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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024.

OR

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

For 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 or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)
3300 Nacogdoches Road, Suite 216, San Antonio, Texas	**78217**
(Address of principal executive offices)	(Zip Code)

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

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

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

Securities registered pursuant to section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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 such 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 Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on that date, as reported by the Nasdaq Capital Market on such date was approximately $22.6 million. Shares of the registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares outstanding of the issuer's common stock, $0.007 par value (the "Common Stock"), is 18,255,824 as of March 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to the 2025 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2024 (the "2025 Proxy Statement").

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual 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 protection for our diagnostic and therapeutic inventions or future diagnostic and therapeutic inventions to expand our product offerings;
- our ability to protect our intellectual property ("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 impact of a health epidemic on our business, our clinical trials, our research programs, healthcare systems, or the global economy as a whole;
- general instability of economic and political conditions in the United States ("U.S."), including inflationary pressures, increased interest rates, economic slowdown or recession, and escalating geopolitical tensions;
- our anticipated uses of net proceeds from our financings;
- the increased expenses associated with being a public company; and
- other factors discussed elsewhere in this Annual Report.

Many of the foregoing risks and uncertainties, as well as risks and uncertainties that are currently unknown to us, are or may be exacerbated by factors such as the ongoing conflict between Ukraine and Russia, escalating tensions between China and Taiwan, the war in the Middle East, increasing economic uncertainty and inflationary pressures, and any consequent worsening of the global business and economic environment. New factors emerge from time to time, and it is not possible for us to predict all such factors. Should one or more of the risks or uncertainties described in this Annual 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 Annual Report and the documents that we reference within it with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

Website and Social Media Disclosure

We use our websites (www.bioaffinitytech.com, ir.bioaffinitytech.com, www.cypathlung.com and www.Precisionpath.us/) to share Company information. Information contained on or that can be accessed through our websites is not, however, incorporated by reference in this Annual Report. Investors should not consider any such information to be part of this Annual Report.

Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected, or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our," and "bioAffinity," refer to bioAffinity Technologies, Inc. and its subsidiaries.

Summary of Risk Factors

Risks Related to Our Financial Position

- Our business plan relies upon our ability to obtain additional sources of capital and financing.
- We must raise additional capital to fund our operations in order to continue as a going concern.
- Our limited operating history makes it difficult to evaluate our business and future prospects.
- We are unable to precisely estimate when we will begin to generate significant profit from Precision Pathology Laboratory Services (PPLS).
- We have limited experience operating a laboratory.

Risks Related to our Diagnostic Product

- Until we secure U.S. Food and Drug Administration ("FDA") clearance for CyPath® Lung as an in vitro diagnostic, the FDA could impose greater regulatory burdens on laboratory developed tests ("LDTs").
- Delays or difficulties in the enrollment of patients could delay or prevent regulatory approvals.
- Clinical trials are expensive, time-consuming, and may not be successful.

Risks Related to Our Diagnostic Tests

- If our tests do not perform as expected, our operating results, reputation, and business will suffer.
- We may experience difficulties that delay or prevent our development, introduction, or marketing of enhanced or new tests.
- If clinical testing of a particular diagnostic test or therapeutic product candidate does not yield successful results, we will be unable to commercialize that test or product candidate.
- Even if our diagnostic tests or therapeutic products receive marketing approval, we may not be successful in commercializing them or they may fail to achieve market acceptance.
- We are currently dependent upon PPLS to offer and perform CyPath® Lung.
- If we are unable to convince physicians of the benefits of our proposed diagnostic tests or therapeutic products, we may incur delays or additional expense in our attempt to establish market acceptance.
- We face substantial competition.
- Our success depends upon our ability to retain key executives and attract and retain qualified personnel.
- Our lack of operating experience may make it difficult to manage our growth.
- We will depend on third parties to manufacture and market our diagnostic tests and to design trial protocols and monitor clinical trials.
- We are exposed to product liability and pre-clinical and clinical liability risks.
- Our failure to comply with privacy and security regulations could result in liability or reputational harm.
- Our ability to obtain adequate reimbursement for our diagnostic tests may impact our revenues.
- Our employees, consultants, partners, and vendors may engage in misconduct or other improper activities.
- Failure to comply with healthcare laws and regulations could result in substantial penalties.
- We face intense competition in the biotechnology and pharmaceutical industries.
- The market for our proposed tests and products is competitive and rapidly changing.
- Healthcare cost containment initiatives and the growth of managed care may limit our returns.
- Disruption of internal information technology systems will adversely affect our business.
- Declining general economic or business conditions may have a negative impact on our business.
- Global climate change and related regulations could negatively affect our business.

Risks Related to the Operation of a CAP/CLIA Laboratory

- PPLS's operations depend upon the relationship of certain of our pathologists with existing customers.
- PPLS may be unable to maintain equipment or generate revenue when its equipment is not operational.
- If our sole laboratory facility becomes damaged or inoperable, loses its accreditation, or is required to vacate the facility, PPLS' ability to sell its products or provide diagnostic assays and pursue its research and development efforts may be jeopardized.
- PPLS relies on commercial courier delivery services to transport sputum samples for CyPath® Lung, the disruption of which could harm its business.
- Security breaches, data loss, and other disruptions could compromise sensitive information of PPLS' business.
- If PPLS uses hazardous chemicals in a manner that causes injury, PPLS could be liable for damages.
- If PPLS is unable to successfully scale its operations to support demand its business could suffer.
- PPLS must dedicate substantial time and resources to its complex billing process to be paid.
- Delays of third-party billing and collection providers and an in-house billing function to transmit claims to payors could have an adverse effect on PPLS.

Risks Related to Intellectual Property Rights

- If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business.
- In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms.
- Our competitive position depends on protection of our intellectual property.
- Diagnostic tests and therapeutic products we develop could be subject to infringement claims.
- We may become involved in lawsuits to protect or enforce our intellectual property.
- If we are unable to protect our trade secrets, our business and competitive position could be harmed.
- Changes in patent law could impair our ability to protect our tests and product candidates.
- Our patent protection could be reduced or eliminated for non-compliance with requirements imposed by governmental patent agencies.
- Patent terms may be inadequate to protect our diagnostic tests or therapeutic product candidates.
- Issued patents could be found invalid or unenforceable.
- If we do not obtain patent term extension, our business may be harmed.
- We enjoy only limited geographical protection with respect to certain patents.
- If our trademarks and trade names are not adequately protected, we may not be able to build name recognition.

Risks Related to Government Regulations

- Should the FDA's regulatory approach to LDTs change, our strategy may be adversely affected.
- Delay by or failure of the FDA to grant our request for de novo classification or our failure to comply with applicable requirements would adversely affect our business.
- Failure to comply with laws pertaining to LDTs or in vitro devices ("IVDs") could adversely affect our business.
- Third-party licensors of our future therapeutic products may be unable to obtain regulatory approval.
- Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed in those jurisdictions that deny approval.
- We may never obtain approval or commercialize such products outside of the U.S., which would limit our ability to realize their full market potential.
- The impact of changes to healthcare policy and future healthcare reform legislation is unknown.

Risks Related to Ownership of Our Common Stock and Warrants

- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.
- We do not expect to pay dividends in the foreseeable future. Any return on investment may be limited to the value of our Common Stock.
- Our Common Stock market price may never exceed the exercise price of our outstanding warrants.
- Holders of our warrants have no rights as stockholders until they exercise their warrants.
- The provisions of our outstanding warrants could limit a warrant holder's ability to choose the judicial forum for disputes.
- Our failure to file timely registration statement pursuant to the terms of a warrant inducement agreement will result in a breach thereof.
- The financial and operational projections that we may make from time to time are subject to inherent risks.
- Our stock price has fluctuated in the past, has recently been volatile, and may be volatile in the future.
- Our Common Stock has often been thinly traded.
- An investment in our Company may involve tax implications.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- Our Certificate of Incorporation permits "blank check" Preferred Stock, which can be designated by our Board without stockholder approval.
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company more difficult.
- Certain provisions in our Charter and Amended and Restated ("A&R") Bylaws could make a merger, tender offer, or proxy contest difficult.
- Certain provisions of Delaware's General Corporation Law ("DGCL") may have anti-takeover effects that could delay, defer, or discourage another party from acquiring control of us.
- Our Charter designates Delaware state or federal courts as the exclusive forum for disputes.
- Certain provisions in our Charter and A&R Bylaws may discourage stockholders from bringing a lawsuit against our directors and officers.
- Our management collectively owns a substantial percentage of our Common Stock.
- If analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Any inability to report and file our financial results accurately and timely could harm our business.

PART I

Item 1. Business

Business Overview

We develop proprietary noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung using flow cytometry and automated analysis developed by machine learning, a form of artificial intelligence ("AI"). Our diagnostic tests analyze cell populations, including cancer and cancer-related cells, that are indicative of a specific diseased state.

We were formed as a Delaware corporation on March 26, 2014. On June 15, 2016, we formed OncoSelect® Therapeutics, LLC ("OncoSelect®"), a Delaware limited liability company and our wholly owned subsidiary which is a preclinical-stage biopharmaceutical discovery company that has advanced our discoveries of novel potential cancer therapies that specifically and selectively target a broad spectrum of cancer cells that have been grown in petri dishes without harm to healthy cells. We expect to present our findings at conferences and publish the results of our research this year and seek strategic partners that have the resources to advance our therapeutic discoveries.

On August 14, 2023, we formed Precision Pathology Laboratory Services, LLC ("PPLS"), a Texas limited liability company and our wholly owned subsidiary, which performs our clinical laboratory services, including CyPath® Lung operations. Research and optimization of our platform technologies for in vitro diagnostics and therapeutic technologies are conducted in laboratories at The University of Texas at San Antonio and PPLS in San Antonio, Texas.

In September 2023, through our wholly owned subsidiary PPLS, we acquired the assets of Village Oaks Pathology Services, P.A. ("Village Oaks"), a Texas professional association d/b/a Precision Pathology Services, including a clinical anatomic and clinical pathology laboratory and related services business in San Antonio, Texas. The laboratory is accredited by the College of American Pathologists ("CAP") and certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

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

CyPath® Lung uses flow cytometry technology to detect and analyze cell populations in a person's sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories. Flow cytometry collects data pertaining to properties of single cells labeled with antibodies and dyes specific to cell types and characteristics. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can provide information about its area of field cancerization and the lung microenvironment. CyPath® Lung uses automated data analysis developed by machine learning, a form of AI, that allows data collection and analysis of an entire sample of sputum in less than 30 minutes, allowing for cost-effective, large-scale commercialization.

