsidiary, PPLS, as a Texas limited liability company, to acquire the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services (“Village Oaks”), including the clinical pathology laboratory it owned.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) and pursuant to the rules and regulations of the SEC for interim financial reporting. The condensed consolidated financial statements are unaudited and in management’s opinion include all adjustments, including normal recurring adjustments and accruals, necessary for a fair presentation of the results for the interim periods presented. The condensed consolidated balance sheet as of December 31, 2022 was derived from the audited consolidated financial statements at that date but does not include all the information and footnotes required by GAAP. Operating results for the periods presented are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2023, or any future period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited annual consolidated financial statements and notes included in the 2022 Form 10-K filed with the SEC on March 31, 2023.

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 \$42.2 million at September 30, 2023. The Company’s cash and cash equivalents at September 30, 2023, were approximately \$4.5 million, representing 44% of total assets. Based on the Company’s current expected level of operating expenditures and the cash and cash equivalents on hand at September 30, 2023, 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. Therefore, the Company may need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations. If such funding is not available or not available on terms acceptable to the Company, the Company’s current development plan may be curtailed. No adjustments have been made to the presented financial statements as a result of this uncertainty.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the valuation allowance on the Company’s deferred tax assets, stock-based compensation, valuation of goodwill and intangible assets related to the business combination, allowance for contractual adjustments and discounts related to service revenues, and the useful lives of fixed assets.

Principles of Consolidation

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

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

Business Combination

On September 18, 2023, the Company, in connection with the Asset Purchase Agreement it entered into with Village Oaks (the Seller”) and Dr. Roby P. Joyce, M.D., dated September 18, 2023, acquired substantially all the assets and assumed certain liabilities of Village Oaks (the “Acquisition”) in exchange for total consideration of \$3,500,000, which consists of: (i) \$2.5 million in cash paid at closing and (ii) 564,972 shares of the Company’s common stock valued at \$1 million, reduced by (iii) the assumption of assumed liabilities totaling \$321,000. The assets purchased included a clinical pathology laboratory regulated by the Centers for Medicare and Medicaid Services (“CMS”) and accredited by the College of American Pathologists (“CAP”) and certified under the Clinical Laboratory Improvement Amendments (“CLIA”) of 1988.

The Company recognized goodwill of \$1,149,000 arising from the Acquisition. The Acquisition is being accounted for as a business combination in accordance with ASC 805. The Company has determined the preliminary fair values of the assets acquired and liabilities assumed in the Acquisition. These values are subject to change as the Company performs additional reviews of its assumptions utilized.

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

Cash	\$	2,500,000
Common Stock		1,000,000
Total purchase consideration	\$	<u>3,500,000</u>
Assets		
Net working capital (including cash)	\$	1,167,000
Property and equipment		326,000
Other assets		8,000
Customer relationships		700,000
Trade names and trademarks		150,000
Goodwill		1,149,000
Total net assets	\$	<u>3,500,000</u>

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

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 approximately \$43,000 and \$13,000 for the nine months and \$10,000 and \$5,000 for the three months ended September 30, 2023 and 2022, respectively.

Loss Per Share

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of the Company’s common stock, par value \$0.007 per share (the “Common Stock”) outstanding during the period. Diluted loss per share is computed by dividing net loss attributable to common stockholders by the sum of the weighted-average number of shares of Common Stock outstanding during the period and the weighted-average number of dilutive Common Stock equivalents outstanding during the period, using the treasury stock method. Dilutive Common Stock equivalents are comprised of in-the-money stock options, convertible notes payable, and warrants based on the average stock price for each period using the treasury stock method.

The following potentially dilutive securities have been excluded from the computations of weighted average shares of Common Stock outstanding as of September 30, 2023 and 2022, as they would be anti-dilutive:

	As of September 30,	
	2023	2022
Shares underlying options outstanding	683,695	806,392
Shares underlying warrants outstanding	4,649,952	4,624,952
Shares underlying convertible notes	—	83,373
	<u>5,333,647</u>	<u>5,514,717</u>

Revenue Recognition

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 revenue is recognized on the date of service (meeting the performance requirement of ASC 606). Pre-acquisition, bioAffinity's revenue was generated in three ways for the nine months and three months ended September 30, 2023: (1) royalties from the Company's diagnostic test, CyPath® Lung, (2) clinical flow cytometry services provided to Village Oaks related to the Company's CyPath® Lung test, and (3) CyPath® Lung tests purchased by the U.S. Department of Defense ("DOD") for an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay (NCT05870592)," and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. The royalty income from CyPath® Lung and clinical flow cytometry services income, beginning September 19, 2023, are related-party income and, therefore, eliminated from consolidated net revenues.

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.

	For three months ended September 30,					
	2023			2022		
	Net Revenue	Related Party ¹	Consolidated	Net Revenue	Related Party ¹	Consolidated
Parent (bioAffinity Technologies):						
CyPath® Lung royalty income ¹	\$ 5,412	\$ (487)	\$ 4,925	\$ 1,150	-	\$ 1,150
Laboratory services ¹	7,423	(1,265)	6,158	-	-	-
Dept. of Defense study	4,500	-	4,500	-	-	-
Subsidiaries ((PPLS) and Controlling Interest Entity²:						
Patient fees	248,654	-	248,654	-	-	-
Histology fees	31,854	-	31,854	-	-	-
Medical director fees	2,392	-	2,393	-	-	-
Total net revenue	<u>\$ 300,236</u>	<u>\$ (1,752)</u>	<u>\$ 298,484</u>	<u>\$ 1,150</u>	<u>-</u>	<u>\$ 1,150</u>

	For the nine months ended September 30,					
	2023			2022		
	Net Revenue	Related Party ¹	Consolidated	Net Revenue	Related Party ¹	Consolidated
Parent (bioAffinity Technologies):						
CyPath® Lung royalty income ¹	\$ 13,164	\$ (487)	\$ 12,677	\$ 2,457	-	\$ 2,457
Laboratory services ¹	10,500	(1,265)	9,315	-	-	-
Dept. of Defense study	14,250	-	14,250	-	-	-
Subsidiaries (VOPS/PPLS)²:						
Patient fees	248,654	-	248,654	-	-	-
Histology fees	31,854	-	31,854	-	-	-
Medical director fees	2,393	-	2,393	-	-	-
Total net revenue	<u>\$ 320,895</u>	<u>\$ (1,752)</u>	<u>\$ 319,143</u>	<u>\$ 2,457</u>	<u>-</u>	<u>\$ 2,457</u>

¹As of September 18, 2023 (date of the Acquisition), royalty and laboratory services income agreements are considered related parties and eliminated upon consolidation.

²The three months ended revenue for PPLS and its controlling interest entity, Village Oaks, only recognizes partial period of September 19 through September 30, 2023.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. The Company reclassified patent expenses and annuity costs of approximately \$142,000 and \$41,000 from research and development to selling, general and administrative for the nine months and three months ended September 30, 2022, 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 nine months ended September 30, 2023 or fiscal year ended December 31, 2022.

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

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

Intangible Assets

Intangible assets, net of accumulated amortization, are summarized as follows as of September 30, 2023:

Description	Date Acquired	Useful Life	Cost	Amortization	Net
Goodwill	9/18/2023		\$ 1,148,553	\$ —	\$ 1,148,553
Trade names and trademarks	9/18/2023	18 years	150,000	(277)	149,723
Customer relationships	9/18/2023	14 years	700,000	(1,666)	698,334
Total Intangible Assets			\$ 1,998,553	\$ (1,943)	\$ 1,996,610

For the three and nine months ended September 30, 2023, amortization of intangible assets totaled \$1,943 compared to \$0 in the prior year comparative periods.

