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 for the period ended September 30, 2022

□ **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	**46-5211056**
(State of Incorporation)	(I.R.S. Employer Identification No.)
22211 W. Interstate 10, Suite 1206, San Antonio, Texas	**78257**
(Address of principal executive offices)	(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	Name of each exchange on which registered
Common Stock, par value $.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 □	Accelerated filer □
Non-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 10, 2022 was 8,369,750.

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 subsidiary, OncoSelect® Therapeutics, LLC, a Delaware limited liability company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- the success, cost and timing of our clinical trials;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our diagnostic tests or therapeutic product candidates;
- our dependence on third parties in 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 tests or future diagnostic 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;
- our reliance on third parties;
- 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 tests and therapeutic product candidates, the size and growth of the potential markets for our current diagnostic tests 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 ongoing 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;
- our anticipated uses of net proceeds from our initial public offering ("IPO");
- 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, escalating tensions between China and Taiwan, increasing economic uncertainty and inflationary pressures, the evolving nature of the COVID-19 pandemic 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 and ir.bioaffinitytech.com) and at times our corporate Twitter account (@bioAffinity) and LinkedIn account (www.linkedin.com/company/bioaffinitytechnologies) to distribute company information. The information we post through these channels may be deemed material. Accordingly, investors should monitor these channels and review our press releases, filings with the SEC and public conference calls and webcasts. In addition, investors and others can be automatically notified in real time when new information is posted on our websites by visiting the homepage of our Company website at www.bioaffinitytech.com and subscribing to "News from bioAffinity Technologies" or visiting the "Email Alerts" section of our investor relations website at ir.bioaffinitytech.com/news-events/email-alerts and enrolling an email address. Information contained on or that can be accessed through our websites and social media channels are not, however, incorporated by reference in this Quarterly Report. Investors should not consider any such information to be part of this Quarterly Report.

FORM 10 – Q
TABLE OF CONTENTS

PART I
FINANCIAL STATEMENTS

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED).

BIOAFFINITY TECHNOLOGIES, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,497,938	$ 1,360,638
Accounts and other receivables, net	9,930	1,530
Inventory	5,715	—
Prepaid and other current assets	541,323	76,065
Total current assets	14,054,906	1,438,233
Deferred offering costs	—	7,942
Property and equipment, net	1,781	4,633
Other assets	6,000	2,500
Total assets	$ 14,062,687	$ 1,453,308
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 149,867	$ 230,407
Accrued expenses	474,035	483,501
Accrued interest	25,168	1,121,392
Current portion of Paycheck Protection Program loan	—	52,074
Loan payable	490,117	—
Convertible notes payable	325,000	11,152,151
Total current liabilities	1,464,187	13,039,525
Paycheck Protection Program loan, less current portion	—	160,184
Total liabilities	1,464,187	13,199,709
Commitments and contingencies (See Note 9)		
Convertible preferred stock, par value $0.001 per share; 20,000,000 shares authorized; 0 and 5,296,044 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively; aggregate liquidation preference of $0 and $5,825,648, at September 30, 2022 and December 31, 2021, respectively	—	4,044,318
Stockholders' equity (deficit):		
Preferred stock, no shares issued or outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, par value $0.007 per share; 14,285,714 shares authorized; 8,369,750 issued and outstanding at September 30, 2022; and 2,677,140 shares issued and outstanding at December 31, 2021, respectively	58,588	18,740
Additional paid-in capital	47,532,797	12,703,896
Accumulated deficit	(34,992,885)	(28,513,355)
Total stockholders' equity (deficit)	12,598,500	(15,790,719)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 14,062,687	$ 1,453,308

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

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 1,150	$ —	$ 2,457	$ —
Cost of sales	146	—	292	—
Gross profit	1,005	—	2,165	—
Operating expenses:				
Research and development	319,744	330,772	949,388	877,674
Clinical development	60,941	33,972	141,684	78,241
General and administrative	596,476	161,549	1,298,409	591,155
Total operating expenses	977,161	526,293	2,389,481	1,547,070
Loss from operations	(976,156)	(526,293)	(2,387,316)	(1,547,070)
Other income (expense):				
Interest income	3	19	850	24
Interest expense	(889,091)	(135,359)	(2,435,941)	(363,828)
Gain on extinguishment of debt	—	—	212,258	239,200
Fair value adjustments on convertible notes payable	(3,053,914)	(852,161)	(1,866,922)	924,099
Net loss before provision for income taxes	(4,919,158)	(1,513,794)	(6,477,071)	(747,575)
Income tax expense	300	—	2,459	1,950
Net loss	$ (4,919,458)	$ (1,513,794)	$ (6,479,530)	$ (749,525)
Net loss per common share, basic and diluted	$ (1.17)	$ (0.57)	$ (2.03)	$ (0.28)
Weighted average common shares outstanding	4,203,781	2,675,054	3,194,765	2,674,924

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

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

For the Three and Nine Months Ended September 30, 2022

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
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	—	—	17,319	121	132,611	—	132,732
Beneficial conversion feature for bridge notes	—	—	—	—	213,942	—	213,942
Return of capital from stock split	—	—	—	—	(185)	—	(185)
Debt discount for warrants issued	—	—	—	—	217,973	—	217,973
Net loss	—	—	—	—	—	(1,560,072)	(1,560,072)
Balance at June 30, 2022	—	$ —	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	—	—	—	—	—	(4,919,458)	(4,919,458)
Balance at September 30, 2022 (Unaudited)	—	$ —	8,369,750	$ 58,588	$ 47,532,797	$ (34,992,885)	$ 12,598,500

For the Three and Nine Months Ended September 30, 2021

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2020	756,558	$ 4,044,318	2,674,860	$ 18,724	$ 7,095,355	$ (22,186,942)	$ (15,072,863)
Stock-based compensation expense	—	—			152,837	—	152,837
Net income	—	—	—	—	—	764,269	764,269
Balance at June 30, 2021	756,558	$ 4,044,318	2,674,860	$ 18,724	$ 7,248,192	$ (21,422,673)	$ (14,155,757)
Stock-based compensation expense	—	—	912	6	(20,312)	—	(20,306)
Net loss	—	—	—	—	—	(1,513,794)	(1,513,794)
Balance at September 30, 2021 (Unaudited)	756,558	$ 4,044,318	2,675,772	$ 18,730	$ 7,227,880	$ (22,936,467)	$ (15,689,857)