We conducted a 150-patient test validation trial of people at high risk for lung cancer including patients with the disease (N=28) and those who were cancer-free (N=122) that resulted in CyPath® Lung's overall 88% specificity, meaning the ability to correctly identify a person without cancer, and 82% sensitivity, meaning the ability to correctly identify cancer in a person with the disease. CyPath® Lung correctly detected 80% of Stage I lung cancers. The test detected multiple lung cancer types including non-small cell, small cell, adenocarcinoma, squamous, and large cell cancers. For the subset of patients in this trial who had lung nodules 20 millimeters ("mm") or smaller, this trial resulted in 92% sensitivity, 87% specificity, 99% negative predictive value, and 88% accuracy. In this subset of 132 individuals with small nodules, 119 patients were cancer-free and 13 had confirmed lung cancer. The detection of small lung nodules in people who have early-stage cancer can increase lung cancer survival.

Current Year Financial Highlights

Key financial results for the year ended December 31, 2024 include:

- Consolidated revenue increased approximately 270% to $9.4 million as compared to $2.5 million for the year ended December 31, 2023, primarily as a result of the acquisition of PPLS in September 2023.
- CyPath® Lung testing revenue increased approximately 1,400% to $0.5 million as compared to $35 thousand for the year ended December 31, 2023, due to an increase in total test results delivered of more than 600 for the current year.
- Raised approximately $6.9 million in gross proceeds from equity transactions to fund operating activities.

Recent Developments

FDA Pivotal Study

In March 2025, we submitted our pivotal clinical trial protocol "Detection of Early-Stage Lung Cancer in Sputum using Flow Cytometry and an Automated Analysis Pipeline" to the Sterling Institutional Review Board ("IRB") for approval after the Company meet met with the FDA on trial design. In third quarter 2024, the National Association of Veterans Research and Education Foundation ("NAVREF") extended a "Call for Interest" to Veterans Administration ("VA") systems to solicit participation in the pivotal trial, which resulted in a positive response from 22 VA medical centers. Academic, private, military, and VA centers currently are being qualified as collection sites for the 3,200-patient clinical trial expected to open in the second quarter of 2025.

Case Studies

In March 2025, we announced the release of physicians' case studies showing the benefit to patients and their doctors of using CyPath® Lung, including one case in which an "Unlikely Lung Cancer" directly prevented a robotic bronchoscopic biopsy or high-risk percutaneous biopsy in a high-risk patient in response to imaging that showed several new, small non-calcified pulmonary nodules for a high-risk patient. In a second case study, a positive CyPath® Lung test result led to diagnosis of a recurrence of breast cancer, and a third case resulted in the diagnosis of a new primary lung cancer after a CyPath® Lung positive test that prompted a biopsy that otherwise would not have been performed.

Targeted Strategic Actions

In March 2025, we announced targeted strategic actions to improve financial performance and accelerate the commercial growth of CyPath® Lung, taking steps to deliver approximately $4 million in annual cost savings at our subsidiary PPLS, while increasing resources to expand CyPath® Lung sales in high-potential national markets. Specifically, cost savings are a result of labor cost reductions, operational efficiency enhancements, and discontinuing certain pathology services with suboptimal profit margins to focus on high-margin services such as CyPath® Lung and by discontinuing certain pathology services with suboptimal profit margins.

Continuation of Department of Defense Research

Beginning in the fourth quarter of 2023 and through 2024, we have been selling CyPath® Lung tests to the Department of Defense (DOD) to conduct an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay," and for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection.

Public and Private Offerings

On February 26, 2025, pursuant to the terms of a warrant inducement agreement (the "February Inducement Agreement"), dated February 25, 2025 that we entered into with certain holders of existing warrants, such holders exercised for cash (i) warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock issued on October 21, 2024 (the "October Warrants"), at the reduced exercise price of $0.58 per share, and (ii) warrants to purchase an aggregate of up to 1,136,391 shares of Common Stock issued on August 5, 2024 (the "August Warrants"), at the reduced exercise price of $0.58 per share. We received aggregate gross proceeds of approximately $1.4 million, before deducting advisory fees and other expenses payable by us. In consideration of the immediate exercise of the October Warrants and August Warrants by the holders thereof in accordance with the February Inducement Agreement, we issued unregistered common warrants to purchase an aggregate of up to 2,926,166 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the October Warrants and August Warrants) to such holders.

On October 21, 2024, we issued to certain institutional investors (i) in a registered direct offering, 2,048,294 shares of our Common Stock, and (ii) in a concurrent private placement, common warrants to purchase an aggregate of 2,662,782 shares of Common Stock, with an exercise price of $1.50, pursuant to a securities purchase agreement, dated October 18, 2024, that we entered into with such institutional investors, and received aggregate gross proceeds from the offerings of approximately $2.7 million, before deducting placement agent fees and other offering expenses payable by us.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed discussion of the foregoing transactions.

Our First Diagnostic Test – CyPath® Lung

Lung cancer remains the most commonly diagnosed cancer and the leading cause of cancer-related deaths worldwide, claiming more than 1.8 million lives with almost 2.5 million new cases reported in 2022 according to a 2024 article in *CA: A Cancer Journal for Clinicians*. Cancer Epidemiology reports that lung cancer is the leading cause of cancer deaths in the European Union with an estimated 17 to 34 million people at high risk. China reported 1,060,600 new cases of lung cancer in 2022. According to the American Lung Association ("ALA"), screening for individuals at high risk for lung cancer has the potential to improve lung cancer survival rates by finding disease at an earlier stage when it is more likely to be curable. An estimated 19.3 million Americans should have annual screening for lung cancer, according to American Cancer Society recommendations. A study published in the *New England Journal of Medicine* titled "Survival of patients with stage I lung cancer detected on CT screening" dated October 26, 2006, reported that the survival rate of individuals with Stage I lung cancer who underwent surgical resection within one month after diagnosis had a ten-year survival rate of 92%, as compared to the overall five-year survival rate in the U.S. of 28.4% as reported by the ALA in its 2024 "State of Lung Cancer" report. Unfortunately, most lung cancer is detected in late stages. The results of a large national clinical trial that was reported in the *New England Journal of Medicine* in an article dated August 4, 2011, titled "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening" showed that screening for lung cancer using low-dose computed tomography ("LDCT") resulted in a reduction of the mortality rate by up to 20% as compared to screening by X-ray if LDCT screening is used by patients at high risk for lung cancer on an annual basis. Therefore, LDCT scans are recommended for screening of an estimated 14 million Americans who are at high risk for lung cancer. If half of these high-risk individuals were screened, more than 12,000 lung cancer deaths could be prevented, according to the ALA. However, the *New England Journal of Medicine* article also reported that LDCT was shown to have a low positive predictive value of less than 4%. This means that for every 100 people who receive a positive result from LDCT screening and are suspected of having lung cancer, only four actually have the disease. A reliable, noninvasive, and cost-effective diagnostic test can increase diagnosis of early-stage lung cancer while lowering the number of unnecessary and invasive procedures for patients with a false positive result from LDCT screening. (A false positive test result indicates that the patient has lung cancer when he or she does not have the disease.)

CyPath® Lung is a test for early-stage lung cancer that is designed to meet the need for greater diagnostic certainty. Based on our internal analysis, its use in conjunction with LDCT is predicted to improve the positive predictive value (the probability that patients with a positive LDCT scan truly have the disease) by a factor of five. Our analysis concludes that improving the positive predictive value of LDCT with the use of CyPath® Lung has the potential to subject fewer patients to the stresses of misdiagnosis or unnecessary diagnostic procedures, such as biopsies, while also reducing healthcare costs.

A study authored by two pulmonologists and published in 2024 in the peer-reviewed *Journal of Health Economics and Outcomes Research* reported that adding CyPath® Lung to the standard of care for Medicare patients with a positive lung cancer screening could have saved an average of $2,773 per patient for total cost savings of $379 million in 2022, while the screening could have saved an average of $6,460 per patient for all patients with a positive lung cancer screening for a total costs savings of $891 million. The peer-reviewed study, "Economic Evaluation of a Novel Lung Cancer Diagnostic in a Population of Patients with a Positive Low-Dose Computed Tomography Result," attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications. Michael J. Morris, M.D., Brooke Army Medical Center ("BAMC") pulmonology and critical care physician and Assistant Dean of Research at San Antonio Uniformed Services Health Education Consortium ("SAUSHEC"), and Sheila A. Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital and Assistant Professor at the University of Texas Health Science Center at San Antonio, were first and second authors on the study published in the *Journal of Health Economics and Outcomes Research*. Economists John E. Schneider, Ph.D., and Maggie L. Do Valle, Master of Public Health, of Avalon Health Economics also contributed to the study.

CyPath® Lung uses flow cytometry technology to detect and analyze cell populations in a person's sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories. Flow cytometry collects data pertaining to properties of single cells labeled with antibodies and dyes specific to cell types and characteristics. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can provide information about its area of field cancerization and the lung microenvironment.

In particular, CyPath® Lung uses a synthetic porphyrin called meso-tetra (4-carboxyphenyl) porphyrin ("TCPP"). Porphyrins are biological pigments that, when exposed to ultraviolet light at certain wavelengths, can result in the cell fluorescing a red or purplish color that can be detected under a microscope or by flow cytometry, according to an article titled "Laboratory Diagnosis of Porphyria," published in *Diagnostics (Basel)* on July 26, 2021. Porphyrins can be man-made, like TCPP, or they can be naturally occurring, like heme that is responsible for the red color in red blood cells. Cancer cells are known to take up certain porphyrins in higher amounts than non-cancer cells, and the high affinity for cancer cells displayed by TCPP makes it an excellent bio-label for cancer, according to an article published in *Progress in Clinical and Biological Research* in 1984 titled "A comparative study of 28 porphyrins and their abilities to localize in mammary mouse carcinoma: uroporphyrin I superior to hematoporphyrin derivative." As used in CyPath® Lung, the proportion of cells with high TCPP fluorescence intensity in a patient's sputum sample is a significant predictor of lung cancer. We hold multiple patents protecting our use of TCPP for the diagnosis, monitoring, and treatment of cancer. In addition, we have multiple domestic and foreign patent applications to protect the use of flow cytometry and our AI-developed automated analysis platform in the detection of lung cancer and other lung diseases using sputum as a sample.