Recent Accounting Pronouncements

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

The Company adopted FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842) on September 18, 2023, with the business combination of Village Oaks Pathology Services, P.A. (VOPS) and Precision Pathology Laboratories Services, LLC (PPLS). The Company has one operating lease for its real estate and office space and multiple finance leases for lab equipment in Texas that was acquired through the September 18, 2023, acquisition.

Note 3. ACCOUNTS AND OTHER RECEIVABLES, NET

The following is a summary of accounts receivable:

	September 30, 2023	December 31, 2022
Parent (bioAffinity):		
CyPath® Lung royalty income	\$ 16,107	\$ 4,803
Laboratory services	12,390	—
Other receivables	4,730	5,686
Subsidiary (PPLS) and Controlling Interest Entity:		
Purchased receivables from acquisition, net of collections	791,852	—
Net patient fees receivable	249,088	—
Histology fees	31,854	—
Medical director fees	2,393	—
Accounts and other receivable, net	\$ 1,108,414	\$ 10,489

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 240,540	\$ 340,078
Legal and professional	30,847	72,048
Other	111,264	119,773
Total prepaid expenses and other current assets	\$ 382,651	\$ 531,899

Note 5. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	September 30, 2023	December 31, 2022
Lab equipment	\$ 649,499	\$ 462,155
Computers and software	68,682	21,463
Leasehold improvements	9,941	—
Vehicles	119,990	—
	848,112	483,617
Accumulated depreciation	(335,960)	(269,180)
Total property and equipment, net	\$ 512,152	\$ 214,438

Depreciation expense was approximately \$66,800 and \$2,900 for the nine months ended and \$23,500 and \$800 for the three months ended September 30, 2023 and 2022, respectively

Note 6. ACCRUED EXPENSES

Accrued expenses are summarized below:

	September 30, 2023	December 31, 2022
Compensation	\$ 554,511	\$ 340,680
Legal and professional	18,487	144,440
Clinical	27,776	50,922
Billing fees	19,525	—
Other	23,487	5,852
Total accrued expenses	\$ 643,786	\$ 541,894

Note 7. UNEARNED REVENUE

During the three months ended September 30, 2023, the Company engaged in an observational study of CyPath[®] Lung with the 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 16 units as of September 30, 2023. The performance obligation is deemed complete after samples have been collected and processed and results analyzed. The unearned revenue balance amounted to approximately \$38,250 as of September 30, 2023.

Note 8. FAIR VALUE MEASUREMENTS

The Company analyzes all financial instruments with features of both liabilities and equity under the FASB accounting standard for such instruments. Under this standard, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts and other receivables, prepaid and other current assets, accounts payable, accrued expenses, and loan payable, are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

Note 9. LEASES

The Company has one operating lease for its real estate and office space and multiple finance leases for lab equipment in Texas that was acquired through the September 18, 2023, acquisition. The operating lease has a remaining lease term of 3.83 years as of September 30, 2023. The Company has finance leases consisting of office and lab equipment with remaining lease terms ranging from approximately 2.5 to 4.25 years as of September 30, 2023, for which the Company has determined that it will use the equipment for a major part of its remaining economic life.

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

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

The Company's existing leases contain escalation clauses and renewal options. The Company has evaluated several factors in assessing whether there is reasonable certainty that the Company will exercise a contractual renewal option. For leases with renewal options that are reasonably certain to be exercised, the Company included the renewal term in the total lease term used in calculating the right-of-use asset and lease liability. Prior to adoption of ASU 2016-02 effective January 1, 2022, the Company accounted for operating lease transactions by recording lease expense on a straight-line basis over the expected term of the lease.

The components of lease expense, which are included in selling, general and administrative expense and depreciation and amortization for the nine months ended September 30, 2023, and 2022 are as follows:

Components of lease expense:	2023	2022
Amortization of right-of-use assets - finance lease	\$ 32,081	\$ —
Interest on lease liabilities - finance lease	8,634	—
Operating lease cost	9,972	—
Total lease cost	<u>\$ 50,687</u>	<u>\$ —</u>

Supplemental balance sheet information relating to leases was as follows as of September 30, 2023 and December 31, 2022:

Operating leases:	2023	2022
Operating lease right-of-use assets	\$ 392,347	\$ —
Operating lease liability, current	\$ 90,863	\$ —
Operating lease liability, long-term	<u>\$ 307,397</u>	<u>\$ —</u>

Finance leases:	2023	2022
Finance lease right-of-use asset, gross	\$ 1,294,168	\$ —
Accumulated amortization	(32,081)	—
Finance lease right-of-use asset, net	1,262,087	—
Finance lease liability, current portion	358,282	—
Finance lease liability, long-term	929,570	—
Total finance lease liabilities	<u>\$ 1,287,852</u>	<u>\$ —</u>

Weighted-average remaining lease term:	2023	2022
Operating leases (in years)	3.83	—
Finance leases (in years)	3.50	—

Weighted-average discount rate:	2023	2022
Operating leases	8.07%	—
Finance leases	8.01%	—

Future minimum lease payment under non-cancellable lease as of September 30, 2023, are as follows:

	Operating Leases	Finance Leases
Remaining 2023	\$ 28,431	\$ 112,126
2024	121,726	448,505
2025	121,726	448,505
2026	121,726	270,395
2027 and thereafter	71,007	202,970
Total undiscounted cash flows	464,616	1,482,501
Less discounting	(66,356)	(194,649)
Present value of lease liabilities	\$ 398,260	\$ 1,287,852

Note 10. COMMITMENTS AND CONTINGENCIES

Operating Leases

In addition to the operating lease listed in Note 9, the Company leases its corporate offices under a month-to-month agreement and leases its laboratory and additional office space under an operating lease that is renewable annually by written notice by the Company and will require renewal in February 2024. Rent expense for office and lab space amounted to approximately \$35,000 and \$15,000 for the three months and \$88,000 and \$41,000 for the nine months ended September 30, 2023, and 2022, respectively.

Legal Matters

From time to time, the Company is involved in various disputes and litigation matters that arise in the ordinary course of business. To date, the Company has no material pending legal proceedings.

Note 11. COMMON STOCK

Common Stock

The Company has authorized a total of 25,000,000 shares of Common Stock, \$0.007 par value per share. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 14,285,715 shares to 25,000,000 shares. The Company has issued 9,350,297 shares of Common Stock of which 133,414 are unvested restricted stock shares as of September 30, 2023, and 8,381,324 shares of Common Stock as of December 31, 2022.

Note 12. STOCK-BASED COMPENSATION

The Company grants options and restricted stock awards under its 2014 Equity Incentive Plan (the "Plan"). Under the Plan, the Company is authorized to grant options or restricted stock for up to 2,000,000 shares of Common Stock. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 1,142,857 to 2,000,000. Options or restricted stock awards may be granted to employees, the Company's board of directors, and external consultants who provide services to the Company. Options and restricted stock awards granted under the Plan have vesting schedules with terms of one to three years and become fully exercisable based on specific terms imposed at the date of grant. The Plan will terminate according to the respective terms of the Plan in March 2024.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 10,304	\$ 4,072	\$ 32,193	\$ 3,318
General and administrative	181,140	74,941	482,120	208,427
	<u>\$ 186,445</u>	<u>\$ 79,013</u>	<u>\$ 514,313</u>	<u>\$ 211,745</u>

The following table summarizes stock option activity under the Plan:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2022	806,392	\$ 4.33		
Granted	—	—		
Exercised	—	—		
Forfeited	(122,697)	5.86		
Outstanding at September 30, 2023	683,695	\$ 3.99	3.2	\$ 254,225
Vested and exercisable at September 30, 2023	681,711	\$ 3.99	3.2	\$ 254,225

As of September 30, 2023, there was no unrecognized compensation cost related to non-vested stock options.