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

BIOAFFINITY TECHNOLOGIES, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (6,479,530)	$ (749,525)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,852	4,023
Accretion of debt issuance costs	1,972,948	—
Fair value adjustments on convertible notes payable	1,866,922	(924,099)
Stock-based compensation expense	211,745	132,531
Gain on extinguishment of debt	(212,258)	(239,200)
Changes in operating assets and liabilities:		
Accounts and other receivables	(8,400)	—
Inventory	(5,715)	—
Prepaid expenses and other assets	(502,177)	(51,760)
Accounts payable	(80,725)	68,100
Accrued expenses	(1,524)	(269)
Accrued interest	465,653	363,661
Net cash used in operating activities	(2,770,209)	(1,396,538)
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	212,258
Payment on loans payable	(31,612)	—
Proceeds from issuance of convertible notes payable	724,000	1,345,000
Repayment of convertible loan payable	(100,000)	—
Payment of debt issuance costs	(55,651)	—
Net cash provided by financing activities	14,907,509	1,557,258
Net increase in cash and cash equivalents	12,137,300	160,720
Cash and cash equivalents at beginning of period	1,360,638	83,108
Cash and cash equivalents at end of period	$ 13,497,938	$ 243,828
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	$ 2,459	$ 1,950
Interest expense paid in cash	$ 3,945	—
Noncash financing activities:		
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	$ 352,250	—
Beneficial conversion feature for bridge notes	$ 379,665	—

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

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

Description of Business

bioAffinity Technologies, Inc., a Delaware corporation (the "Company," "we," or "our"), addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung and for targeted cancer treatment. Our Company develops proprietary noninvasive diagnostic tests and cancer therapeutics using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Our first diagnostic test, CyPath® Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. Research and optimization of our proprietary platform for *in vitro* diagnostics and technologies are conducted in our laboratories at The University of Texas at San Antonio. We are developing our platform technologies so that, in the future, they will be able to detect, monitor, and treat diseases of the lung and other cancers.

Organization and Initial Public Offering

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 September 6, 2022, the Company completed its initial public offering (the "IPO") of 1,282,600 units (the "Units") at an offering price of $6.125 per Unit (the "Offering Price"). Each Unit consists of (i) one share of the Company's common stock, par value $0.007 per share ("Common Stock"), (ii) one tradeable warrant (a "Tradeable Warrant") exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and (iii) one non-tradeable warrant (a "Non-tradeable Warrant") exercisable for the purchase of one share of Common Stock at an exercise price of $7.656 per share. The sale of Units in the IPO generated gross proceeds to the Company of approximately $7.8 million before deducting underwriting discounts, commissions, and other offering expenses. The Company intends to use the net proceeds from the Offering for working capital and for general corporate purposes, including product and test development, general and administrative matters, and capital expenditures.

In connection with the closing of the IPO (the "IPO Closing"), the Company converted 5,296,044 shares of the convertible preferred stock into 756,558 shares of Common Stock ("Common Shares"). Additionally, the Company converted approximately $10.6 million in convertible notes, bridge notes and related accrued interest into 2,533,964 Common Shares.

In June 2022, the Company completed a 1-for-7 reverse stock split of its Common Stock. All share and per share amounts have been adjusted on a retroactive basis in these condensed consolidated financial statements to reflect the effect of the reverse stock split. In addition, the stock split resulted in the par value of the Company's Common Stock increasing to $0.007 per share.

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. Operating results for the periods presented are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2022 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 our final IPO prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on September 2, 2022 (the "Final Prospectus").

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 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 $35.0 million at September 30, 2022. Our cash and cash equivalents at September 30, 2022 were approximately $13.5 million, representing 96% of our total assets. Based on our current expected level of operating expenditures, the Company believes its cash on hand at September 30, 2022 is sufficient to fund the Company's ongoing operations for a period of a least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Thereafter, 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.

COVID-19

The rapid global spread of the COVID-19 virus since December 2019 has affected production and sales worldwide, disrupted supply chains across a range of industries, and created significant economic volatility. The impact of COVID-19 on the Company's operational and financial performance will depend on numerous factors, including the spread, duration, and intensity of the pandemic (including resurgences), the emergence of new viral variants, and the impact of the pandemic on the Company's customers, employees, clinical trial sites, and vendors.

As the COVID-19 pandemic continues to evolve, the ultimate impact of the pandemic on the Company's operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, additional or modified government actions, and the actions taken to contain COVID-19 or address its impact, among others. Management does not yet know the full extent of potential delays or impacts on the Company, clinical trials, research programs, healthcare systems or the global economy but continues to monitor the situation closely.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. 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 fair value of the Company's Common Stock used to measure stock-based compensation for options granted to employees and non-employees; the valuation allowance on the Company's deferred tax assets; and the fair value of the convertible notes payable.

Principles of Consolidation

The accompanying consolidated financial statements include all of the accounts of the Company and its wholly owned subsidiary, OncoSelect® Therapeutics, LLC. All significant intercompany balances and transactions have been eliminated.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly related to the Company's equity financings, including its IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the financing. The Company capitalized certain legal, accounting and other third-party fees that were directly related to the Company's IPO. After the completion of the IPO in September 2022, total deferred offering costs of approximately $1.8 million were offset against the proceeds from the IPO and reclassified to additional paid-in capital in the accompanying condensed balance sheets. At December 31, 2021, deferred offering costs totaling approximately $8,000 were included as non-current assets in the accompanying condensed balance sheet.

Loss Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of Common Shares outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to common stockholders by the sum of the weighted-average number of Common Shares outstanding during the period and the weighted-average number of dilutive Common Share equivalents outstanding during the period, using the treasury stock method. Dilutive Common Share 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 outstanding as of September 30, 2022 and 2021, as they would be anti-dilutive:

	As of September 30,	
	2022	2021
Convertible preferred stock	—	756,558
Shares underlying options outstanding	806,392	828,386
Shares underlying warrants outstanding	4,624,952	6,428
Shares underlying convertible notes outstanding	83,373	1,591,372
	5,514,717	3,182,744

Revenue Recognition

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee, that began a limited market launch in the second quarter of 2022 to pulmonologists in the San Antonio, Texas, area designed to refine future positioning and develop strategic insight for our CyPath® Lung test. The services are completed upon release of a patient's test result to the ordering healthcare provider.