We developed an algorithm as part of a test validation trial that used machine learning to distinguish samples from high-risk patients who had lung cancer from those who are cancer-free. Results of the trial were published January 21, 2023, in the peer-reviewed journal *Respiratory Research.* Village Oaks developed CyPath® Lung for sale as an LDT in accordance with the standards of the CAP and the regulations and guidance of the CLIA program, which is administered by the Centers for Medicare and Medicaid Services ("CMS").

CyPath® Lung has been put into routine lab use without requiring expert evaluation of samples or being subject to operator bias. Our approach allows the entire sputum sample to be rapidly analyzed. The numerical analysis developed with machine learning captures complex interactions between lung cancer, the microenvironment, and areas of field cancerization that would be impossible for individuals to predict or detect reliably by eye. For example, during test development, we discovered that viability staining density suggests a link with apoptosis, or cell death, that is linked to many cancers, including lung cancer. Our model also suggests that specific markers of immune cell populations are informative as to the presence of cancer in the lung. These findings are the result of our machine learning approach to automated analysis.

CyPath® Lung uses sputum that is obtained noninvasively by patients in the privacy of their home. Physicians most often order the test for patients after CT imaging reveals one or more pulmonary nodules that have a higher risk but are not certain to be lung cancer. A patient collects his or her sample using a hand-held, noninvasive assist device, ICU Medical's Acapella® Choice Blue, that acts to break up mucus in the lungs and help a person cough up sputum from the lung into a collection cup. The Acapella® Choice Blue has been 510(k)-cleared by the FDA as a positive expiratory pressure device to help mobilize lung secretions in people with certain lung conditions

The sputum sample is shipped overnight by the patient to PPLS and processed into a single-cell suspension, then labeled with antibodies that distinguish different cell types and the synthetic porphyrin TCPP that identifies cancer cells and/or cancer-associated cells. Our test can collect sample data and analyze a sputum sample in less than 30 minutes using integrated software for high-throughput, user-friendly standardized analysis. A physician's report is generated within minutes after data acquisition. The report stratifies the patient into one of two risk groups. Those patients deemed "likely or very likely" to have cancer may benefit from aggressive intervention. Those "unlikely or very unlikely" to have a malignancy may continue imaging surveillance in accordance with local standard of care. The physician's report also shows a numerical score between 0.1 to 1.0, with 0.1 to less than 0.5 being a negative result and 0.5 to 1.0 considered positive for lung cancer. The proprietary automated analysis software was developed and is wholly owned and patent protected by bioAffinity Technologies.

Physicians receive test results within three days after the laboratory receives the patient's sputum sample. CyPath® Lung testing helps identify patients who should undergo more aggressive follow-up procedures to confirm a suspected lung cancer. When CyPath® Lung sample analysis determines a patient is unlikely or very unlikely to have lung cancer, the result can serve to guide and support a physician's decision to monitor the patient using LDCT or CT imaging.

As reported in an article titled "Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning," published in *Respiratory Research* on January 21, 2023, we conducted a 150-patient test validation trial of people at high risk for lung cancer including patients with the disease (N=28) and those who were cancer-free (N=122) that resulted in CyPath® Lung's overall 88% specificity, meaning the ability to correctly identify a person without cancer, and 82% sensitivity, meaning the ability to correctly identify cancer in a person with the disease. For the subset of patients in this trial who had lung nodules 20 mm or smaller or no nodules detected by imaging, this trial resulted in 92% sensitivity, 87% specificity, 99% negative predictive value, and 88% accuracy. In this subset of 132 individuals with small nodules, 119 patients were cancer-free and 13 had confirmed lung cancer. Eight out of 10 (80%) of Stage I tumors were correctly identified. Sensitivity is the percentage of persons with the disease – in this case, lung cancer – who are correctly identified by the test. Specificity is the percentage of persons without lung cancer who are correctly identified by the test. The cancer group included all lung cancer types, but mostly squamous cell carcinoma and adenocarcinoma lung cancer (in near equal numbers), showing that CyPath® Lung detects all types of lung cancer. Furthermore, clinical trial results reported an Area Under the Curve (AUC) value of 0.89 for CyPath® Lung. AUC value indicates the ability of a test to distinguish between positive and negative cases. An AUC value of 0.7 to 0.8 is considered acceptable; 0.8 to 0.9 is excellent; more than 0.9 is outstanding. In study participants with lung nodules less than 20 mm, the test performed with an AUC value of 0.94.

In this 19-month trial, participants provided a sputum sample and were released from the study after a physician either confirmed the individual was cancer-free by examination of CT imaging or confirmed the presence of lung cancer by biopsy. Flow cytometry and patient data used in the analysis produced results that included (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age.

The CyPath® Lung technology is based on scientific work originating at Los Alamos National Laboratory in collaboration with St. Mary's Hospital in Colorado. In the Los Alamos research study, sputum samples from lung cancer patients were differentiated from non-cancer samples with 100% accuracy. This early research was conducted with sputum from 12 uranium miners. Microscope slides of sputum samples were labeled with the synthetic fluorescent porphyrin TCPP. The Los Alamos research study of 12 uranium miners included eight men with cancer and four healthy individuals. Researchers were blinded to the sample origin and looked for the presence of highly fluorescent cells indicating uptake of TCPP as an indicator of lung cancer. The length of the study and specific follow-up was not reported, but researchers did report that one patient in the study who had been incorrectly considered to be a healthy subject was correctly diagnosed with cancer by the test. Later, a blinded clinical trial was conducted and results published September 2015 in an article titled "Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum" in the *Journal of Thoracic Oncology*. This study reported on an earlier version of CyPath® Lung that used a fluorescent microscope to directly identify cells labeled with TCPP in one-third or less of the sputum sample. For each trial participant, researchers manually scanned 12 microscope slides labeled with TCPP for the presence of red fluorescent cells ("RFCs") displaying a spectral signature that indicated uptake of TCPP in the cell. In addition to measuring the spectral signature, the fluorescent intensity and cell size of RFCs were measured. The test data, including fluorescent intensity over cell size, was analyzed. The trial was conducted over 24 months and resulted in 81% test accuracy, 77.9% sensitivity, and 65.7% specificity in the ability to correctly differentiate between samples from lung cancer patients and those at high risk who were cancer-free. The earlier trial required participants to provide a sputum sample and CT imaging of the lungs. Those in the cancer cohort underwent a biopsy to confirm lung cancer. High-risk patients displaying indeterminate nodules were followed for 18 months to confirm they were cancer-free. The study concluded that optimizing the test to provide for analysis of the entire sputum sample would improve results.

On January 1, 2024, the Medicare reimbursement code 0406U specific for CyPath® Lung became effective after multiple regulatory decisions in 2023 leading to approval. On June 6, 2023, the American Medical Association ("AMA") approved a Current Procedural Terminology ("CPT") Proprietary Laboratory Analysis ("PLA") code specifically for use with CyPath® Lung, which was publicly released on June 30, 2023. CyPath® Lung is on CMS' clinical laboratory fee schedule. The CPT PLA code assigned to CyPath® Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer."

We have an agreement with GO2 Partners to produce patient collection kits and to provide warehousing and distribution services for sending out the kits. Laboratory reagents, supplies, and equipment are commercially available through multiple vendors. Sample processing, labeling, and data collection can be accomplished by a laboratory technician skilled in general laboratory techniques. Data analysis leading to a physician's report is done by automated analysis software fully integrated into the test.

To our knowledge, CyPath® Lung is the first cancer diagnostic that combines flow cytometry and automated analysis to predict the presence of lung cancer from sputum samples.

The Cancer Diagnostics Market and CyPath® Lung

The global lung cancer diagnostic market is projected to grow from an estimated $15.1 billion in 2023 to $34.8 billion by the end of 2034, with a compound annual growth rate ("CAGR") of 7.9%, according to a market research report issued by Transparency Market Research in October 2024. Our Company has the potential to play a significant role in the global cancer diagnostic market because we hold a strong and expanding IP portfolio for CyPath® Lung, a noninvasive, cost-effective, and high performing test that has the potential to better patient outcomes.

Comparison of CyPath® Lung to Current Standards of Care

Diagnostic Test or Procedure	Intended Patient	Sensitivity	Specificity	Procedural Risk	Source
CyPath® Lung	High risk	82%	88%	None	"Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning," published in *Respiratory Research* on January 21, 2023
CyPath® Lung	High risk – nodules less than 20 mm	92%	87%	None	"Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning," published in *Respiratory Research* on January 21, 2023
Low-dose CT screening	High risk	94%	73%	Radiation exposure	"Results of initial low dose computed tomographic screening for lung cancer," published in the *New England Journal of Medicine* on May 23, 2013
FDG PET imaging	Suspicious lung nodules	89%	75%	Radiation exposure	"Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: a meta-analysis," published in *JAMA* in September 2014
Bronchoscopy	Suspicious lung nodules – central lesions	88%	47%	Invasive; risk of collapsed/bleeding lung; infection	"A bronchial genomic classifier for the diagnostic evaluation of lung cancer," published in the *New England Journal of Medicine* on July 16, 2015
Fine needle biopsy	Suspicious lung nodules	90%	75%	Invasive; risk of collapsed/bleeding lung; infection	"Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review," published in *Current Oncology* in February 2012
Core needle biopsy[21]	Suspicious lung nodules	89%	89%	Invasive; risk of collapsed/bleeding lung; infection	"Global patterns and trends in lung cancer incidence: a population-based study," published in the *Journal of Thoracic Oncology* on February 16, 2021

As seen in the above table, CyPath® Lung performs similar to current Standard of Care, including more invasive and riskier diagnostic procedures. Moreover, lung nodules are commonly found on CT scans. Studies suggest up to 50% of lung nodules may be considered "indeterminate" without clear indication of being benign or malignant, posing difficult choices for physicians and their patients on steps. Our business model is to address the need for a noninvasive, cost-effective, high-performing lung cancer diagnostic that meets the need for more diagnostic certainty leading to quicker diagnosis at earlier stage for longer survival and reduced medical costs. The U.S. Preventive Services Task Force recommended new guidelines for screening in March 2021, nearly doubling the number of Americans at high risk for lung cancer who are recommended for annual screening to 14 million people, according to the ALA. In November 2023, the American Cancer Society updated its guidelines for lung cancer screening to include all former smokers over the age of 50 regardless of when they quit, increasing the estimated number of American adults eligible for screening to 19 million. China has an estimated 300 million smokers, according to the World Health Organization. In Europe, it is estimated that there is one new case of lung cancer diagnosed every minute, with incidence rates for males the highest in Eastern European countries and a five-year survival rate of only 13%, as reported by a May 2021 article, "Lung cancer screening in Europe: where are we in 2021?" published in *Translational Lung Cancer Research.* We expect to pursue CE marking of CyPath® Lung for sale in the European Union ("EU").