During the nine months ended September 30, 2023, no options were exercised. During the nine months ended September 30, 2022, 64,848 options were exercised for proceeds of \$74,900. During the nine months ended September 30, 2023, no options were issued by the Company to purchase shares of Common Stock. During the nine months ended September 30, 2022, the Company issued options to purchase 7,142 shares of Common Stock. The per share weighted-average fair value of the options granted during 2022 was estimated at \$2.84 on the date of grant.

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

	Number of restricted stock awards (RSA)	Weighted-average grant price	FMV on grant date	Vested number of RSA	Unvested number of RSA
Balance at December 31, 2022	114,920	\$ 3.56	\$ 409,437	79,814	35,106
Granted	326,068	1.86	607,313	227,760	98,308
Forfeited	(4,979)	2.76	(13,742)	(4,979)	—
Balance at September 30, 2023	436,009	\$ 2.30	\$ 1,003,008	302,595	133,414

During the nine months ended September 30, 2023, the Company issued restricted stock awards (RSAs) for 326,068 shares of Common Stock to employees, non-employees, and the board of directors. The shares vest in equal monthly installments over terms of between immediately up to three years, subject to the employees and non-employees providing continuous service through the vesting date. During the nine months ended September 30, 2023, 42,825 shares vested from RSAs granted prior to January 1, 2023, and 227,760 shares vested from RSAs granted during the nine months ended September 30, 2023.

During the nine months ended September 30, 2022, the Company issued RSAs for 14,999 shares of Common Stock to employees and non-employees. The shares vest in equal monthly installments over terms of between immediately up to one year, subject to the employees and non-employees providing continuous service through the vesting date. During the nine months ended September 30, 2022, approximately 21,000 shares vested from RSAs previously issued.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the options grants issued during the nine months ended September 30, 2022. No stock options have been issued during the nine months ended September 30, 2023:

	2023	2022
Fair value of Common Stock	\$ —	\$ 4.62
Volatility	—%	63.9%
Expected term (years)	—	6.0
Risk-free interest rate	—%	2.20%
Dividend yield	—%	0%

Note 13. WARRANTS

The Company accounts for Common Stock warrants as equity instruments. As of September 30, 2023, and December 31, 2022, the Company had 4,649,952 warrants outstanding to purchase one share of the Company's Common Stock for each warrant at a weighted average exercise price of \$5.03 and expire at various dates through September 2027. During the nine months ended September 30, 2023, no warrants were exercised into an equivalent number of Common Shares as compared to 1,036,486 warrants being exercised during the nine months ended September 30, 2022.

On September 17, 2023, the Company entered into a warrant amendment with certain holders of (i) tradeable warrants (the "Tradeable Warrants") to who have the right to purchase 73,568 shares of Common Stock; (ii) non-tradeable warrants (the "Non-Tradeable Warrants") who have the right to purchase 73,568 shares of Common Stock and (iii) other outstanding warrants (the "Pre-IPO Warrants") who have the right to purchase 1,109,475 shares of Common Stock. The warrant amendment provides that such warrants will not be exercisable until the date that the Company files a certificate of amendment to its certificate of incorporation with the State of Delaware which increases the number of shares of its authorized Common Stock to allow for sufficient authorized and unissued shares of Common Stock for the full exercise of all of the outstanding Pre-IPO Warrants, Tradeable Warrants, and Non-Tradeable Warrants of the Company and the issuance of all of the shares of Common Stock underlying such warrants.

Note 14. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the condensed consolidated financial statements were available to be issued. Based upon this review, the Company did not identify any subsequent events that would have required adjustment or disclosure in the condensed consolidated financial statements.

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

This section presents management's perspective on our financial condition and results of operations. The following discussion and analysis (the "MD&A") is intended to highlight and supplement data and information presented elsewhere in this Quarterly Report, and should be read in conjunction with our interim unaudited condensed consolidated financial statements and notes elsewhere in this Quarterly Report and our audited consolidated financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2022, included in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023 (the "2022 Form 10-K"). The MD&A is also intended to provide you with information that will assist you in understanding our consolidated financial statements, the changes in key items in those consolidated financial statements from year to year, and the primary factors that accounted for those changes. To the extent that this discussion describes prior performance, the descriptions relate only to the periods listed, which may not be indicative of our future financial outcomes. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties, and assumptions that could cause the Company's financial results to differ materially from management's expectations. Factors that could cause such differences are discussed in the "Cautionary Note Regarding Forward-Looking Statements" section of this Quarterly Report and in the "Risk Factors" section of the 2022 Form 10-K.

Data as of and for the nine months ended September 30, 2023 and 2022, has been derived from our unaudited condensed consolidated financial statements appearing at the beginning of this Quarterly Report. Results for any interim period should not be construed as an inference of what our results would be for any full fiscal year or future period.

Our MD&A is organized as follows:

- *Company Overview* – Discussion of our business plan and strategy to provide context for the remainder of the MD&A.
- *Results of Operations* – Analysis of our financial results comparing the nine months ended September 30, 2023, to the comparable period in 2022.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Estimates* – Accounting estimates that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

Company Overview

Business

bioAffinity Technologies, Inc. (the "Company," "bioAffinity Technologies," "we," or "our") develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We also are conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. We develop proprietary noninvasive diagnostic tests using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Research and optimization of our platform technologies are conducted in laboratories at our wholly owned subsidiary, Precision Pathology Laboratory Services, LLC ("PPLS"), and The University of Texas at San Antonio.

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

Through our wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC, our research has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells. We are focused on expanding our broad-spectrum platform technologies to develop tests that detect and therapies that target various types of cancer and potentially other diseases.

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

Recent Developments

In September 2023, the Centers for Medicare and Medicaid ("CMS") released a preliminary payment decision for a Current Procedural Terminology ("CPT") code for use with CyPath[®] Lung that had been issued by the American Medical Association ("AMA") in June, 2023. The CPT code became effective October 1, 2023, and is used for private payers and public health insurance programs. The CPT Proprietary Laboratory Analyses ("PLA") code assigned to CyPath[®] Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer." bioAffinity Technologies submitted comments during the 30-day comment period in support of the preliminary decision. In November 2023, CMS is expected to finalize the 2024 payment for CPT 0406U, which will be effective January 1, 2024. The recommended CMS payment amount will favorably impact PPLS' established fee schedule for CyPath[®] Lung determining reimbursement by private insurance carriers.

On September 18, 2023, PPLS, our wholly owned subsidiary, consummated the acquisition (the “Acquisition”) of a clinical anatomic and clinical pathology laboratory and related services business in San Antonio, Texas (the “Laboratory Assets”) pursuant to the terms of an Asset Purchase Agreement (the “Asset Purchase Agreement”) dated September 18, 2023 that we entered into with Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services (“Village Oaks”) and Dr. Roby P. Joyce, M.D. PPLS is accredited by the College of American Pathologists (“CAP”) and certified under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”). Founded in 2007 by Dr. Roby Joyce, the Medical Director and Laboratory Director of the clinical pathology laboratory prior to and after the Acquisition, Village Oaks has provided pathology services to physicians practicing in a variety of outpatient settings. Since September 2021, Village Oaks, under the trade name Precision Pathology Services, has offered CyPath® Lung for sale as a laboratory developed test (“LDT”) for the detection of early-stage lung cancer. In addition to CyPath® Lung, PPLS intends to continue to offer a range of laboratory services including respiratory testing for SARS-CoV-2 and influenza, anatomical pathology, morphological stains, histological services, DNA extractions, STI testing and women’s and men’s health testing.