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.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12). ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistency in application. ASU 2019-12 will be effective for public entities for interim and annual periods beginning after December 15, 2020, with early adoption permitted. The Company adopted ASU 2019-12 and concluded there is no impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and simplifies the diluted earnings per share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. The new standard will be effective for fiscal years beginning after December 15, 2023 for smaller reporting companies. The Company has not yet determined the potential impact the adoption may have on our consolidated financial statements.

Note 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

	September 30, 2022	December 31, 2021
Insurance	$ 471,270	$ 16,765
Legal and professional	61,219	55,081
Other	8,834	4,219
Total prepaid expenses and other current assets	$ 541,323	$ 76,065

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	September 30, 2022	December 31, 2021
Lab equipment	$ 242,168	$ 242,168
Computers and software	21,463	21,463
	263,631	263,631
Accumulated depreciation	(261,850)	(258,998)
Total property and equipment, net	$ 1,781	$ 4,633

Depreciation and amortization expense was approximately $800 and $1,200 for the three months ended September 30, 2022, and 2021, respectively. Depreciation and amortization expense was approximately $2,900 and $4,000 for the nine months ended September 30, 2022, and 2021, respectively.

Note 5. ACCRUED EXPENSES

Accrued expenses are summarized below:

	September 30, 2022	December 31, 2021
Compensation	$ 231,628	$ 277,185
Legal and professional	188,524	166,069
Clinical	49,630	39,482
Other	4,253	765
Total accrued expenses	$ 474,035	$ 483,501

Note 6. LOAN PAYABLE

In March 2021, the Company received a second U.S. Small Business Administration (the "SBA") Paycheck Protection Program ("PPP") Loan for $0.2 million bearing interest at a one percent (1.0%) fixed annual rate, and will mature in two years, and is eligible for forgiveness under certain conditions. In light of the technical two-year nature of the loan, the Company presented a portion of the PPP balance as a current liability. In April 2022, the Company received forgiveness from the SBA. The Company recorded a gain of $0.2 million on the extinguishment of debt in the accompanying condensed consolidated statements of operations in each of the nine months ended September 30, 2022 and 2021, respectively.

In September 2022, the Company obtained short-term financing of approximately $0.5 million with ten monthly payments of approximately $42,000 and interest at a 4.3% fixed annual rate for director and officer insurance policies.

Note 7. CONVERTIBLE NOTES PAYABLE

In September 2022, in connection with the closing of the IPO, the Company converted approximately $10.6 million in convertible notes, bridge notes and related accrued interest into 2,533,964 shares of Common Stock.

From August 2018 through July 2020, the Company issued a total of $5.0 million in notes payable, including $2.6 million to related parties, which were convertible into the next class of equity securities in which the Company issued and sold equity securities with aggregate gross proceeds of at least $5.0 million. The conversion price was determinable as seventy percent (70%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing had occurred, and the note was still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. The convertible notes payable had a maturity date of December 31, 2020, and bore interest at 8% annually, and was secured by the intellectual property of the Company. The Company obtained the necessary noteholder approvals to extend the maturity date of the notes in November 2021 to May 31, 2022, and in May 2022 to August 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date from August 31, 2022, to October 31, 2022 for certain bridge notes in exchange for a Common Stock purchase warrant equal to the principal amount of each note divided by 10.5. As a result, the Company issued warrants to purchase 478,446 shares of Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, the notes automatically converted into shares of Common Stock. Conversion of the note at the IPO Closing extinguished this security and resulted in the Company wholly owning all its intellectual property without a security interest.

From October 2020 through June 2021, the Company issued a total of $1.0 million in notes payable, including $0.4 million to related parties, which were convertible into the next class of equity securities in which the Company issued and sold equity securities with aggregate gross proceeds of at least $5.0 million. The conversion price was determinable as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing had occurred, and the note was still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. The convertible notes payable bore interest at 8% annually and had a maturity date in October 2021. The Company obtained the necessary noteholder approvals to extend the maturity date of the notes in December 2021 to May 2022 and in May 2022 to August 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date from August 31, 2022, to October 31, 2022 for certain bridge notes in exchange for a Common Stock purchase warrant equal to the principal amount of each note divided by 10.5. As a result, the Company issued warrants to purchase 79,795 shares of the Company's Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, the $0.9 million of the notes automatically converted into shares of Common Stock. In October 2022, the Company repaid $100,000 for the note that was not converted at the time of the Company's IPO.

In the second and third quarters of 2021, the Company issued a total of approximately $0.9 million in additional notes payable, including $0.1 million to related parties, which were convertible into the next class of equity securities in which the Company issued and sold equity securities with aggregate gross proceeds of at least $5.0 million. The conversion price was determinable as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing had occurred, and the note was still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. The terms provided that upon completion of a bridge financing sufficient to provide working capital to complete an IPO, the notes would be convertible into the Company's equity securities on the same terms as the conversion feature established in the bridge financing. The convertible notes payable had a maturity date in December 2022 and bore interest at 8% annually. Upon completion of the IPO, the notes automatically converted into shares of Common Stock.

Bridge Notes

In the fourth quarter of 2021 and the first quarter of 2022, the Company issued a total of $2.6 million in bridge notes, which were convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at $4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bore interest at 6% and had a maturity date of May 31, 2022. In May 2022, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to August 31, 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date to October 31, 2022, for certain bridge notes in exchange for a Common Stock purchase warrant equal to principal amount of the note divided by 10.5. As a result, the Company issued warrants to purchase 199,986 shares of the Company's Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, approximately $2.3 million the notes automatically converted into shares of Common Stock. In October 2022, the Company repaid $175,000 for those notes that were not converted at the time of the Company's IPO.

Additionally, each noteholder received a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to $5.25 per share. In connection with the IPO, we paid commissions of nine percent (9%) and issued our placement agent a warrant to purchase 29,464 shares of Common Stock. The warrant issued to our placement agent has substantially the same terms as the warrants issued to our noteholders.