CyPath® Lung Business Development Plan

We believe in the viability of our business plan based on the circumstances surrounding our business that are known to us as of the date of this Annual Report. However, the timing, strategies, and stages of our business plan may evolve in light of new circumstances that cannot be predicted with certainty at this time. Our business plan envisions four phases of expanding market entry into the U.S., the EU, and worldwide that are timed to maximize our resources and minimize market risk. Phase 1 of our business plan was completed in 2024 with a limited market launch of our LDT CyPath® Lung in Texas. This limited test market launch was 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 allowed us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market.

We believe that our strategy related to a limited market launch proved successful. In January 2025, we reported the results of the Company's CyPath® Lung pilot marketing program using Texas for our beta launch with sales growth Quarter-over-Quarter and more than 600 tests delivered in 2024. We attribute the growth in sales to three 2023 initiatives that came to fruition in 2024: (1) CMS' inclusion of reimbursement for CyPath® Lung on its 2024 clinical laboratory fee schedule and subsequent reimbursement by Medicare and private insurance carriers; (2) the hiring of our new National Director of Sales in late 2023 and subsequent sales persons in 2024 who are experienced and well respected in the pulmonary field; and (3) marketing materials for the newly branded CyPath® Lung that emphasize our test's ability to assist physicians with next steps in patient care.

In October 2024, CyPath® Lung was awarded listing on the U.S. Federal Supply Schedule (FSS), making the test available to U.S. Veterans and active military personnel across government health systems. We view this market opportunity as the next step in expanding sales nationally in the U.S., including strategic expansion into regional markets in 2025. Phase 2 of our business plan anticipates entering the EU market with CyPath® Lung as a CE-marked IVD test beginning with sales in the Netherlands, followed by a staged EU expansion. Phase 3 of our business plan focuses on the marketing of an FDA-cleared CyPath® Lung test, beginning with conducting a pivotal clinical trial in the U.S. Toward that end, we have voluntarily sought FDA guidance with the intention of obtaining clearance after completion of the pivotal trial of a Class II IVD medical device for use in the diagnosis of lung cancer in individuals with indeterminate pulmonary nodules between 6 mm to less than 20 mm.

To differentiate our LDT test from the future FDA cleared diagnostic test, we have named the test for which we are seeking FDA clearance "FlowPath Lung." In December 2024, we met with FDA to discuss our pre-submission and subsequently incorporated the requested protocol changes to improve the trial design. Our revised trial protocol is now under review by an IRB. In third quarter 2024, the National Association of Veterans Research and Education Foundation ("NAVREF") extended a "Call for Interest" to VA systems to solicit participation in the pivotal trial, which resulted in a positive response from 22 VA medical centers. We are in the process of qualifying VA, academic and private medical centers that have asked to participate. Our Clinical Research Organization ("CRO") is Courante Oncology. Retired Army Col. Michael Morris, MD., of Brooke Army Medical Center has accepted the position as national Principal Investigator for the clinical trials. We anticipate a three-to-four-year clinical trial including an 18-month patient enrollment of approximately 3,400 patients, with the first clinical site expected to open and patient enrollment expected to begin in in the second quarter of 2025.

The pivotal trial will analyze sputum using flow cytometry data and patient data using the algorithm used for our LDT CyPath® Lung, including (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age. Patient enrollment is scheduled to begin in the second quarter of 2025 at up to 20 collection sites. Assuming the study is successful, we intend to submit a de novo classification request to the FDA within six months of study completion. Phase 4 of our business plan accelerates the market presence of CyPath® Lung in the U.S. as well as countries in Asia, Eastern Europe, and Australia after obtaining FDA marketing authorization.

We have developed messaging and marketing programs that will continue to grow both in size and scope with each phase of development, including key convention attendance, digital marketing, social media presence, and advertising, to create an "inbound" lead generation mechanism that delivers our message to our target audience. In addition, we will continue to expand our collaboration with regional and national key opinion leaders ("KOLs") and support efforts with collateral materials, including posters, presentations, videos, and peer-reviewed papers, to our KOLs who will present data and case studies of their use of CyPath® Lung. This content can be shared across platforms, including websites and sales tools, and will be used as references to support our product claims as well as sales and marketing efforts to physicians, reference laboratories, and patients. We are also working with lung cancer advocacy groups throughout all phases to support the message that routine lung cancer screening can save lives by diagnosing cancer at an early stage.

The Competition for CyPath® Lung

CyPath® Lung has not been tested directly against its competitors' products, but a comparison of the published performance numbers suggests CyPath® Lung is among the highest performing tests on the market. Furthermore, CyPath® Lung is noninvasive – not even requiring a needle stick – and cost effective, and processing and analysis procedures are easy to perform.

Published data and the results of clinical trials allow us to group lung cancer diagnostic tests into three categories: (1) balanced tests;(2) rule-out tests, and (3) rule-in tests. Balanced tests aim at excluding patients without cancer from unnecessary follow-up diagnostic procedures and detecting patients with early-stage cancer who can proceed to more aggressive procedures to confirm diagnosis. Rule-out tests aim to exclude patients without cancer from unnecessary follow-up procedures with high accuracy (if the test provides a "negative" result), but among the remainder of patients who do not receive an unambiguous negative result, there is still uncertainty about who has cancer and who does not. Cancer patients for whom time is of the essence are included in this group of patients still in uncertainty. The patient can lose precious time with a rule-out test. Rule-in tests aim to identify patients with cancer but in doing so may identify many people without cancer as positive. Therefore, rule-in tests have a low positive predictive value.

The recent economic journal article evaluating the significant healthcare cost benefits of using CyPath® Lung as a standard of care (Morris, et al., 2024) shows that balanced tests, like CyPath® Lung, can be the most cost effective. Those that perform well are most useful to a physician and his or her patient because they provide the most information, allowing a quicker decision on what follow-up path to choose: whether to move forward with more aggressive follow-up procedures (i.e., in the case of CyPath® Lung, if the test reveals a "likely" or "highly likely" cancer result) or to follow a more conservative approach (i.e., when the CyPath® Lung test reveals an "unlikely" or "very unlikely" cancer result).

Our competitive analysis reviewed published research that was sufficient to provide a scientific basis for evaluation. We found only seven tests, including CyPath® Lung, that represent a balanced test for early lung cancer detection and have advanced to the point that there is sufficient data for evaluation. One test is sold by two companies: one from the U.S. and one from China. In the U.S., the test is called Lung LB (sold by LungLife AI) and is now on the market. LungLB is a FISH-based test that requires a significant amount of experience to conduct. Four companies, each selling unique tests for early lung cancer detection, conducted their studies on a population that does not match the high-risk population for which the test is intended. Their clinical data, therefore, is not necessarily representative of the results that would be achieved in the population of patients who actually will use the test. The remaining balanced test, ProLung, is from IONIQ Sciences. The test requires an expensive machine to measure transcutaneous bioconductance. The test is not on the market at this time.

Delphi's First Look was recently launched to assist in determining whether a person should be screened by LDCT. While CyPath® Lung is positioned to help diagnose lung nodules in patients who have already undergone screening by LDCT, First Look is intended to be used *prior* to LDCT. As such, this test may increase lung cancer screening uptake and potentially increase the need for CyPath® Lung.

We found two rule-out tests on the market. Both REVEAL, offered by MagArray, and Nodify-XL2, offered by Biodesix, are rule-out tests, meaning the tests aim to exclude patients without cancer. The REVEAL test is a blood test intended for patients with indeterminant nodules. In their 97-patient clinical validation trial, only patients with an intermediate risk of cancer, based either on a physician's judgement or a clinical model, took part. This requirement led to 30% of high -risk patients being excluded at the onset of their analysis. In addition, the positive predictive value of the REVEAL test was 13.5% as compared to CyPath® Lung's positive predictive value of 43.2%. Importantly, CyPath® Lung trial participants included those at high risk for lung cancer as defined by CMS, and none were excluded based on physician's judgement which can be highly subjective. The tests had negative predictive values of 98% and 97.8%, respectively. The second rule-out test, Nodify-XL2, is used only by people with a pre-test probability of cancer less than 50%. As with the REVEAL test, a large number of patients were excluded from analysis. In the case of Nodify-XL2, about 55% of patients with lung nodules that physicians considered indeterminate, namely lung nodules sized between 8-30 mm, were excluded from the study. In addition, Nodify XL-2 reported an AUC of 0.62 (unacceptable) and 0.76 (acceptable) for their two clinical trials, as compared to CyPath® Lung with an AUC of 0.89 and 0.90 in two independent study groups (excellent).

Finally, the Percepta nasal swab test offered by Veracyte is not widely available and reportedly is seeking a reimbursement code. The test classifies patients in low- and high-risk categories, or for those whose results are unclear, an intermediate category. Test performance is different in each risk category. In a 2023 published paper of the test validation trial, the sensitivity and specificity for low-risk classification was 97% and 40%, respectively, with those at low risk having an 8% calculated risk of having a malignancy. The sensitivity and specificity for the high-risk classification was 57% and 92%, respectively, and those patients who were put into the high-risk category had a 90% risk of a malignancy. One of the limitations of this study is that the participants in the validation trial had a cancer prevalence of 54% as compared to the overall high-risk population that has an estimated lung cancer prevalence of 1.1%, according to the National Lung Cancer Screening Trial. Therefore, we believe the nasal swab test's performance may suffer when the classifier is tested on more realistic cohorts with a cancer prevalence lower than 10%. In addition, nearly half of all patients who took part in the validation trial could not be classified as either low- or high-risk; instead, they are considered "intermediate risk" with a 50:50 chance of having cancer. Thus, in nearly half of the patients who received the Percepta nasal swab test, the results would not help advance the diagnostic process. In fact, for those patients in this indeterminate category who ***do*** have cancer, valuable time in diagnosis may be lost.