Pursuant to the terms of the Asset Purchase Agreement, PPLS acquired the Laboratory Assets, which included all of the assets owned by Village Oaks other than medical assets, including the CLIA certification and CAP accreditation, which are assets Village Oaks used in connection with its management and operation of a clinical pathology laboratory, now owned by PPLS, and related services business and assumed certain liabilities and obligations. Pursuant to the terms of the Asset Purchase Agreement, Village Oaks received \$3,500,000 in consideration for the assets to be purchased by PPLS, of which \$1,000,000 was paid by the issuance of 564,972 shares of our restricted Common Stock to a trust controlled by Dr. Joyce (the “Joyce Trust”), which share number was determined by dividing \$1,000,000 by \$1.77, the average of the trading day closing prices for the 30 days prior to September 15, 2023, rounded to the nearest whole share.

Pursuant to the Asset Purchase Agreement, PPLS assumed all liabilities and obligations and obtained any and all rights, title and interest of Village Oaks in and to (i) all leases for equipment and personal property related to the Laboratory Assets (the “Assumed Leases”), pursuant to an Assumption Agreement by and between Village Oaks and PPLS (the “Assumption Agreement”); (ii) certain other contracts related to the Laboratory Assets, including the license to develop, manufacture, use, market, and sell CyPath® Lung (the “Assumed Contracts”) pursuant to the Assumption Agreement; (iii) all accounts payable of Village Oaks as of September 18, 2023, that were incurred in the ordinary course of business consistent with past custom and practice; and (iv) the lease of the premises used in connection with operation of the CLIA-certified and CAP-accredited clinical pathology laboratory, pursuant to an Assignment and Assumption of Lease by and between Village Oaks and PPLS (the “Assignment of Lease”).

In connection with the Asset Purchase Agreement, PPLS entered into various other agreements, including a Management Services Agreement with Village Oaks (the “Management Services Agreement”), a Succession Agreement with Village Oaks and Dr. Joyce (the “Succession Agreement”) and a Professional Services Agreement with Village Oaks (the “Professional Services Agreement”) pursuant to which PPLS will provide comprehensive management and administrative services to Village Oaks in connection with the operation of Village Oaks’ professional cytopathology, histopathology, and clinical and anatomic pathology interpretation medical services practice. PPLS will provide space, equipment, administrative, management and clinical personnel, billing and collection, and related management services to Village Oaks in exchange for a management fee of 70% of the net revenues received by Village Oaks from the provision of the medical services.

The Succession Agreement provides that Dr. Joyce, as holder of 100% of the issued and outstanding stock of Village Oaks, and Village Oaks are restricted from disposing of their equity interests in Village Oaks, subject to certain exceptions, without the prior written consent of us and Village Oaks.

Pursuant to a Professional Services Agreement, Village Oaks provides pathology interpretation services as requested on behalf of PPLS based on the professional fees approved for the CPT code for the services provided under the Medicare Physician Fee Schedule in the locality where the test is performed.

In connection with the Asset Purchase Agreement, we entered into an Executive Employment Agreement with Dr. Joyce (the “Joyce Employment Agreement”), for a term of three years, pursuant to which he serves as the Medical Director and Laboratory Director of PPLS, at a base salary of \$333,333 per year. Pursuant to the Joyce Employment Agreement, Dr. Joyce was also appointed to serve on our Board of Directors.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our diagnostic test, CyPath® Lung. As a result, since our inception in 2014, we have funded our operations principally through private sales of our equity or debt securities. As of September 30, 2023, we had cash and cash equivalents of \$4.5 million.

Prior to the Acquisition, Village Oaks, under the trade name Precision Pathology Services, had licensed and developed CyPath® Lung as an LDT for sale to physicians. The license agreement provided that revenues from the sale would be split evenly between the Company and Village Oaks. In the second quarter of 2022, prior to the Acquisition, we started to recognize revenue as part of a limited beta market testing program of the CyPath® Lung test. We have never been profitable, and as of September 30, 2023, we had total working capital of \$4.0 million and an accumulated deficit of approximately \$42.2 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and advance our diagnostic tests through clinical trials; however, we do expect revenue to increase due to the Acquisition. We intend to license our therapeutic products for clinical development should animal and pre-clinical studies prove successful.

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

Forecast

With the acquired revenue stream from PPLS, the Company's projected revenue over the next 12 months will significantly change. For the year ended December 31, 2022, Village Oaks generated net revenue of approximately \$6.9 million and net loss of approximately \$461,000 and for the six months ended June 30, 2023, Village Oaks generated revenue of approximately \$3.6 million and net loss of approximately \$493,000. The Company has consolidated in its net revenue \$283,000 of net revenues generated by PPLS for the provision of laboratory services for the period from September 19, 2023, through September 30, 2023 (September 18, 2023, being the date of the Acquisition). The laboratory revenue is projected to contribute between \$2.1 million and \$2.3 million of net revenues for 2023. These projections are based on historical average annual growth rates of 10% net revenues.

In addition to the forecasted PPLS revenue, CyPath[®] Lung adoption is expected to contribute \$456,000 gross revenues the next 12 months. The data points supporting these projections are: (1) learnings from the current beta market test of commercialization, (2) developed branding and marketing collateral, (3) increased onboarding of sales representatives, (4) additional publications of scientific data supporting the product, and (5) the CMS approval of payment for the AMA-approved CPT code specific for CyPath[®] Lung and the increase in the test price based on the expected CMS payment decision and its resulting impact on the PPLS established fee schedule for private insurance carriers. The table below provides the results of our beta market test program (2q2022-3q2023) on which we base our 12-month forecast (4q2023-3q2024) that is also provided.

	2q2022-3q2023 <i>Beta Test Results</i>	4q2023-3q2024 <i>Forecast</i>
ADOPTION METRICS		
HCPs - enrolled	20	82
HCPs - ordered	15	61
CyPath [®] Lung Tests ordered	44	284
Sales Representatives	2	5
Avg. HCP per Sales Rep	7.5	12.3
Avg. Test per Sales Rep	22.0	56.8
PENETRATION METRICS		
HCP in addressable market	1320	6261
Target segment of HCPs	244	782
Penetration % of target segment - enrolled	7.8%	10.5%
Penetration % of target segment - ordered	6.1%	7.8%
REVENUE		
Gross revenue	\$ 19,910	\$ 456,000

Notes:

- (1) HCP enrolled = the number of healthcare physicians ("HCP" comprising of pulmonologist, internists, family, and general practice physicians) who have enrolled as clients of PPLS with the purpose of ordering CyPath[®] Lung and, in *Forecast*, the addition number of HCPs forecasted to enroll.
- (2) HCP ordered = the number of healthcare physicians who have ordered one or more CyPath[®] Lung tests and, in *Forecast*, the additional number of HCPs who we forecast will order the test
- (3) CyPath[®] Lung Tests Ordered = number of CyPath[®] Lung tests ordered that result in revenue, and, in *Forecast*, the additional number of tests we forecast to be ordered and result in revenue
- (4) Sales Representatives = number of dedicated sales representatives employed by the Company. Beta Test Results reflect one sales representative in Austin/San Antonio area (2q2022 – present) and one sales representative in the Rio Grande Valley area, Texas (2q2023). Forecasted results reflect recent hire of our National Sales Director (3q23) and assume one additional sales representative in Houston (hire 4q23) and one additional sales representative in Dallas (hire 2q24)
- (5) Avg. HCP per Sales Rep = average number of HCPs who are ordering CyPath[®] Lung per sales representative assigned to the market area
- (6) Avg. Test per Sales Rep = average number of tests ordered that result in revenue per sales representative assigned to the market area.
- (7) HCP in addressable market = the Beta Test Market is comprised of the total number of HCPs in the Austin, San Antonio, and the Rio Grande Valley greater areas of Texas who have ordered procedures to diagnose pulmonary nodules.. The *Forecast* includes expansion of the addressable market to Houston and Dallas, Texas. Market data used to define the addressable market is based on a third-party commissioned report.
- (8) Target segment of HCPs = HCPs (largely pulmonologists) in the addressable markets who on an annual basis have ordered more than 50 procedures for patients who required further diagnosis of pulmonary nodules. Market data used to define the target segment of HCPs is based on a third-party commissioned report.
- (9) Penetration % of target segment – enrolled = the percentage of HCPs in the target segment who enrolled as clients of PPLS with the purpose of ordering CyPath[®] Lung. The *Forecast* calculates the percentage based on the number of HCPs in the target segment forecasted to be enrolled during the period indicated. The target segment is based on market data provided by a third-party commissioned report.
- (10) Penetration % of target segment – ordered = the percentage of HCPs in the target segment who ordered one or more CyPath[®] Lung tests. The *Forecast* includes HCPs forecasted to order the test as a percentage of the total target segment.

Results of Operations

Three Months Ended September 30, 2023, Compared to Three Months Ended September 30, 2022

Net loss for the three months ended September 30, 2023, was approximately \$2.3 million, compared to a net loss of approximately \$4.9 million for the three months ended September 30, 2022.

Revenue

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. Pre-acquisition, bioAffinity Technologies' revenue was generated in three ways for the nine months and three months, respectively, ended September 30, 2023: (1) royalties from the Company's diagnostic test, CyPath[®] Lung, (2) clinical flow cytometry services provided to Village Oaks related to the Company's CyPath[®] Lung test, and (3) CyPath[®] Lung tests purchased by the U.S. Department of Defense ("DOD") for an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath[®] Lung Assay (NCT05870592)," and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post-COVID-19 infection. The royalty income from CyPath[®] Lung and clinical flow cytometry services income, beginning September 19, 2023, are related party income, and therefore, eliminated from consolidated net revenues. See net revenue summarized in the table below.

In the first quarter of 2023, we engaged the marketing and advertising firms of Havas Health & You and Trinity Life Sciences to build the CyPath[®] Lung brand and position it for success in the cancer diagnostics sector. Havas Health & You, a large global health network, has created the branding to align with the need for a patient-friendly diagnostic that gives physicians another tool to assess the potential or presence of lung cancer in their high-risk patients. Trinity Life Sciences used the insights and analytics it gathered from healthcare practitioners to focus the short-term objectives of our marketing strategy for CyPath[®] Lung. The limited test market launch in South Texas is designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath[®] Lung test before expanding to a larger market.

For three months ended September 30 ,						
	2023			2022		
	Net Revenue	Related Party ¹	Consolidated	Net Revenue	Related Party ¹	Consolidated
Parent (bioAffinity Technologies):						
CyPath® Lung royalty income ¹	\$ 5,412	\$ (487)	\$ 4,925	\$ 1,150	-	\$ 1,150
Laboratory services ¹	7,423	(1,265)	6,158	-	-	-
Dept. of Defense study	4,500	-	4,500	-	-	-
Subsidiaries ((PPLS) and Controlling Interest Entity²:						
Patient fees	248,654	-	248,654	-	-	-
Histology fees	31,854	-	31,854	-	-	-
Medical director fees	2,392	-	2,393	-	-	-
Total net revenue	<u>\$ 300,236</u>	<u>\$ (1,752)</u>	<u>\$ 298,484</u>	<u>\$ 1,150</u>	<u>-</u>	<u>\$ 1,150</u>

¹ As of September 18, 2023 (date of the Acquisition), royalty and laboratory services income agreements are considered related parties and eliminated upon consolidation.

² The three months ended revenue for PPLS and its controlling interest entity, Village Oaks, only recognizes partial period of September 19 through September 30, 2023.

Cost of Sales

Historically, cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers for CyPath® Lung. Starting September 19, 2023, cost of sales also consists of consumable lab supplies, reagents, and direct labor from the patient and histology lab services.

Operating Expenses

	Three Months Ended September 30, ⁽¹⁾		Change in 2023 Versus 2022	
	2023	2022	\$	%
Operating expenses				
Research and development	\$ 330,400	\$ 319,800	\$ 10,600	3%
Clinical development	106,400	60,900	45,500	75%
Selling, general and administrative	2,023,900	595,700	1,428,200	240%
Depreciation and amortization	57,600	800	56,800	7100%
Total operating expenses	<u>\$ 2,518,300</u>	<u>\$ 977,200</u>	<u>\$ 1,541,100</u>	<u>158%</u>

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the three-month period ended September 30, 2023 and 2022, respectively.

Operating expenses totaled approximately \$2.5 million and \$1.0 million during the three months ended September 30, 2023 and 2022, respectively. The increase in operating expenses is the result of the following factors.

Research and Development Expenses

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

Research and development expenses totaled approximately \$330,400 and \$319,800 for the three months ended September 30, 2023, and 2022, respectively. The increase of approximately \$10,600, or 3%, for the three months ended September 30, 2023, compared to the same period in 2022, was primarily due to an increase in compensation costs and benefits as we added research personnel, as well as a related increase in costs for lab supplies and reagents. Additionally, equipment costs, including depreciation and maintenance costs, increased as we purchased capital equipment to support research and development efforts.

Clinical Development

Clinical development expenses totaled approximately \$106,400 and \$60,900 for the nine months ended September 30, 2023 and 2022, respectively. The increase of approximately \$45,500, or 75%, for the nine months ended September 30, 2023, compared to the same period in 2022, was primarily attributable to an increase in professional fees, including consulting fees, related to evaluating the clinical strategy in the prior year for our pivotal clinical trial designed to confirm the sensitivity and specificity of CyPath® Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate pulmonary nodules between 6mm and 30mm in size which often present a challenge in diagnosis.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately \$2.0 million and \$0.6 million for the three months ended September 30, 2023 and 2022, respectively. The increase of approximately \$1.4 million, or 240%, for the three months ended September 30, 2023, compared to the same period in 2022, was primarily attributable to accounting, legal and professional fee costs associated with the acquisition of PPLS (\$595,000), the accounting, legal and professional fee costs associated with the SEC filing of a registration statement on Form S-1 (\$197,000), increase in stock-based compensation (\$186,000), increase in employee compensation (\$238,000), increase in branding and marketing collateral (\$117,000), as well as an increase related to board compensation, public company expense, and other operational expenses. Patent costs increased in the current year as we maintain and expand our patent portfolio to protect our diagnostic and therapeutic platforms. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Other Income (Expense)

Other income (expense), net totaled approximately \$6,000 and \$3.9 million for the three-month period ended September 30, 2023 and 2022, respectively.

Interest Income (Expense), net

Interest income (expense), net was approximately \$18,400 for the three months ended September 30, 2023, compared to \$889,100 for the three months ended September 30, 2022.