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the consolidated statements of operations until the convertible notes are settled. The fair value of the convertible notes was determined with the assistance of a third-party specialist, considering the value of the notes payable that would be received by converting into common stock in each scenario, plus a put option. In coordination with the Company's IPO, the notes were converted to Common Stock. Convertible notes payable consisted of the following at December 31, 2021:

	September 30, 2022	December 31, 2021
Secured convertible notes payable	$ 5,041,957	$ 5,041,957
Unsecured convertible notes payable	4,364,000	3,740,000
Principal amount of convertible notes payable	9,405,957	8,781,957
Debt issuance costs	—	(1,185,382)
Fair value adjustments on convertible notes payable	5,422,498	3,555,576
Conversion on IPO	(14,503,455)	3,555,576
Total convertible notes payable	$ 325,000	$ 11,152,151

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 receivable, prepaid and other expenses, accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments. The table below summarizes the Company's assets and liabilities that are measured at fair value at September 30, 2022 and December 31, 2021, respectively:

	Fair value measured at September 30, 2022			
	Total at September 30, 2022	Using Quoted Prices in active markets (Level 1)	Using Significant other observable inputs (Level 2)	Using Significant unobservable inputs (Level 3)
Convertible notes payable	$ 325,000	$ —	$ 325,000	$ —

	Fair value measured at December 31, 2021			
	Total at December 31, 2021	Using Quoted Prices in active markets (Level 1)	Using Significant other observable inputs (Level 2)	Using Significant unobservable inputs (Level 3)
Convertible notes payable	$ 11,152,151	$ —	$ —	$ 11,152,151

A description of the valuation techniques and the values used for significant unobservable inputs to derive fair value measurements for those assets and liabilities measured at fair value at and December 31, 2021:

	Fair Value	Valuation Technique	Unobservable Input	Range (Weighted Average)
Convertible notes payable at December 31, 2021	$ 11,152,151	Risky Put + Stock Payoff	Probability weighting assigned to automatic and optional conversion scenarios	90%/10%
			Applied discount rate	79.1%
			Common share class volatility	46.1%
			Preferred stock class volatility	3.9%
			Negotiation discount	1.6%

The Company transferred $325,000 of convertible notes payable from level 3 to level 2 during the nine months ended September 30, 2022, to account for notes that were not converted at the time of the Company's IPO. See Note 7. There were no transfers into or out of level 3 during the nine months ended September 30, 2021. The Company issued a total of $0.7 million and $0.5 million in convertible notes during for the nine months ended September 30, 2022, and 2021, respectively, which are included in the level 3 liabilities. The following table summarizes the fair values of convertible note payables and the change in fair value at each measurement date:

Fair value of convertible notes payable at December 31, 2021	$ 11,152,151
Additional convertible notes payable issued	724,000
Repayment of convertible notes payable	(100,000)
Debt discount for warrants issued	(787,566)
Accretion of debt issuance costs	1,972,948
Change in fair value of convertible notes payable	1,866,922
Transfer from level 3 to level 2	(325,000)
Conversion of convertible notes payable	(14,503,455)
Fair value of convertible notes payable at September 30, 2022 (Unaudited)	$ —

Fair value of convertible notes payable at December 31, 2020	$	9,767,461
Additional convertible notes payable issued		3,295,000
Debt discount for warrants issued		(1,665,956)
Accretion of debt issuance costs		480,574
Change in fair value of convertible notes payable		(724,928)
Fair value of convertible notes payable at December 31, 2021	$	11,152,151

Note 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its corporate offices under an agreement that is renewable on September 1, 2023. The Company 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 2023. Rent expense for office and lab space amounted to approximately $15,000 and $13,000 for each of the three months ended September 30, 2022 and 2021, respectively. Rent expense for office and lab space amounted to approximately $41,000 and $39,000 for each of the nine months ended September 30, 2022 and 2021, 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 had no material pending legal proceedings.

Note 10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

In June 2022, the Company completed a 1-for-7 reverse stock split of its Common Stock. All share and per share amounts have been adjusted on a retroactive basis in these condensed consolidated financial statements to reflect the effect of the reverse stock split. The Company will make a cash payment to stockholders for all fractional shares that it would otherwise be required to issue as a result of the stock split. In addition, the stock split resulted in the par value of the Company's Common Stock increasing to $0.007 per share.

Convertible Preferred Stock

The Company has authorized a total of 20,000,000 shares of preferred stock, $0.001 par value per share. Prior to the IPO, the Company issued 5,296,044 shares of preferred stock, designated as Series A. In July 2017, the Company completed a private placement of securities in which 1.3 million shares of Series A Preferred Stock were sold, resulting in net proceeds of $1.5 million. As part of the closing, the Company issued 4.0 million shares of Series A Preferred Stock in exchange for $2.6 million of the Company's convertible notes payable and related accrued interest.

In accordance with the Certificate of Designation of the Series A Preferred Stock, all of the shares of Series A Preferred Stock that were issued and outstanding at the time of the IPO Closing were automatically converted into 745,558 fully paid and nonassessable shares of Common Stock at a 1-for-7 conversion rate (as adjusted for the 1-for-7 reverse stock split). The shares of Series A Preferred Stock that were so converted ceased to be part of the Company's authorized stock and will never again be issued by the Company. As of September 30, 2022, no Preferred Stock is outstanding.

Common Stock

The Company has authorized a total of 14,285,714 shares of Common Stock, $0.007 par value per share. In November 2021, the Company received stockholder approval to increase the number of authorized shares from 7,142,857 shares to 14,285,714 shares. As of September 30, 2022, the Company has issued 8,369,750 shares of Common Stock.

Note 11. STOCK-BASED COMPENSATION

The Company grants options under its 2014 Equity Incentive Plan (the "Plan"). Under the Plan, the Company is authorized to grant options for up to 1.1 million shares of Common Stock. The Company has reserved 1.0 million shares to be used under the Plan. Options may be granted to employees, the Company's board of directors and external consultants who provide services to the Company. Options granted under the Plan have vesting schedules with terms of one to four 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 September 2026.