We believe there are many reasons why CyPath® Lung is a superior test when compared to its competitors. First, lung sputum is an excellent medium for early lung cancer detection because sputum is in close contact with the tumor and pre-cancerous areas that shed cancer and pre-cancerous cells directly into the sputum, can be obtained noninvasively, and can be transported easily. Moreover, sputum contains immune cell populations in reaction to the presence of a tumor. Second, our proprietary technology is straightforward. Our CyPath® Lung platform technology is not a molecular test and does not collect genetic material that requires immediate processing. CyPath® Lung uses well-established flow cytometry techniques to investigate cells contained in the sputum for characteristics that indicate the likelihood of lung cancer. Sample processing is straightforward, and laboratory technicians can be easily trained. Reagents used by the test are widely available. Data acquisition and analysis is fully automated, allowing for non-biased, efficient test results. Third, CyPath® Lung has shown high specificity and sensitivity that is similar to far more invasive and more expensive procedures currently used to detect lung cancer. Fourth, CyPath® Lung is cost effective, with a Medicare reimbursement code billable to both government and private insurance carriers. A 2024 study authored by Michael Morris, M.D., and Sheila Habib, M.D., reported on CyPath® Lung's economic impact when used as companion test to the current Standard of Care predicting savings of more than $2,700 per Medicare patient and more than $6,400 per patient with private payer insurance who have pulmonary nodules sized less than 30 mm. Fifth and as important as any of our test's benefits, CyPath® Lung is patient friendly, providing at-home, noninvasive sample collection.

Building on our Flow Cytometry Platform to Develop COPD and asthma precision diagnostics

We are conducting research to expand our platform technology to detect other lung diseases, including development of precision diagnostics to identify patients who can best use commercial therapies and treatments in late-stage clinical phases that treat asthma and Chronic Obstruction Pulmonary Disease (COPD).

An estimated 23 million adults in the U.S. and 27 million people in the EU have been diagnosed with asthma; and 4.2% of Chinese adults presented with asthma in a representative sample of adults recruited for a national cross-sectional China Pulmonary Health study between 2012 and 2015, representing 45.7 million adults in China. Furthermore, an estimated 14.2 million U.S. adults had COPD in 2021 and approximately 36.6 million people in Europe had COPD in 2020, with the expectation that almost 50 million people in Europe will have COPD in 2050. The diagnostics market for COPD alone was valued at $5.6 billion in 2023 and is expected to reach $8.2 billion by 2029, according to a market research study published by *Research and Markets* in November 2023. We are building on our expertise in using sputum as a sample for flow cytometric analysis to develop tests to detect COPD and asthma, including research to detect the presence of specific therapeutic targets to identify patients who can benefit from specific treatments. We expect to continue research through 2025 with patient studies expected in 2026.

OncoSelect® Therapeutics Research

We have completed and expect to report at one or more scientific conferences our findings describing the results of our research to advance our own scientific discoveries demonstrating that inhibition of the expression of two specific cell membrane proteins results in the selective killing of various cancer cell types grown in the laboratory with little or no effect on normal (non-cancerous) cells. We expect to pursue additional research and clinical development in this area with strategic partners that have the resources to advance our discoveries.

Our therapeutic platforms originated from our research on how TCPP, the synthetic porphyrin used in CyPath® Lung, enters cancer cells. We conducted research to better understand the mechanism of TCPP's selective uptake in cancer cells. Our research identified receptors, cell-membrane proteins which capture small molecules outside of the cell and bring them inside the cell, that are associated with TCPP. Experiments that we conducted confirmed that at least two of these receptors, CD320 and LRP2, contributed to TCPP uptake by cancer cells. When these receptors were individually "knocked down" in cancer cells and therefore could not be made by the cell, TCPP uptake was significantly decreased. Knock-down of CD320 and LRP2 receptors was achieved by introducing siRNA molecules into the cells that cause the destruction of CD320 and LRP2 gene products. These gene products were the messenger (m)RNAs that are the precursors of the receptor protein. An siRNA is a small, chemically synthesized piece of RNA that specifically binds to mRNA, prohibiting the further production of the corresponding proteins. Thus, the reduction of CD320 or LRP2 mRNAs reduced the CD320 or LRP2 protein, respectively, and resulted in decreased TCPP uptake in a variety of cancer cells, with a larger decrease observed when CD320 was knocked down. We subsequently discovered that the simultaneous knockdown of these two cell-surface receptors, CD320 and LRP2, was deadly to cancer cells or inhibited their growth significantly but left normal cells virtually unharmed.

We designed siRNAs to effectively eliminate CD320 and LRP2 protein production to study their role in TCPP uptake into the cell. With these CD320 and LRP2 siRNAs, we achieved a reduction of CD320 and LRP2 protein levels of up to 90%. Simultaneous siRNA knock-down of CD320 and LRP2 in normal cells, including skin fibroblasts and breast epithelial cells, did not affect cell growth. However, knock-down of CD320 and LRP2 in cancer cell lines derived from diverse tissues (lung, breast, prostate, brain, and skin cancers) inhibited cell growth or killed the cells, in some cases up to 80%. Interestingly, in some cell lines, when either CD320 or LRP2 were silenced individually, a concurrent increase in protein expression of the other receptor was observed, suggesting that CD320 and LRP2 compensate for each other's function; hence, silencing *both* receptors is required for optimal cell killing.

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 3300 Nacogdoches, Suite 216, San Antonio, Texas 78217, and our telephone number at that address is (210) 698-5334. Our website address is https://www.bioaffinitytech.com/. Information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report. Investors should not consider any such information to be part of this Annual Report.

Intellectual Property Portfolio

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover our commercialized diagnostic test, pipeline product candidates and their use, as well as other inventions that are important to our business. In addition to patent protection, we also protect valuable company assets with copyright, trademark, trade secret, and know-how through confidentiality agreements, invention assignment agreements, and a trade secret program to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. The confidentiality agreements are designed to protect our proprietary information, and the invention assignment agreements are designed to gain company control and ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises, physical and electronic security of our information technology systems, and non-disclosure agreements with those that produce or receive company confidential information. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions, and trade secrets related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology companies like ours are generally uncertain and can involve complex legal, scientific, and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties.

As of December 31, 2024, we and our OncoSelect® subsidiary have a patent estate that includes 17 issued U.S. and foreign counterpart patents including two U.S. patents and 15 foreign counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, India, Italy, Mexico, Japan, Spain, Sweden, and the United Kingdom. We and OncoSelect® own all patents and trademarks in our intellectual property portfolio. One U.S. patent and nine counterpart foreign patents directed at diagnostic applications expire in 2030 and one foreign patent directed at a diagnostic application expires in 2039. One U.S. patent and five counterpart foreign patents directed at therapeutic applications expire in 2037.

With regard to our diagnostic patent portfolio, we have one issued U.S. patent and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom with another recently awarded diagnostic patent in Japan. Our diagnostic patent applications, fall into one of two families: one directed at diagnosing lung health using flow cytometry and the other directed at proprietary compensation beads used in analysis by flow cytometry. The diagnostic family of pending patent applications is directed at diagnosing lung health and includes three pending non-provisional U.S. patent applications and 18 foreign counterpart patent applications in Australia, Canada, China, European Patent Office, Hong Kong, Japan, Mexico, and Singapore filed in 2019 and 2024, one non-provisional U.S. patent application directed to compensation beads for flow cytometry and one International Patent Application filed in 2023 directed to diagnosing lung health.

With regard to our therapeutic product candidates, we have one issued U.S. patent, five issued foreign patents in Australia, China, Hong Kong, India and Mexico, two pending U.S. applications, and 10 foreign applications pending in Canada, China, European Patent Office, and Hong Kong. The therapeutic intellectual property is made up of two families, including one family directed at our siRNA product candidates for the treatment of cancer, and another family directed at our porphyrin conjugates for treating cancer.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering each of our therapeutic product candidates may be entitled to patent term extensions. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available; however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted and, if granted, the length of such extensions.

In addition to patent protection, we also rely on know-how and trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, to develop and maintain our proprietary position. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our know-how, trade secrets, and other proprietary information.

In addition, we plan to rely on regulatory protection based on orphan drug exclusivities, data exclusivities, and market exclusivities.

Government Regulation

United States

Diagnostic Products (including Medical Devices and Tests)

In the U.S., medical devices, including IVDs are subject to extensive regulation by the FDA, under the federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution, and import and export of medical devices, including IVDs. IVDs are a category of medical device that can be purchased by clinical laboratories and used to perform laboratory testing. IVDs include reagents and instruments used to detect the presence of certain chemicals or other biomarkers in human specimens for the purpose of diagnosis or detection of diseases or conditions. IVDs can also be used to perform predictive, prognostic, and screening testing. Like other medical devices, IVDs may require premarket review and clearance, authorization, or approval by the FDA. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative and judicial sanctions, such as FDA refusal to approve pending premarket approval ("PMA") applications, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

Laboratory Developed Tests

CyPath® Lung completed its certification as an LDT in accordance with CAP and CLIA regulations and guidance in 2023. The FDA considers LDTs to be tests that are developed, validated, and performed within a single laboratory. While CMS oversees clinical laboratory operations through the CLIA program, the FDA has the authority to regulate LDTs as IVDs under the FDCA. On May 6, 2024, FDA promulgated a final rule phasing out over four years its enforcement discretion over LDTs. The agency said it will expect compliance with premarket review and quality system requirements for LDTs marketed after May 6, 2024. The FDA states that the agency will generally not enforce premarket review requirements for LDTs that were marketed before May 6, 2024, if they are not modified in certain ways. In particular, the rule states that the LDT is exempt if marketed before May 6, 2024, and is not modified in a way that changes its indications for use; does not alter its operating principle; does not include significantly different technology; and, the LDT does not adversely change its performance or safety specifications. The Company has no expectation or intention to modify CyPath® Lung in any manner that will change its indications for use, alter its operating principal, include different technology, or change its performance or safety specifications.