Gain (loss) on change in fair value of convertible notes

There was a loss of approximately \$3.1 million on the change in fair value of convertible notes during the three months ended September 30, 2022, compared to no loss during the three months ended September 30, 2023. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term, and other assumptions during the reported periods. All convertible and bridge notes were converted as a result of our initial public offering (the “IPO”) in the prior year, resulting in no additional changes in fair value related to the convertible and bridge notes.

Nine Months Ended September 30, 2023, Compared to Nine Months Ended September 30, 2022

Net loss for the nine months ended September 30, 2023, was approximately \$5.6 million, compared to a net loss of approximately \$6.5 million for the nine months ended September 30, 2022.

Revenue

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. Pre-acquisition, bioAffinity Technologies’ revenue was generated in three ways for the nine months and three months, respectively, ended September 30, 2023: (1) royalties from the Company’s diagnostic test, CyPath® Lung, (2) clinical flow cytometry services provided to Village Oaks related to the Company’s CyPath® Lung test, and (3) CyPath® Lung tests purchased by the DOD for an observational study, “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay (NCT05870592),” and research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. The royalty income from CyPath® Lung and clinical flow cytometry services income, beginning September 19, 2023, are related party income, and therefore, eliminated from consolidated net revenues. See net revenue summarized in the table below.

In the first quarter of 2023, we engaged the marketing and advertising firms of Havas Health & You and Trinity Life Sciences to build the CyPath® Lung brand and position it for success in the cancer diagnostics sector. Havas Health & You, a large global health network, has created the branding to align with the need for a patient-friendly diagnostic that gives physicians another tool to assess the potential or presence of lung cancer in their high-risk patients. Trinity Life Sciences used the insights and analytics it gathered from healthcare practitioners to focus the short-term objectives of our marketing strategy for CyPath® Lung. The limited test market launch in South Texas is designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market.

	For the nine months ended September 30,					
	2023			2022		
	Net Revenue	Related Party ¹	Consolidated	Net Revenue	Related Party ¹	Consolidated
Parent (bioAffinity Technologies):						
CyPath® Lung royalty income ¹	\$ 13,164	\$ (487)	\$ 12,677	\$ 2,457	-	\$ 2,457
Laboratory services ¹	10,500	(1,265)	9,315	-	-	-
Dept. of Defense study	14,250	-	14,250	-	-	-
Subsidiaries (VOPS/PPLS)²:						
Patient fees	248,654	-	248,654	-	-	-
Histology fees	31,854	-	31,854	-	-	-
Medical director fees	2,393	-	2,393	-	-	-
Total net revenue	<u>\$ 320,895</u>	<u>\$ (1,752)</u>	<u>\$ 319,143</u>	<u>\$ 2,457</u>	<u>-</u>	<u>\$ 2,457</u>

¹ As of September 18, 2023 (date of the Acquisition), royalty and laboratory services income agreements are considered related parties and eliminated upon consolidation.

² The three months ended revenue for PPLS and its controlling interest entity, Village Oaks, only recognizes partial period of September 19 through September 30, 2023.

Cost of Sales

Historically, cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers for CyPath® Lung. Starting September 19, 2023, cost of sales also consists of consumable lab supplies, reagents and direct labor from the patient and histology lab services.

Operating Expenses

	Nine Months Ended September 30, ⁽¹⁾		Change in 2023 Versus 2022	
	2023	2022	\$	%
	(unaudited)			
Operating expenses				
Research and development	\$ 1,035,100	\$ 949,400	\$ 85,700	9%
Clinical development	161,300	141,700	19,600	14%
Selling, general and administrative	4,576,700	1,295,600	3,281,100	253%
Depreciation and amortization	100,800	2,800	98,000	3500%
Total operating expenses	<u>\$ 5,873,900</u>	<u>\$ 2,389,500</u>	<u>\$ 3,484,400</u>	<u>146%</u>

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the six-month period ended September 30, 2023 and 2022, respectively.

Operating expenses totaled approximately \$5.9 million and \$2.4 million during the nine months ended September 30, 2023 and 2022, respectively. The increase in operating expenses is the result of the following factors.

Research and Development Expenses

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

Research and development expenses totaled approximately \$1.0 million and \$0.9 million for the nine months ended September 30, 2023, and 2022, respectively. The increase of approximately \$85,700, or 9%, for the nine months ended September 30, 2023, compared to the same period in 2022, was primarily due to an increase in compensation costs and benefits due to additional research personnel, as well as a related increase in costs for lab supplies and reagents. Additionally, equipment costs, including depreciation and maintenance costs, increased as we purchased capital equipment to support research and development efforts.

Clinical Development

Clinical development expenses totaled approximately \$161,300 and \$141,700 for the nine months ended September 30, 2023, and 2022, respectively. The increase of approximately \$19,600, or 14%, for the nine months ended September 30, 2023, compared to the same period in 2022, was primarily attributable to a decrease in professional fees, including consulting fees, related to evaluating the clinical strategy in the prior year for our pivotal clinical trial designed to confirm the sensitivity and specificity of CyPath® Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate lung nodules between 6mm and 30mm in size which often present a challenge in diagnosis.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately \$4.6 million and \$1.3 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of approximately \$3.3 million, or 253%, for the nine months ended September 30, 2023, compared to the same period in 2022, was primarily attributable to accounting, legal, and professional fee costs associated with the acquisition of PPLS (\$811,000), the accounting, legal, and professional fee costs associated with the SEC filing of a registration statement on Form S-1 (\$197,000), increase in stock-based compensation (\$313,000), increase in employee compensation (\$628,000), increase in branding and marketing collateral (\$391,000), increase in directors and officers ("D&O") insurance (\$290,000), increase in public company-related expenses (\$294,000) as well as an increase related to board compensation (\$147,000), and other operational expenses. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Other Income (Expense)

Other income (expense), net totaled approximately \$85,700 and \$4.1 million for the nine-month period ended September 30, 2023 and 2022, respectively.

Interest Income (Expense), net

Interest income (expense), net was approximately \$98,200 for the nine months ended September 30, 2023, compared to \$2.4 million for the nine months ended September 30, 2022.

Gain (loss) on change in fair value of convertible notes

There was a loss of approximately \$1.9 million on the change in fair value of convertible notes during the nine months ended September 30, 2022, compared to no loss during the nine months ended September 30, 2023. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term, and other assumptions during the reported periods. All convertible and bridge notes were converted as a result of our IPO in the prior year, resulting in no additional changes in fair value related to the convertible and bridge notes.

Liquidity, Capital Resources, and Going Concern

To date, we have funded our operations primarily through our IPO, exercise of warrants, and the sale of our equity and debt securities, resulting in gross proceeds of approximately \$34.3 million. 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.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic test or therapeutic products to generate revenue. For the nine months ended September 30, 2023 and 2022, we had net losses of \$5.6 million and \$6.5 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$42.2 million as of September 30, 2023. Based on the Company's current expected level of operating expenditures and the cash and cash equivalents on hand at September 30, 2023, 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. Cash and cash equivalents were approximately \$4.5 million as of September 30, 2023. We need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. There can be no assurance that we will be successful in accomplishing these objectives.

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

Summary Statements of Cash Flows

The following information reflects cash flows for the periods presented:

	Nine Months Ended	
	September 30,	
	2023	2022
(amounts in thousands)		
Cash and cash equivalents at beginning of period	\$ 11,414	\$ 1,360
Net cash used in operating activities	(4,431)	(2,770)
Net cash used in investing activities	(2,216)	—
Net cash provided by (used in) financing activities	(258)	14,908
Cash and cash equivalents at end of period	<u>\$ 4,509</u>	<u>\$ 13,498</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$4.4 million and \$2.8 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of approximately \$1.4 million in cash used by operations during the nine months ended September 30, 2023, compared to the same period in 2022, was primarily attributable to an increase of \$916,000 in our loss from operations as compared to the prior year as described above.