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

	Nine Months Ended September 30,	
	2022	2021
Research and development	$ 3,318	$ 12,094
General and administrative	208,427	120,437
	$ 211,745	$ 132,531

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, 2021	878,380	$ 4.12		
Granted	7,142	4.20		
Exercised	(64,848)	1.16		
Forfeited	(14,282)	5.95		
Outstanding at September 30, 2022	806,392	$ 4.33	4.3	$ 647,793
Vested and exercisable at September 30, 2022	787,746	$ 4.31	4.1	$ 647,793

As of September 30, 2022, there was no unrecognized compensation cost related to non-vested stock options. During the nine months ended September 30, 2022, 64,848 options were exercised for proceeds of approximately $75,000. During the nine months ended September 30, 2021, no options were exercised.

During the nine months ended September 30, 2022, the Company issued options to purchase 7,142 shares of Common Stock to a non-employee. The per share weighted-average fair value of the options granted during 2022 was estimated at $2.84 on the date of grant.

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

During the nine months ended September 30, 2021, the Company issued options to purchase 29,279 shares of Common Stock and 11,752 RSUs. The per share weighted-average fair value of the options granted during 2021 was estimated at $1.85 on the date of grant.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the nine months ended September 30, 2022 and 2021, respectively:

	2022	2021
Fair value of Common Stock	$ 4.62	$ 3.08
Volatility	63.9%	88.1%
Expected term (years)	6.0	6.2
Risk-free interest rate	2.20%	0.92%
Dividend yield	0%	0%

Note 12. WARRANTS

We account for Common Stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Warrants are accounted for as derivative liabilities if the warrants allow for cash settlement or provide for modification of the warrant exercise price in the event subsequent sales of Common Stock by the Company are at a lower price per share than the then-current warrant exercise price. We classify derivative warrant liabilities on the condensed consolidated balance sheet at fair value, and changes in fair value during the periods presented in the condensed consolidated statement of operations, which is revalued at each balance sheet date subsequent to the initial issuance of the stock warrant. During the nine months ended September 30, 2022, 1,036,486 warrants were exercised into an equivalent number of Common Shares for proceeds of approximately $7.7 million. During the nine months ended September 30, 2021, no warrants were exercised into an equivalent number of Common Shares.

In September 2022, in connection with our IPO, we issued a total of 1,282,600 Tradeable Warrants, each exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and 1,282,600 Non-tradeable Warrants, each exercisable for the purchaseof one share of Common Stock at an exercise price of $7.656 per share. The Common Stock and the Tradeable Warrants trade on The Nasdaq Capital Market under the symbols “BIAF’ and “BIAFW”, respectively.

Pursuant to the underwriting agreement dated August 31, 2022 (the “Underwriting Agreement”) between the Company and WallachBeth Capital, LLC, as representative of the underwriters (the “Underwriters”), and solely for purposes of covering any over-allotments made in connection with our IPO, we granted the Underwriters an option to purchase up to an additional 192,390 shares of Common Stock at the Offering Price per Unit less $0.02, and/or up to 192,390 Tradeable Warrants at $0.01 per Tradeable Warrant, and/or up to 192,390 Non-tradeable Warrants at $0.01 per Non-tradeable Warrant, or any combination of additional shares of Common Stock, Tradeable Warrants, and Non-tradeable Warrants representing, in the aggregate, up to 15% of the number of Units sold in the IPO (the “Over-Allotment Option”). The Over-Allotment Option was exercisable for a period of 45 days from the date of our Final Prospectus. The Underwriters exercised a portion of their overallotment option and purchased 110,167 Tradeable Warrants at a purchase price of $0.01 per warrant, and 110,167 non-tradable warrants at a purchase price of $0.01 per warrant.

In 2022, the Company issued $724,000 in convertible promissory notes (“Bridge Notes”), which accrued interest at a rate of 6% per year. Originally, all principal and unpaid interest on the Bridge Notes was due, if not settled prior, on May 31, 2022. See Note 7. Each Bridge Note was issued with an accompanying warrant to purchase one share of the Company’s Common Stock for each conversion share based on the principal balance of each Bridge Note at an exercise price equal to $5.25 per share.

The Company issued an aggregate of 167,557 equity-classified Common Stock warrants. Proceeds from the Bridge Notes were allocated to the notes and warrants on a relative fair value basis resulting in a beneficial conversion feature (“BCF”) of $0.4 million and equal to the excess fair value of the Company’s Common Stock over the effective conversion price of the Bridge Notes. The BCF was recorded as a debt discount and is being amortized over the life of the Bridge Notes using the effective interest method. For the nine months ended September 30, 2022, the Company recognized approximately $2.0 million in interest expense related to the amortization of the debt discount and issuance costs.

The following table summarizes the calculated aggregate fair values for the warrants using the Black-Scholes method based on the following assumptions at September 30, 2022:

Exercise price per share of warrant	$	5.25
Fair market closing price per share of Common Stock	$	4.13
Volatility		107-121%
Expected term (years)		5.0
Risk-free interest rate		1.37-1.62%
Dividend yield		0%

Note 13. RELATED PARTY TRANSACTIONS

Convertible Bridge Promissory Notes

On August 11, 2022, certain officers and directors of the Company purchased convertible promissory Bridge Notes from the Company that bore interest at 6% per year and had maturity dates of October 31, 2022. The unpaid principal and accrued interest under each such Bridge Note was convertible into shares of Common Stock at a conversion price of $4.20 per share. Upon the IPO Closing, each Bridge Note automatically converted into a certain number of shares of Common Stock based on the outstanding principal balance and accrued and unpaid interest under such note as of September 6, 2022. Additionally, in connection with purchasing a Bridge Note, each purchaser received a warrant (“Bridge Warrant”) that had a five-year term and was convertible into the number of shares of Common Stock specified below at an exercise price of $5.25 per share.

Zannes Note and Warrant

Maria Zannes, the founder, President, Chief Executive Officer, and a director of the Company, purchased a Bridge Note in the principal amount of $99,000. Upon the IPO Closing, the Bridge Note automatically converted into 23,672 shares of Common Stock. In connection with her Bridge Note purchase, Ms. Zannes received a Bridge Warrant to purchase 23,571 shares of Common Stock at an exercise price of $5.25 per share.

Girgenti Note and Warrant

Steven Girgenti, the Executive Chairman and a director of the Company, purchased a Bridge Note in the principal amount of $150,000. Upon the IPO Closing, the Bridge Note automatically converted into 35,866 shares of Common Stock. In connection with his Bridge Note purchase, Mr. Girgenti received a Bridge Warrant to purchase 35,714 shares of Common Stock at an exercise price of $5.25 per share.