Clinical Laboratory Improvement Amendments of 1988

Clinical laboratories testing specimens collected in the U.S. for the purpose of disease diagnosis or health assessment are subject to CLIA, unless exempt. CLIA establishes quality standards for all clinical laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. In particular, these regulations mandate that clinical laboratories must be certified by the federal government or an accreditation organization with deemed status from the federal government or must be located in a state that has been granted exemption from CLIA requirements because the state has laws in effect that provide for requirements equal to or more stringent than CLIA requirements. CLIA also requires that laboratories meet quality assurance, quality control and personnel standards, perform proficiency testing, and undergo inspections. The CLIA standards applicable to clinical laboratories are based on the complexity of the testing performed by the laboratory, which ranges from "waived" to "moderate complexity" to "high complexity." In the case of tests performed using IVDs, test complexity categorization of the IVD is performed by the FDA.

CAP is a member-based physician organization comprising approximately 18,000 board-certified pathologists. CAP's Laboratory Accreditation Program has been granted deeming authority from the federal government, meaning that CAP accreditation can be used to qualify for CLIA certification and to satisfy CLIA inspection requirements.

Medical Devices

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are low risk and are subject only to general regulatory controls. Class II devices are moderate risk. They are subject to general controls and may also be subject to special controls. Class III devices are generally the highest risk devices. They are required to obtain premarket approval and comply with postmarket conditions of approval in addition to general regulatory controls.

Generally, establishments that design and/or manufacture devices are required to register their establishments with the FDA. They also must provide the FDA with a list of the devices that they design and/or manufacture at their facilities.

The FDA enforces its requirements by market surveillance and periodic inspections, both announced and unannounced, to review records, equipment, facilities, laboratories, and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483 notice of observations, listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures. The FDA may also issue a public warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA may take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

- cease and desist orders;
- injunctions, or consent decrees;
- civil monetary penalties;
- recall, detention, or seizure of products;
- operating restrictions, partial or total shutdown of production facilities;
- refusal of or delay in granting requests for 510(k) clearance, *de novo* classification, or premarket approval of new products or modified products;
- withdrawing 510(k) clearances, *de novo* classifications, or premarket approvals that are already granted;
- refusal to grant export approval or export certificates for devices; and
- criminal prosecution.

Premarket Authorization and Notification

While most Class I and some Class II devices may be marketed without prior FDA authorization, many Class II and most Class III medical devices can be legally sold within the U.S. only if the FDA has: (1) approved a PMA application prior to marketing, generally applicable to most Class III devices; (2) cleared the device in response to a premarket notification (a "510(k) submission"), generally applicable to some Class I and most II devices; or (3) authorized the device to be marketed through the *de novo* classification process, generally applicable for novel low- or moderate-risk devices. PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of user fees.

510(k) Premarket Notification

Product marketing in the U.S. for most Class II and a limited number of Class I devices typically follows the 510(k) premarket notification pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the "predicate device." A predicate device may be a previously 510(k) cleared device or a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for PMA applications, or a product previously placed in Class II or Class I through the *de novo* classification process. The manufacturer must show that the proposed device has the same intended use as the predicate device, and that it either has the same technological characteristics, or has different technological characteristics but is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

The FDA has a user fee goal to apply no more than 90 calendar review days to 510(k) submissions. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond, although during the COVID-19 Public Health Emergency, the FDA permitted companies an additional 180 days in which to respond. Therefore, the total review time absent the Public Health Emergency could be up to 270 days, and in practice may be longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval or *de novo* classification. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510(k) clearance, *de novo* classification, or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III regardless of the level of risk they pose. To avoid requiring PMA review of novel low- to moderate-risk devices classified in Class III by operation of law, Congress enacted a provision that allows the FDA to reclassify a novel low- to moderate-risk device into Class I or II in the absence of a predicate device that would support 510(k) clearance. The FDA evaluates the safety and effectiveness of devices submitted for review under this *de novo* pathway and devices determined to be Class II can serve as predicate devices for future 510(k) applicants. The *de novo* pathway can require clinical data.

The FDA has a user fee goal to review a *de novo* request in 150 calendar review days. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be as long as 330 days and in practice may be longer. During the COVID-19 public health emergency, applicants were given an additional 180 days in which to respond.

PMA Approval

A Class III product generally must follow the PMA approval pathway. The PMA must be supported by sufficient valid scientific evidence, including clinical study data, to assure that the device is safe and effective for its intended use(s). After completion of clinical testing, a PMA including the results of all non-clinical, clinical, and other testing and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and *de novo* classification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation ("QSR") requirements, which impose elaborate testing, control, documentation, and other quality assurance procedures. The FDA has a user fee goal to review a PMA in 180 calendar review days if the submission does not require advisory committee input, or 320 review days if the submission does require advisory committee input. During the process, the FDA may issue a major deficiency letter, which stops the review clock. The applicant has up to 180 days to respond. Therefore, the total review time could be up to 360 days, if the submission does not require advisory committee input, or 500 days if the submission does require advisory committee input, and in practice may be longer. The COVID-19 pandemic significantly increased the FDA's workload because of the need to review emergency use authorization requests for IVDs and other regulated products, which delayed review timelines for some non-COVID-19 products.

If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale, and distribution or a requirement for postmarket surveillance or completion of postmarket studies. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling, or its manufacturing process. Supplements to a PMA may require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

Generally, at least one clinical trial is required to support a PMA application. Clinical studies also may be required for *de novo* classification or a 510(k) premarket notification. Clinical trials may also be conducted or continued to satisfy post-approval requirements for devices with PMAs. For significant risk investigational device studies, the FDA regulations require that human clinical investigations conducted in the U.S. be subject to an approved investigational device exemption ("IDE"). An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor prior to that time that the IDE is approved, approved with conditions, or disapproved. A nonsignificant risk investigational device study does not require FDA approval of an IDE. Some types of device studies, including many IVD studies, are exempt from IDE requirements altogether.

Clinical trials must be conducted in accordance with good clinical practice ("GCP") requirements contained in federal regulations and in international guidelines. Clinical trials, for both significant and nonsignificant risk devices, as well as exempt studies, must be approved by an IRB, an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions or sanctions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Postmarket Requirements

After a device is placed on the market, numerous general regulatory controls apply. These include the QSR, labeling regulations, medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). Failure to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject a manufacturer to warning letters, recalls, or other sanctions and penalties.

Advertising, marketing, and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDCA and the FDA's implementing regulations.

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling).

Violations of the FDCA relating to inappropriate promotion of medical devices may also lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a PMA or Class II 510(k) or *de novo* device, the FDA also may require postmarketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality control, manufacture, packaging, and labeling procedures must continue to conform to the QSR after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with the QSR and other applicable regulatory requirements. The FDA may withdraw product approvals or recommend or require product recalls if a company fails to comply with regulatory requirements.

Therapeutic Products

FDA Approval Process

In the U.S., therapeutic products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending new drug applications ("NDAs"), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Development for a new therapeutic product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA premarket approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, a general investigational plan, and a proposed clinical trial protocol. Long-term preclinical tests, such as tests of reproductive toxicity and carcinogenicity in animals, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the IND is placed on clinical hold, the sponsor must resolve any issues to the satisfaction of the FDA before the clinical hold is lifted and the clinical trial may proceed.

Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted (1) in compliance with federal regulations; (2) in compliance with GCP requirements; and (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support NDAs for marketing authorization are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

These phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose escalation stage and a dose expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within 10 months of the date the FDA files the NDA. Applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel products, as well as products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee – typically a panel that includes clinicians, statisticians and other experts – for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee but generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug product is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices ("cGMP") is satisfactory. After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing or information in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, manufacturing processes, or facilities, require submission and FDA approval of a new NDA, or a supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including diagnostic and drugs products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites, and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. A drug may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require postmarket testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, product manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies.

Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug product's manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

European Union

A medical device or diagnostic test must be CE marked to be sold in the EU. The In Vitro Diagnostic Device Regulation ("IVDR") of the EU defines the necessary pre-conditions that must be fulfilled to CE mark an IVD test or in vitro medical device in the EU. The manufacture of the test and/or device must fulfill all applicable regulatory requirements in the IVDR. Objective evidence of fulfilment of these requirements must be provided by the manufacturer prior to placing a test on the EU market. The manufacturer is required to establish a Quality Management System ("QMS") as well as processes for manufacturing, importing, distribution, post-market surveillance, and vigilance. Regulations also require that the product is fully documented. In addition, it is likely that our CyPath® Lung test is classified in a risk class that requires a review by an external party, a Notified Body, prior to placing the test on the EU market. This process is expected to require an additional six to 12 months after required documents and systems are in place. There currently is a general shortage in the EU of available Notified Bodies designated for IVDR devices. Further, we will need to contract a European Authorized Representative ("EAR") that acts as the Company's legal representative in the EU. Medical devices also must be registered with the competent authority in the country in which they are based. In addition to the CE mark and the registration done by the EAR, there is a need for an administrative national notification with certain member states of the EU.

European Data Collection

The collection and use of personal data (including health data) in the European Economic Area ("EEA") are governed by the EU General Data Protection Regulations ("EU GDPR") and national implementing legislation in EEA member states. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions for "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors. The EU GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EEA states may result in fines up to 20 million euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the EU GDPR affords various data protection rights to individuals (i.e., the right to erasure of personal data) in certain circumstances, and the ability for data subjects to claim material and non-material damages resulting from infringements of the EU GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the EU GDPR will require significant time, resources, and expense, and we may be required to put in place additional mechanisms ensuring compliance with the evolving data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations, and prospects.

Rest of the World Regulation

For other countries outside of the EU (or in some cases, EEA) and the U.S., such as China, Southeast Asia, and Australia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Human Capital

We employ 57 employees at the time of this filing, 21 employed by bioAffinity and 36 employed by PPLS. We place significant emphasis on the recruitment, development, and retention of our employees who include award-winning scientists dedicated to advancing scientific discovery from bench to bedside. Of our seven employees engaged in research and development, all of whom are employed full-time, three hold Ph.Ds in biology or medicinal chemistry. Of the 36 employees at PPLS, nearly 40% have worked at our clinical laboratory for more than five years.