Net Cash Used in Investing Activities

The Company used approximately \$2.2 million for the nine months ended September 30, 2023, in investing activities related primarily related to the Acquisition on September 18, 2023 and to a lesser extent to the purchase of computer and lab equipment, compared to no cash used in investing activities for the nine months ended September 30, 2022.

Net Cash Used by Financing Activities

Cash used in financing activities was approximately \$258,000 compared to cash proceeds in financing activities of approximately \$14.9 million for the nine months ended September 30, 2023 and 2022, respectively. The change in proceeds from prior year was primarily related to net proceeds from the IPO and exercise of warrants totaling \$13.8 million in September 2022.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials and other services and products used for research and development and operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that any non-cancelable obligations under these agreements are not material.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make significant judgments and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases these significant judgments and estimates on historical experience and other assumptions it believes to be reasonable based upon information presently available. Actual results could differ from those estimates under different assumptions, judgments, or conditions.

Patient Fee Revenues

We follow ASC 606, *Revenue from Contracts with Customers*, which requires revenue recognition in the period in which the service was performed. To be able to report timely net revenues for the period, estimates are used for a portion of uncollected balances. These estimates relate to 3rd party historical contractual discounts and adjustments (e.g. insurance providers) and patient historical uncollectible amounts. There can be a significant delay from the time a patient has been serviced to the invoicing of that service and then the net proceeds collected. Historical data is used to determine estimates for those “in service” revenues that have not been billed or collected at the reporting period.

Stock-Based Compensation

We follow ASC 718, *Compensation – Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, directors, and non-employees based on estimated fair values. We have used the Black-Scholes option pricing model to estimate grant date fair value for all option grants. The assumptions we use in calculating the fair value of share-based payment awards represent management’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. Since we use different assumptions based on a change in factors, our stock-based compensation expense could be materially different in the future.

Accounting for Income Taxes

We are governed by U.S. income tax laws, which are administered by the Internal Revenue Service (“IRS”). We follow ASC 740, *Accounting for Income Taxes*, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which the related temporary difference becomes deductible.

Emerging Growth Company Status

We are both an “emerging growth company” and a “smaller reporting company” as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and are therefore subject to reduced public company reporting requirements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a smaller reporting company, pursuant to Item 305(e) of Regulation S-K promulgated under the Securities Act, we are not required to provide the information required by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our “disclosure controls and procedures” (as defined in the Exchange Act) Rules 13a-15(e) and 15d-15(e)). Rule 13a-15(e) under the Exchange Act defines “disclosure controls and procedures” as controls and other procedures of a company that are designed to ensure that the 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 SEC’s rules and forms, and that such information is accumulated and communicated to a company’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that due to limited resources and the limited number of employees, its internal control over financial reporting was ineffective as of September 30, 2023, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. To mitigate the limited resources and employees, we rely heavily on direct management oversight of transactions, along with the use of legal and accounting professionals. As we grow, we expect to increase the number of employees, which we believe will enable us to implement adequate segregation of duties within the internal control framework.

Changes in Internal Control over Financial Reporting

As previously disclosed, on May 1, 2023, Michael Dougherty, Chief Financial Officer, joined the Company. Further segregation of duty over financial transactions and reconciliations have been put in place as of September 30, 2023. In addition, a new Senior Accountant was hired in July 2023 to increase the resources required to implement preparer and reviewer financial controls. A risk control approach has begun to evaluate all material risk, mitigating controls and identify any gaps related to financial reporting. In addition, the Company will rely on direct management oversight of transactions, along with the use of legal and accounting professionals. There have been no other changes to 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.

As a smaller reporting company, we are not required to provide disclosure pursuant to this Item 1A. However, in addition to other information set forth in this Quarterly Report, you should carefully consider the “Risk Factors” discussed in the 2022 Form 10-K filed with the SEC on March 31, 2023, pursuant to Rule 424(b)(4) under the Securities Act, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Quarterly Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition, and operating results. The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, “Risk Factors,” contained in our 2022 Form 10-K filed with the SEC on March 31, 2023. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2022 Form 10-K filed with the SEC on March 31, 2023.

Risks Related to the Acquisition

The combined company may not experience the anticipated strategic benefits of the Acquisition.

While we anticipate benefits from the Acquisition, we may not be able to realize the expected benefits. We may not be able to integrate the two businesses successfully, and despite due diligence we could assume previously unidentified or contingent liabilities. Ownership of a CAP/CLIA laboratory and related services business may not have the clinical value and commercial potential which we envision. Any substantive failure of the Acquisition to meet our expectations could have a material negative effect on our results of operations. There can be no assurance that the anticipated benefits of the Acquisition will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

We may be unable to successfully integrate the PPLS business with our current management and structure.

Our failure to successfully complete the integration of PPLS could have an adverse effect on our prospects, business activities, cash flow, financial condition, results of operations, and stock price. Integration challenges may include the following:

- assimilating and retaining former Village Oaks personnel who joined PPLS as part of the Acquisition;
- estimating the capital, personnel, and equipment required for the operation of PPLS based on the historical experience of management with the businesses they are familiar with; and
- minimizing potential adverse effects on existing business relationships.

We may not be able to enforce claims with respect to the representations, warranties, and indemnities that Village Oaks has provided to us under the Asset Purchase Agreement.

In connection with the Acquisition, Village Oaks has given certain representations, warranties, and indemnities. There can be no assurance we will be able to enforce any claims against Village Oaks’ breaches of such representations, warranties, or indemnities. Village Oaks’ liability with respect to breaches of such representations, warranties, and indemnities under the Asset Purchase Agreement may be limited, or the amount and coverage of any insurance obtained with respect to representations and warranties may be limited. Even if we ultimately succeed in recovering any amounts, we may temporarily be required to bear these losses ourselves.

We are unable to precisely estimate when we will begin to generate significant profit from revenue, if ever, from PPLS' services, nor to estimate the amount of profit or revenue that will be generated or the expenses that will be incurred.

We do not expect to immediately derive profit from revenue from PPLS' services. 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.

The market price of our common stock following the Acquisition may decline as a result of such Acquisition.

The market price of our common stock may decline as a result of the Acquisition for a number of reasons including if:

- investors react negatively to the prospects of our business after the Acquisition;
- the effect that the Acquisition has on our business and prospectus is not consistent with the expectations of financial or industry analysts; or
- after the Acquisition, the Company does not achieve the perceived benefits of the Acquisition as rapidly or to the extent anticipated by financial or industry analysts.

Operating a clinical laboratory is a new business for us, and the members of our management team have limited experience operating a CAP-accredited, CLIA-certified laboratory, which may limit the ability of investors to make an informed investment decision.

We have never operated a clinical laboratory. To date, only our Chief Operating Officer, Xavier Reveles, has operated a CAP-accredited, CLIA-certified clinical laboratory, and therefore it may be difficult for investors to analyze our ability to successfully operate a clinical laboratory. Our management team may not successfully or efficiently manage our transition to operating a CAP-accredited and CLIA-certified laboratory subject to significant regulatory oversight and reporting obligations. However, to ease the transition, Dr. Joyce, the Medical Director and Laboratory Director of Village Oaks prior to the Acquisition, continues to serve as the Medical Director and Laboratory Director of PPLS and continues to be an integral part of our management team. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition, and operating results.