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, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the consolidated financial statements.

In October 2022, the Company repaid $275,000 in convertible notes, Bridge Notes and related accrued interest for those notes that were not converted at the time of the Company's IPO. See Note 7.

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, 2021 included in our Final Prospectus filed with the SEC on September 2, 2022. 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 our Final Prospectus.

Data as of and for the three and nine months ended September 30, 2022 and 2021 has been derived from our unaudited condensed consolidated financial statements appearing at the beginning of this Quarterly Report. Results for any interim period should not be construed as an inference of what our results would be for any full fiscal year or future period.

Our MD&A is organized as follows:

- *Company Overview* – Discussion of our business plan and strategy to provide context for the remainder of the MD&A.
- *Results of Operations* – Analysis of our financial results comparing the three and nine months ended September 30, 2022 to the comparable period in 2021.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows, and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Policies and Use of Estimates* – Accounting policies 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," "we," or "our") develops noninvasive, early-stage diagnostics to detect, and is researching targeted therapies to treat, diseases of the lung and cancer at the cellular level. Our Company develops proprietary noninvasive diagnostic tests and cancer therapeutics 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 our laboratories at The University of Texas at San Antonio.

Our first 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 they suspect may have lung cancer, which will enable physicians to more confidently distinguish between patients who will likely benefit from timely intervention and more invasive follow-up procedures and patients who are likely without disease and can continue annual screening. CyPath® Lung has the potential to increase overall diagnostic accuracy of lung cancer, which could lead to increased survival, lower the number of unnecessary invasive procedures, reduce 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 therapeutics that specifically and selectively target cancer cells. We are focused on expanding our broad platform technologies to continue developing tests that detect and therapies that target various types of cancer and potentially other diseases.

Recent Developments

- In the third quarter of 2022, the Company completed our IPO, with net proceeds of $6.0 million after deducting underwriting discounts, commissions and offering expenses. In connection with our IPO, the Company converted almost $11 million in debt and related accrued interest into shares of Common Stock.

- In the third quarter of 2022, the Company raised additional proceeds of $7.7 million from the sale of warrants.

- We have determined that an estimated 1,800 participants will be required to be enrolled in our pivotal clinical trial that is designed to confirm the sensitivity and specificity of CyPath® Lung in detecting lung cancer in persons at high risk for the disease, and in particular those people who display indeterminant lung nodules sized between 6mm and 30 mm that often present a challenge in diagnosis.

- In the third quarter of 2022, the Company was awarded therapeutic patents in The People's Republic of China, Mexico and Australia directed at compounds comprised of porphyrins conjugated to chemotherapeutic agents that can provide selective treatment for cancer.

- In October 2022, Sheila Habib, MD, Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans' Hospital joined the Company's Scientific and Medical Advisory Board.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our first 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. From October 2021 through the third quarter of 2022, the Company raised an additional $2.7 million through the sale of bridge notes. In September 2022, we completed our IPO, with net proceeds of $6.0 million after underwriting discounts, commissions and offering expenses, and sold warrants for proceeds of approximately $7.7 million. As of September 30, 2022, we had cash and cash equivalents of $13.5 million. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of this Quarterly Report.

In the second quarter of 2022, we started to recognize revenue from sales of the CyPath® Lung test by our licensee, Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee. We have never been profitable and, as of September 30, 2022, we had total working capital of $12.6 million, and an accumulated deficit of approximately $35.0 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and therapeutic products and advance them through clinical trials.

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

Results of Operations

Three Months Ended September 30, 2022 Compared to Three Months Ended September 30, 2021

Net loss for the three months ended September 30, 2022 was approximately $4.9 million, compared to a net loss of approximately $1.5 million for the three months ended September 30, 2021, resulting from the operational activities described below.

Revenue

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee. Although Precision Pathology Services placed CyPath® Lung on its list of tests offered to physicians in second quarter 2022, there was limited marketing of the product until September's IPO made available funds to assemble a marketing team of experts focused on demonstrating the clinical value of CyPath® Lung in the marketplace. The limited test-market launch in the San Antonio area 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. We had revenue of approximately $1,000 during the three months ended September 30, 2022 from the sale of CyPath® Lung as a laboratory-developed test (an "LDT"), compared to no revenue in 2021.

We expect our revenue to continue to grow for CyPath® Lung as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of Sales

Cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers. The increase in cost of sales for the three months ended September 30, 2022 is primarily due to sales of our diagnostic kits in the second quarter of 2022, compared to no sales in the prior year.

Operating Expenses

	Three months Ended September 30,[1]		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amount in thousands)			
Operating Expenses				
Research and development	$ 320	$ 331	$ (11)	-3%
Clinical development	61	34	27	79%
General and administrative	596	162	434	268%
Total operating expenses	$ 977	$ 527	$ 450	85%

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the three-month period ended September 30, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Operating expenses totaled approximately $1.0 million and $0.5 million during the three months ended September 30, 2022 and 2021, 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 studies, compensation and consulting costs.

Research and development expenses totaled approximately $320,000 and $331,000 for the three months ended September 30, 2022, and 2021, respectively. The decrease of approximately $11,000, or -3%, for the three months ended September 30, 2022, compared to the same period in 2021, was primarily attributable to a decrease in legal costs related to patents and annuities compared to prior year, as well as a decrease in compensation costs due to several employees who were furloughed in the prior year, but are now back full time. The decrease was partially offset due to an increase of $25,000 due to costs related to lab supplies and reagents.

Clinical Development

Clinical development expenses totaled approximately $61,000 and $34,000 for the three months ended September 30, 2022 and 2021, respectively. The increase of approximately $27,000, or 79%, for the three months ended September 30, 2022, compared to the same period in 2021 was primarily attributable to an increase of approximately $20,000 in professional fees including consulting fees, as well as increases of approximately $22,000 in clinical study activities related to site costs, compared to 2021 as operations were still being affected by the global pandemic.