Our Chief Science Officer, William Bauta, Ph.D., was the Associate Director of Science at Genzyme Corporation and held a similar position at Ilex Products, Inc., where he was responsible for the discovery, development and FDA approval of therapeutics in the companies' pipelines, and Manager of Medicinal and Process Chemistry at Southwest Research Institute. Business development is led by our Chief Operating Officer, Xavier Reveles, who has 25 years of experience as a clinical geneticist skilled in the creation and management of CLIA clinical laboratories, coding, and CPT reimbursement valuations. Mr. Reveles is board certified by the American Society of Clinical Pathology as a clinical specialist in cytogenetics who has successfully launched multiple diagnostics and commercial laboratories. We have attracted experienced salespeople with a proven record in the pulmonary field. In November 2023, we hired a National Sales Director who has more than 15 years of experience in medical sales and marketing, most recently as Executive Account Manager for the respiratory portfolio of Olympus America's therapeutic solutions division. Our innovative and collaborative culture is in part responsible for our ability to attract and retain highly skilled professionals seeking professional advancement. Outside partnerships and collaborations that advance business and scientific research are encouraged, allowing us to multiply workforce efforts without expending significant capital.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to other public companies. These provisions include, but are not limited to:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and selected financial data, and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement;

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended ("SOX");

- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements, and proxy statements; and

- exemptions from the requirements to seek non-binding advisory votes on executive compensation or stockholder approval of any golden parachute arrangements.

We may take advantage of some or all of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the first fiscal year in which our annual gross revenues exceed $1.235 billion, (3) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with new or revised accounting standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these accounting standards.

We are also a "smaller reporting company" as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an "emerging growth company" may continue to be available to us as a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a "smaller reporting company" until we have $250 million or more in public float (based on our Common Stock) measured as of the last business day of our most recently completed second fiscal quarter or in the event we have no public float (based on our Common Stock) or a public float (based on our Common Stock) that is less than $700 million, annual revenues of $100 million or more during the most recently completed fiscal year.

Item 1A. Risk Factors.

Risks Related to Our Financial Position

Our business plan relies upon our ability to obtain additional sources of capital and financing. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, we may be required to cease operations.

Prior to 2022, we had not generated any revenue. During the years ended December 31, 2024, and December 31, 2023, we generated revenue of approximately $9.4 million and $2.5 million, respectively.

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

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

- Develop, enhance, and protect our diagnostic tests and therapeutic products;

- Raise sufficient funding to support our diagnostic tests and therapeutic product development program(s);

- Complete pre-clinical testing;

- Work with our partners to expand commercialization of our first diagnostic test, CyPath® Lung, as an LDT under the CAP/CLIA guidelines and regulations administered by CMS and CAP;

- Obtain *de novo* classification from FDA for our CyPath® Lung as a Class II in vitro diagnostic

- Work with our partners to develop and commercialize our first diagnostic test, CyPath® Lung, as a CE-marked test in accordance with the IVDR of the EU;
- Synthesize, test, and attract licensing partners for drug conjugates, siRNAs, and other therapeutics (and methods for their use) developed by the Company;
- Develop and conduct human clinical studies to support the regulatory approval and marketing of our diagnostic test(s) and therapeutic product(s);
- Develop and manufacture the test(s) and product(s) to FDA standards, appropriate EU standards, and appropriate standards required for the commercialization of our tests and products in countries in which we seek to sell our diagnostic test(s) and therapeutic product(s);
- Obtain the necessary regulatory approvals to market our diagnostic test(s) and therapeutic product(s);
- Secure the necessary personnel and infrastructure to support the development, commercialization, and marketing of our diagnostic test(s) and therapeutic product(s); and
- Develop strategic relationships to support development, manufacturing, and marketing of our diagnostic test(s) and therapeutic product(s).

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain the research and development efforts, diversify our diagnostic tests and therapeutic product offerings, or even continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

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

As of December 31, 2024, we had an accumulated deficit of $53.6 million and $1.1 million cash on hand. For the year 2024, cash used in operations was $7.1 million and net loss was $9.0 million. Despite raising an additional $1.4 million in gross proceeds in February 2025 through a private placement offering, we 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 our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that our cash resources are sufficient to continue operations through April 2025. Our future is dependent upon the ability to obtain financing and upon future profitable operations from the development of new business opportunities. There can be no assurance that we will be successful in accomplishing these objectives. Without such additional capital, we may be required to curtail or cease operations and be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. WithumSmith+Brown, PC, our independent registered public accounting firm for the fiscal year ended December 31, 2024, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2024, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

We have a limited operating history, which makes it difficult to evaluate our current business and future prospects.

We are a company with limited operating history, and our operations are subject to all of the risks inherent in establishing a new business enterprise. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the formation of a new business, the development of new technologies or those subject to clinical testing, and the competitive and regulatory environment in which we will operate. To date, we have generated revenue from a limited market launch of CyPath® Lung in Texas. There can be no assurance that we will be able to successfully expand our commercialization efforts or that we will obtain the necessary regulatory approvals that will allow us to expand our marketing efforts. We may not be able to maintain certification of CyPath® Lung as an LDT in accordance with CAP/CLIA guidance and regulations, or obtain approval of our diagnostic tests in development by the CMS, the FDA, European Medicines Agency, or Chinese National Medical Products Administration. Even if we do so and are also able to commercialize our diagnostic tests, we may never generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely cause our securities to decrease in value or become worthless.

In addition, while we anticipate generating continued revenue from PPLS, our CAP-accredited, CLIA-certified clinical pathology laboratory, we do not expect to immediately derive profit from revenue from PPLS' services. Once we begin to generate such profit, there is no guarantee that it will be sufficient to realize the expected financial benefits of the acquisition and that revenue generated will cover necessary operating expenses. In addition, since we have limited experience operating a clinical laboratory, we may not accurately estimate the expenses we will incur. Ownership of a CAP/CLIA laboratory and related services business may not have the clinical value and commercial potential which we envision. Any substantive failure of PPLS laboratory to meet our expectations could have a material negative effect on our results of operations. There can be no assurance that the anticipated benefits of PPLS will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

We will require additional financing to implement our business plan, which may not be available on favorable terms or at all, and we may have to accept financing terms that would place restrictions on us.

We believe that we must raise additional funds to be able to continue our business operations. We may not be able to obtain equity or debt financing on acceptable terms or at all to implement our growth strategy. As a result, adequate capital may not be available to finance our current development plan, take advantage of business opportunities, or respond to competitive pressures. If we are unable to raise additional funds, we may be forced to curtail or even abandon our business plan and focus on fewer commercial opportunities that may result in more limited growth than forecast.

Until such time, if ever, as we can generate substantial income from sale of our diagnostic test(s) and therapeutic product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our Common Stock (the "Common Stockholders"). In addition, the terms of any future financing may impose restrictions on our right to declare dividends or on the manner in which we conduct our business. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or making acquisitions or significant asset sales.

If we raise additional funds through collaborations, strategic alliances or marketing, or distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, and research programs, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our Common Stock.

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

We do not expect to immediately derive profit from revenue from PPLS' services. Since its acquisition in September 2023, we have generated $2.5 million in 2023 and $9.4 million in 2024 in revenue from PPLS. Once we begin to generate such profit, there is no guarantee that it will be sufficient to realize the expected financial benefits of the acquisition. In addition, since we have limited experience operating a clinical laboratory, we may not accurately estimate the expenses we will incur.

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

We began operating a clinical laboratory in September 2023. Previously, only our Chief Operating Officer, Xavier Reveles, had operated a CAP-accredited, CLIA-certified clinical laboratory and therefore it may be difficult for investors to analyze our ability to successfully operate a clinical laboratory. Our ability to generate revenue from the clinical laboratory will depend, in part, on our ability to attract and maintain customers and on the amount spent by the customers on such services. If our laboratory fails to attract customers and operate at sufficient capacity, our margins will suffer, and we may not be able to fund the costs we incur to operate it. The success of our clinical laboratory will also depend, in part, on our ability to attract and retain an appropriately skilled and sufficient workforce to operate the laboratory and our ability to comply with various quality standards and environmental, health and safety laws and regulations.

We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early-stage company with respect to operating a clinical laboratory. Our revenue and income potential for the clinical laboratory is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise and cannot assure you that we will be able to successfully address these risks.

Risks Related to our Diagnostic Product

Until we secure FDA clearance for CyPath® Lung as a Class II in vitro diagnostic, we may encounter physicians who will not order an LDT.

In order to market our CyPath® Lung as an IVD medical device, we must receive *de novo* classification from the FDA as a Class II in vitro diagnostic. Subject to obtaining necessary financing, we intend to launch a pivotal trial later this year in an effort to attain such classification; however, there can be no assurance that the trial will have favorable results or that it will generate the results necessary to obtain such classification. Until such time as we receive *de novo* classification, which we may never receive, our marketing efforts are limited to the marketing and sale of CyPath® Lung as an LDT. Without clearance of CyPath® Lung by the FDA, some physicians may not order the test.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S., such as the European Medicines Agency.

Patient enrollment is affected by many other factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during the trial period; and
- the proximity and availability of clinical trial sites for prospective patients.

We are unable to forecast with precision our ability to enroll patients. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our Company to decline and limit our ability to obtain additional financing.

Clinical trials are expensive, time consuming, and may not be successful.

Clinical trials are expensive, time consuming, and may not be successful. They involve the evaluation of diagnostic tests and testing of potential therapeutic agents and effective treatments in humans to determine the safety and efficacy of the diagnostic tests and therapeutic products necessary for an approved diagnostic and therapeutic technology. Many tests and products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our tests and products progress successfully through initial or subsequent human testing, they may fail in later phases of development. We may engage others to conduct our clinical trials, including clinical research organizations and government-sponsored agencies. These trials may not start or be completed as we forecast or may not achieve desired results.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our diagnostic and therapeutic technologies, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product and test development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate; or
- regulators may revise the requirements for approving our diagnostic or therapeutic technologies, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval;
- not obtain marketing approval at all, which would seriously impair our viability;

- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the diagnostic test or therapeutic product removed from the market after obtaining marketing approval.