Our stockholders will experience substantial dilution from the issuance of the consideration paid in connection with the Acquisition and may not realize a benefit from the Acquisition commensurate with the ownership dilution they will experience in connection with the Acquisition.

Our stockholders will experience substantial dilution from the issuance of the consideration paid in connection with the Acquisition. If after the Acquisition we are unable to realize the full strategic and financial benefits currently anticipated from the Acquisition, our securityholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the post-acquisition company is able to realize only part of the strategic and financial benefits currently anticipated from the Acquisition.

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 year ended December 31, 2022, we generated approximately \$5,000, and during the nine months ended September 30, 2023, we generated approximately \$283,000 in revenue from laboratory services for the period from September 19, 2023, through September 30, 2023. During the nine months ended September 30, 2023 we generated \$13,000 from royalties from sales of our first diagnostic test, CyPath[®] Lung, by Village Oaks, a CAP-accredited, CLIA-certified clinical pathology laboratory to which we had previously granted a license to develop CyPath[®] Lung for commercialization and to use, market, and sell CyPath[®] Lung as an LDT prior to the Acquisition, which license was assigned to and assumed by PPLS in connection with the Acquisition, that began a limited market launch in the second quarter of 2022 to pulmonologists in South Texas. During the nine months ended September 30, 2023, we also generated revenue from clinical flow cytometry services provided to Village Oaks related to CyPath[®] Lung in the approximate amount of \$9,000 and in connection with CyPath[®] Lung tests purchased by the DOD in the approximate amount of \$14,000 for an observational study.

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

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

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

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

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain the research and development efforts, diversify our diagnostic tests and therapeutic product offerings, or even continue our operations. A decline in the value of our Company could also cause 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 December 31, 2022, we had an accumulated deficit of \$36.7 million. As of September 30, 2023, we had an accumulated deficit of \$42.2 million. We need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that our cash resources are sufficient to continue operations through May 2024. Our future is dependent upon its ability to obtain financing and upon future profitable operations from the development of its 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, 2022, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2022, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

Unregistered Sales of Equity Securities

We did not sell any equity securities during the quarter ended September 30, 2023, in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC and as described below. We believe that each transaction was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof.

On July 1, 2023, we issued an aggregate of 71,715 restricted shares of our Common Stock to our seven directors, which shares of restricted stock will vest ratably over three months of continued service and which represents a restricted stock award to each director valued at \$18,750 granted by us to each of our directors each quarter during the calendar year as part of our director compensation policy.

Between July 1, 2023, and September 30, 2023, we issued an aggregate of 8,226 shares of our Common Stock to a consultant pursuant to the terms of a consulting agreement in consideration of services provided.

On August 9, 2023, we issued 26,315 restricted shares of our Common Stock to an officer pursuant to the terms of his employment agreement.

On September 18, 2023, we issued 564,972 shares of our Common Stock to the Joyce Trust pursuant to the terms of the Asset Purchase Agreement.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable.

ITEM 6. EXHIBITS.

Exhibit No.	Title of Document
3.1	<u>Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (Incorporated by reference as Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)</u>
3.2	<u>Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on June 16, 2022)</u>
3.3	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016 (Incorporated by reference as Exhibit 3.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)</u>
3.4	<u>Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
3.5	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021 (Incorporated by reference as Exhibit 3.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)</u>
3.6	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)</u>
3.7	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)</u>
4.1	<u>Form of Amendment to Common Share Purchase Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
4.2	<u>Form of Amendment to Initial Public Offering Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.1	<u>bioAffinity Technologies, Inc. Amended and Restated 2014 Equity Incentive Plan (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)</u>
10.2	<u>Amendment, effective as of August 1, 2023, to Employment Agreement, dated February 1, 2015, by and between the Registrant and Maria Zannes (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on July 28, 2023)</u>
10.3	<u>Asset Purchase Agreement, effective September 18, 2023, by and among, Precision Pathology Laboratory Services, LLC, Dr. Roby P. Joyce and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.4	<u>Subscription Agreement, dated September 18, 2023, by and between The Joyce Living Trust, dated March 19, 2013, and bioAffinity Technologies, Inc. (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.5	<u>Management Services Agreement, effective as of September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.6	<u>Succession Agreement, effective September 18, 2023, by and among, Precision Pathology Laboratory Services, LLC, Dr. Roby P. Joyce and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.7	<u>Professional Services Agreement, effective as of September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.8	<u>Executive Employment Agreement, dated September 18, 2023, by and between bioAffinity Technologies, Inc. and Roby Joyce, M.D. (Incorporated by reference as Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.9	<u>Assignment and Assumption of Lease Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.10	<u>Office Lease, dated July 31, 2019, by and between Village Oaks Pathology Services, P.A. and 343 West Sunset, LLC (Incorporated by reference as Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.11	<u>Assignment and Assumption Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.12	<u>Equipment Usage Attachment, dated effective as of August 9, 2019, by and between Gen-Probe Sales & Service, Inc., together with its subsidiaries and affiliates and Village Oaks Pathology Services, P.A. d/b/a Precision Pathology, as amended by that certain Amendment No. 1 to Equipment Usage Attachment dated November 2, 2020, as further amended by that certain Amendment No. 2 to Equipment Usage Attachment dated November 2, 2020, and as further amended by that certain Amendment No. 3 to Equipment Usage Attachment dated December 21, 2022 (Incorporated by reference as Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.13	<u>Master Agreement, dated as of January 29, 2015, by and between Leica Microsystems, Inc. and Precision Pathology, as amended by Amendment No. 1 to the Master Agreement, dated on or about April 4, 2018, as further amended by that certain Amendment No. 2 to Master Agreement, dated March 23, 2021 (Incorporated by reference as Exhibit 10.11 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>

10.14	<u>Strategic Relationship License Agreement, dated December 1, 2022, by and between Pathology Watch, Inc. and Precision Pathology Services (Incorporated by reference as Exhibit 10.12 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
10.15	<u>Bill of Sale signed by Village Oaks Pathology Services, P.A., effective as of September 18, 2023 (Incorporated by reference as Exhibit 10.13 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002</u>
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheet, (ii) Condensed Consolidated Statement of Operations, (iii) Condensed Consolidated Statement of Stockholders' Equity, (iv) Condensed Consolidated Statement of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104*	The cover page from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL
101.INS	Inline XBRL Instance Document *
101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *

* Filed herewith.

† Indicates management contract or compensatory plan.

SIGNATURES

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

BIOAFFINITY TECHNOLOGIES, INC.

(Registrant)

By: /s/ Maria Zannes

Maria Zannes

Chief Executive Officer, President, Founder, and Director

Date: November 14, 2023

By: /s/ Michael Dougherty

Vice President and Chief Financial Officer

Date: November 14, 2023

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended September 30, 2023

I, Maria Zannes, certify that:

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

Date: November 14, 2023

/s/ Maria Zannes

Maria Zannes

President and Chief Executive Officer
 (Principal Executive Officer)

Certification of the Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
For the Quarterly Period Ended September 30, 2023

I, Michael Dougherty, certify that:

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

Date: November 14, 2023

/s/ Michael Dougherty

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

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

In connection with the Quarterly Report on Form 10-Q of bioAffinity Technologies, Inc., a Delaware Corporation (“Company”), for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (“Report”), each of the undersigned officers of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer’s knowledge:

- 1) the Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of September 30, 2023 (the last date of the period covered by the Report).

/s/ Maria Zannes

Maria Zannes
President and Chief Executive Officer
(Principal Executive Officer)
Date: November 14, 2023

/s/ Michael Dougherty

Michael Dougherty
Vice President and Chief Financial Officer
(Principal Financial Officer)
Date: November 14, 2023