General and Administrative

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

General and administrative expenses totaled approximately $596,000 and $162,000 for the three months ended September 30, 2022 and 2021, respectively. The increase of approximately $434,000, or 268%, for the three months ended September 30, 2022, compared to the same period in 2021, was primarily attributable to an increase of approximately $240,000 due to consulting, legal and professional fees incurred in 2022 compared to 2021 related to board compensation, and other legal and professional fees as a result of being a publicly traded company. Additionally, compensation increased approximately $68,000 as we increased personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Other Income (Expense)

	Three Months Ended September 30,		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amount in thousands)			
Interest income (expense), net	$ (889)	$ (135)	$ (754)	559%
Gain (loss) on change in fair value of convertible notes	(3,054)	(852)	(2,202)	258%
Total other income (expense)	$ (3,943)	$ (987)	$ (2,956)	299%

Other expense totaled approximately $3.9 million and $1.0 million for the three-month period ended September 30, 2022 and 2021, respectively.

Interest Income (Expense), net

Interest expense increased approximately $0.8 million, or 559%, to approximately $0.9 million for the three months ended September 30, 2022, compared to $0.1 million for the three months ended September 30, 2021. The increase was due to additional convertible notes outstanding during the quarter compared to the same period in the prior year, partially offset by substantially all convertible and bridge notes being converted during the quarter as a result of our IPO. Additionally, in 2022 the Company recorded interest expense of approximately $0.8 million for the amortization of debt discount related to the issuance of bridge notes.

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 a loss of approximately $0.9 million during the three months ended September 30, 2021. 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. Refer to our notes to unaudited condensed consolidated financial statements for further discussion on our convertible notes.

Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

Net loss for the nine months ended September 30, 2022 was approximately $6.5 million, compared to a net loss of approximately $0.8 million for the nine months ended September 30, 2021, resulting from the operational activities described below.

Revenue

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee. Although Precision Pathology Services placed CyPath® Lung on its list of tests offered to physicians in second quarter 2022, there was limited marketing of the product until September's IPO made available funds to assemble a marketing team of experts focused on demonstrating the clinical value of CyPath® Lung in the marketplace. The limited test-market launch in the San Antonio area 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. We had revenue of approximately $2,500 during the nine months ended September 30, 2022, from the sale of CyPath® Lung as an LDT, compared to no revenue in 2021.

We expect our revenue to continue to grow for CyPath® Lung as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of Sales

Cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers. The increase in cost of sales for the nine months ended September 30, 2022 is primarily due to the launch of sales in the second quarter of 2022, compared to no sales in the prior year.

Operating Expenses

	Nine months Ended September 30,[1]		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amount in thousands)			
Operating Expenses				
Research and development	$ 949	$ 878	$ 71	8%
Clinical development	142	78	64	82%
General and administrative	1,298	591	707	120%
Total operating expenses	$ 2,389	$ 1,547	$ 842	54%

(1) Represents operating expenses from our unaudited condensed consolidated financial statements for the nine-month period ended September 30, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Operating expenses totaled approximately $2.4 million and $1.5 million during the nine months ended September 30, 2022 and 2021, 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 studies, compensation and consulting costs.

Research and development expenses totaled approximately $949,000 and $878,000 for the nine months ended September 30, 2022, and 2021, respectively. The increase of approximately $71,000, or 8%, for the nine months ended September 30, 2022, compared to the same period in 2021, was primarily attributable to an increase in compensation costs as we added additional research personnel, partially offset by a decrease in the prior year due to several employees who were furloughed for several months and later returned to their positions with the Company. Additionally, the increase was due to an increase of $25,000 in costs related to lab supplies and reagents, as well as an increase of $20,000 related to legal costs in the current year as we maintain our patent portfolio, as well as expand our portfolio to include expanding and protecting our diagnostic and therapeutic platforms.

Clinical Development

Clinical development expenses totaled approximately $142,000 and $78,000 for the nine months ended September 30, 2022 and 2021, respectively. The increase of approximately $64,000, or 82%, for the nine months ended September 30, 2022, compared to the same period in 2021 was primarily attributable to an increase of approximately $40,000 in professional fees including consulting fees, as well as increases of approximately $13,000 in clinical study activities related to site costs, compared to 2021 as operations were still being affected by the global pandemic.

General and Administrative

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

General and administrative expenses totaled approximately $1.3 million and $591,000 for the nine months ended September 30, 2022 and 2021, respectively. The increase of approximately $707,000, or 120%, for the nine months ended September 30, 2022, compared to the same period in 2021, was primarily attributable to an increase of approximately $470,000 related to consulting, legal and professional fees incurred in 2022 compared to 2021 as we prepared for a potential IPO. Additionally, compensation increased approximately $90,000 as we increased personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Other Income (Expense)

	Nine Months Ended September 30,[1]		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amount in thousands)			
Interest income (expense), net	$ (2,435)	$ (364)	$ (2,071)	569%
Gain on debt extinguishment	212	239	(27)	-11%
Gain (loss) on change in fair value of convertible notes	(1,867)	924	(2,791)	-302%
Total other income (expense)	$ (4,090)	$ 799	$ (4,889)	-612%

(1) Represents other income (expense) from our unaudited condensed consolidated financial statements for the nine-month period ended September 30, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Other income (expense) totaled approximately ($4.1) million and $0.8 million for the nine months ended September 30, 2022 and 2021, respectively.

Interest Income (Expense), net

Interest expense increased $2.1 million, or 569%, to approximately $2.4 million for the nine months ended September 30, 2022, compared to $228,000 for the nine months ended September 30, 2021. The increase was due to additional convertible notes outstanding during the same period in the prior year. Additionally, in 2022 the Company recorded interest expense of approximately $2.0 million for the amortization of debt discount related to the issuance of bridge notes.

Gain on Extinguishment of Debt

In March 2021, the Company received a second draw $0.2 million PPP Loan (the "PPP Loan"), and in April 2022, received forgiveness from the SBA, and recorded a gain of $212,000 on the extinguishment of the PPP Loan. In April 2020, the Company received an initial $0.2 million PPP Loan, and in June 2021, received forgiveness from the SBA, and recorded a gain of $239,000 on the extinguishment of the PPP Loan.

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 a gain of approximately $0.9 million during the nine months ended September 30, 2021. 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. Refer to our notes to unaudited condensed consolidated financial statements for further discussion on our convertible notes.

Liquidity and Capital Resources

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

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, 2022 and 2021, we had net losses of $6.5 million and $0.8 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately $35.0 million as of September 30, 2022. Cash and cash equivalents were approximately $13.5 million as of September 30, 2022. Based on our current level of expected operating expenditures, we expect to be able to fund our operations for at least 12 months following the date of this Quarterly Report.

We continue to seek sources of financing, including 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 or 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,	
	2022	**2021**
	(amounts in thousands)	
Cash and cash equivalents at beginning of period	$ 1,360	$ 83
Net cash used in operating activities	(2,770)	(1,396)
Net cash used in investing activities	—	—
Net cash provided by financing activities	14,908	1,557
Cash and cash equivalents at end of period	$ 13,498	$ 244

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $2.8 million and $1.4 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of approximately $1.4 million in cash used by operations during the nine months ended September 30, 2022, compared to the same period in 2021, was primarily attributable to an increase of $5.7 million in our loss from operations as compared to prior year as described above. These increases were partially offset by fair value adjustments and the amortization of debt discount related to the issuance of bridge notes, as well as changes in prepaid and other assets, and accrued interest.

Net Cash Used in Investing Activities

The Company did not use any cash in investing activities for the nine months ended September 30, 2022, and 2021, respectively.

Net Cash Provided by Financing Activities

Cash provided by financing activities was approximately $14.9 million compared to approximately $1.6 million for the nine months ended September 30, 2022, and 2021, respectively. The increase in cash provided by financing activities for the nine months ended September 30, 2022, compared to 2021, is primarily attributable to the net proceeds of approximately $6.0 million from issuance of Common Stock in our IPO, as well as proceeds of approximately $7.7 million from the exercise of warrants. Additionally, the increase is due to the issuance of $0.7 million of our bridge notes during the period partially offset by debt issuance costs and the repayment of one bridge note for $100,000, compared to the issuance of $1.0 million of our convertible notes the same period in the prior year, as well as receiving a second draw on our PPP Loan of $212,000 in March 2021. Additionally, the Company had an increase in deferred offering costs related to the anticipated initial public offering.

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 Policies and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 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.

Share-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. As such, as 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 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. 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are not required to provide the information required by this item as we are considered a smaller reporting company, as defined by Rule 229.10(f)(1).

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)). Based on that evaluation, management has concluded that due to limited resources and limited number of employees, its internal control over financial reporting was ineffective as of September 30, 2022 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles. 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

There were no changes in our internal controls (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) over financial reporting during the three months ended September 30, 2022 covered by this Quarterly Report that could materially affect, or are reasonably likely to materially affect, our financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS.

From time to time, the Company is involved in various disputes and litigation matters that arise in the ordinary course of business. To date, the Company 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 our Final Prospectus filed with the SEC on September 2, 2022 pursuant to Rule 424(b)(4) under the Securities Act and elsewhere in this Quarterly Report 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.

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

Use of Proceeds from Initial Public Offering

On September 6, 2022, we completed our IPO of 1,282,600 Units at an Offering Price of $6.125 per Unit. Each Unit consisted of one share of Common Stock, one Tradeable Warrant exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and one Non-tradeable Warrant exercisable for the purchase of one share of Common Stock at an exercise price of $7.656 per share. The total number of shares of Common Stock sold in the IPO does not include the Over-Allotment Option that we granted to the Underwriters to purchase up to an additional 192,390 shares of Common Stock at the Offering Price per Unit less $0.02, and/or up to 192,390 Tradeable Warrants at $0.01 per Tradeable Warrant, and/or up to 192,390 Non-tradeable Warrants at $0.01 per Non-tradeable Warrant, or any combination of additional shares of Common Stock, Tradeable Warrants, and Non-tradeable Warrants representing, in the aggregate, up to 15% of the number of Units sold in the IPO. The shares of Common Stock and Tradeable Warrants underlying the Units offered in our IPO and the Over-Allotment Option were registered for sale pursuant to our Registration Statement on Form S-1, as amended (File No. 333-264463), filed with and declared effective by the SEC on August 29, 2022.

The aggregate offering price for the registered shares of Common Stock and Tradeable Warrants was approximately $7.9 million. We received net proceeds of approximately $6.0 million from the IPO, after deducting underwriting discounts and commissions of approximately $0.7 million and offering expenses of approximately $1.2 million. The representative of the Underwriters was WallachBeth Capital, LLC. No payments for the foregoing expenses were made by us to any of our officers, directors or persons owning ten percent (10%) or more of our Common Stock, or to the associates of any of the foregoing, or to their affiliates, other than payments in the ordinary course of business to our officers for salaries, bonuses and expense reimbursements.

There has been no material change in the planned use of proceeds as described in our Final Prospectus filed with the SEC on September 2, 2022. The expected use of net proceeds from the IPO represents our intentions based upon our present plans and business conditions. We cannot predict with certainty all of the particular uses for the proceeds of the IPO or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds we received from the IPO, and investors will be relying on the judgment of our management regarding the application of our net proceeds. While we expect to use the net proceeds for the purposes described above, the timing and amount of our actual expenditures will be based on many factors, including cash flows from operations, the anticipated growth of our business, and the availability and terms of alternative financing sources to fund our growth.

Unregistered Sales of Equity Securities

None

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
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002
101*	The following financial statements from the bioAffinity Technologies, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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, 2022, 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.
† Furnished herewith.

SIGNATURES

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

bioAffinity Technologies, Inc.
(Registrant)

By: */s/ Maria Zannes*
Maria Zannes
Chief Executive Officer, President, Founder, and Director

By: */s/ Michael Edwards*
Chief Financial Officer

Exhibit 31.1

Certification
For the Quarterly Period Ended September 30, 2022

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)) 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) [intentionally omitted];

    (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, 2022

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer

Exhibit 31.2

Certification
For the Quarterly Period Ended September 30, 2022

I, Michael Edwards, 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)) 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) [intentionally omitted];

    (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, 2022

/s/ Michael Edwards
Michael Edwards
Chief Financial Officer

Exhibit 32.1

Certification 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, 2022 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, 2022 (the last date of the period covered by the Report).

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer
Date: November 14, 2022

/s/ Michael Edwards
Michael Edwards
Chief Financial Officer
Date: November 14, 2022