Our product and test development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our diagnostic technology or allow our competitors to bring diagnostic tests and therapeutic products to market before we do, potentially impairing our ability to successfully commercialize our diagnostic and therapeutic technologies and harming our business and results of operations.

Risks Related to Our Diagnostic Tests

If our tests do not perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that PPLS can provide reliable, high-quality clinical testing services. There is no guarantee that the accuracy and reproducibility that our CAP/CLIA clinical pathology laboratory has demonstrated to date will continue as its test volume increases. We believe that PPLS' customers are likely to be particularly sensitive to test limitations and errors, including inaccurate test results. As a result, if PPLS does not perform its diagnostic services as expected, our operating results, reputation and business will suffer. We may be subject to legal claims arising from such limitations, errors, or inaccuracies.

We may experience difficulties that delay or prevent our development, introduction, or marketing of enhanced or new tests.

Our success may also depend on our ability to effectively introduce enhanced or new tests. The development of enhanced or new tests is complex, costly, and uncertain. Furthermore, enhancing or developing new tests requires us to anticipate patients', clinicians', and payors' needs and emerging technology trends accurately. We may experience research and development, regulatory, marketing, and other difficulties that could delay or prevent our introduction of enhanced or new tests. The research and development process in diagnostics generally takes a significant amount of time from the research and design stage to commercialization. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may have to abandon a test in which we have invested substantial resources. In order to successfully commercialize tests that we may develop in the future, we may need to conduct lengthy, expensive clinical trials and develop dedicated sales and marketing operations or enter into collaborative agreements to achieve market awareness and demand. Any delay in the research and development, approval, production, marketing, or distribution of enhanced or new tests could adversely affect our competitive position, branding, and results of operations.

We cannot be certain that:

- any tests that we may enhance or develop will prove to be effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, regulatory approvals, if needed;
- any tests that we may enhance or develop will be ordered and used by healthcare providers;
- any tests that we may enhance or develop can be provided at acceptable cost and with appropriate quality; or
- any of our tests can be successfully marketed.

These factors and other factors beyond our control could delay the launch of enhanced or new tests.

If clinical testing of a particular diagnostic test or therapeutic product candidate does not yield successful results, we will be unable to commercialize that test or product candidate.

We must demonstrate the product safety and efficacy of our candidates for diagnostic tests and therapeutic products in humans through extensive clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any test or product, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;
- after reviewing test results, we may abandon projects that we might previously have believed to be promising;
- we or our regulators may suspend or terminate clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and
- our test or product candidates may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Even if our diagnostic tests or therapeutic products receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

Even if our products receive marketing approval, if needed, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If we do not generate significant product revenues, we may not become profitable. The degree of market acceptance of our products and tests, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety, and other potential advantages compared to alternative tests or products;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative diagnostics or treatments;
- the willingness of the target patient population to try new diagnostic tests and of physicians to order these tests;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of governmental agencies and third-party medical insurance and adequate reimbursement for our diagnostic tests or therapeutic products;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other diagnostic methods or therapeutic treatments;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other medications;
- inability of certain types of patients to produce adequate samples for analysis in the use of our diagnostic tests;
- inability of certain types of patients to use our diagnostic tests or take our therapeutic products; and
- the prevalence and severity of side effects from our therapeutic products.

If we are unable to address and overcome these and similar concerns, our business and results of operations could be substantially harmed.

If we are unable to establish effective sales, marketing, and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our diagnostic tests or therapeutic products if and when they are approved.

We are building our sales and marketing organizations and have limited experience in the sale, marketing, or distribution of our diagnostic tests and therapeutic products. To achieve commercial success for any diagnostic test or therapeutic product for which we obtain marketing approval, we will need to successfully establish and maintain relationships directly and with third parties to perform sales and marketing functions.

Factors that may inhibit our efforts to commercialize our diagnostic tests or therapeutic products on our own include:

- our inability to recruit, train, and retain adequate numbers of effective sales, technical support, and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our diagnostic tests or therapeutic products;
- the lack of complementary diagnostic tests or therapeutic products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive diagnostic tests or therapeutic product lines;
- unforeseen costs and expenses associated with creating an independent sales, technical support, and marketing organization; and
- the inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our diagnostic tests or therapeutic products.

We are currently dependent upon our pathology laboratory PPLS to offer and perform CyPath® Lung.

PPLS is currently the only commercial laboratory offering CyPath® Lung and, therefore we are dependent upon our subsidiary PPLS for the generation of our revenue. PPLS performs testing when ordered by physicians for their patients. PPLS also generates revenue related to the use of CyPath® Lung tests for a DOD observational study titled "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay," and when performed for DOD research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection.

If we are unable to convince physicians of the benefits of our proposed diagnostic tests or therapeutic products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our proposed diagnostic tests and products may require pathology laboratories and physicians to be informed regarding our proposed diagnostic tests and products and their intended benefits. Inability to carry out this physician education process may adversely affect market acceptance of our proposed diagnostic tests or therapeutic products. We may be unable to timely educate physicians regarding our proposed diagnostic tests or therapeutic products in sufficient numbers to achieve our marketing plans or to achieve acceptance of our diagnostic tests or therapeutic products. Any delay in physician education may materially delay or reduce demand for our diagnostic tests or therapeutic products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our proposed diagnostic tests or therapeutic products is created, if at all.

We face substantial competition, which may result in others discovering, developing, or commercializing competing diagnostic tests or therapeutic products before or more successfully than we do.

The development and commercialization of new diagnostic and therapeutic technologies is highly competitive. We will always face competition with respect to any diagnostic and therapeutic technology that we may seek to develop or commercialize in the future from major diagnostic and pharmaceutical companies, LDT laboratories, smaller diagnostic and pharmaceutical companies, and biotechnology companies worldwide.

A substantial number of the companies against which we are competing or may compete against in the future may have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved diagnostic tests or therapeutic products. Mergers and acquisitions in the diagnostic, pharmaceutical, and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic tests or therapeutic products that are more accurate, more convenient, or less expensive than any diagnostic tests or therapeutic products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their diagnostic tests or therapeutic products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors.

We may be unable to compete in our target marketplaces, which could impair our ability to generate revenues, thus causing a material adverse impact on our results of operations.

Our success depends upon our ability to retain key executives and to attract, retain, and motivate qualified personnel, and the loss of these persons could adversely affect our operations and results.

We are highly dependent on the principal members of our management, scientific, and clinical teams, including Maria Zannes, J.D., our President and Chief Executive Officer, Xavier Reveles, MS, CG(ASCP)^{cm}, our Chief Operating Officer, and Michael Edwards, our Chief Financial Officer, as well as Roby Joyce, M.D., the Medical Director of PPLS.

The loss of the services of any of our executive officers or other members of our management team could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize diagnostic tests or therapeutic products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate key personnel on acceptable terms given the competition among numerous biotechnology companies for similar expertise. We also face competition from universities and research institutions for qualified scientific and clinical personnel. In addition, we rely and expect to continue to rely to a significant degree on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be engaged by other entities and may have commitments under consulting or advisory contracts that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our lack of operating experience may make it difficult to manage our growth which could lead to our inability to implement our business plan.

We have limited experience in marketing and selling diagnostic tests and pharmaceutical products. Any growth will require us to expand our management and our operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our operational, managerial, and financial resources.

We will depend on third parties to manufacture our kits, reagents and supplies and help in marketing our diagnostic tests and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

We do not have, and do not now intend to develop, facilities for the manufacture of the contents of our collection kits needed for clinical or commercial production. In addition, we are not a party to any long-term agreement with any of our suppliers such as the reagents used in processing sputum samples, and accordingly, we have the products used in our diagnostic tests manufactured on a purchase-order basis from primary suppliers. We have entered into relationships with manufacturers on a contract basis but will need to expand those relationships. We expect to depend on such collaborators to supply us with reagents and other materials manufactured in compliance with standards imposed by the CMS, FDA, and foreign regulators.

Moreover, as we develop our diagnostic tests or therapeutic products eligible for clinical trials, we intend to contract with independent parties to design the trial protocols, arrange for and monitor the clinical trials, and collect and analyze the data. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks, including reduced control over the timing and other aspects of our clinical trials.

We are exposed to product liability and pre-clinical and clinical liability risks which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of diagnostic tests and therapeutic products. Such claims may be asserted against us. In addition, using diagnostic tests and therapeutic products that may be developed with potential collaborators in our clinical trials and the subsequent sale of these tests and products by bioAffinity or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim, or series of claims, brought against us could have a material adverse effect on our business, financial condition, and results of operations.

While we have obtained product liability insurance covering CyPath® Lung as a commercialized LDT to be sold by our CAP-accredited, CLIA-certified clinical pathology laboratory PPLS, in the future we may not be able to obtain or maintain adequate product liability insurance, when needed, on acceptable terms, if at all, or such insurance may not provide adequate coverage against our potential liabilities. Furthermore, potential partners with whom we intend to have collaborative or strategic agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition, and results of operations.

In addition, we may be unable to obtain or to maintain clinical trial liability insurance on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any tests or products we develop.

Our collection, use, and disclosure of personal information, including health and employee information, is subject to U.S. state and federal privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

The privacy and security of personal information stored, maintained, received, or transmitted, including electronically, is a major issue in the U.S. and abroad. Numerous federal and state laws and regulations, including state privacy, data security and breach notification laws, federal and state consumer protection and employment laws, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the Genetic Information Nondiscrimination Act of 2008, govern the collection, dissemination, use, and confidentiality of personal information, including genetic, biometric, and health information. These laws and regulations are increasing in complexity and number, may change frequently, and sometimes conflict. Penalties for violations of these laws vary but can be severe.

While we strive to comply with all applicable privacy and security laws and regulations, including our own posted privacy policies, these laws and regulations continue to evolve, and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others or could cause us to lose customers, which could have a material adverse effect on our business. Recently, there has been an increase in public awareness of privacy issues in the wake of revelations about the data collection activities of various government agencies and in the number of private privacy-related lawsuits filed against companies. Concerns about our practices with regard to the collection, use, retention, disclosure, or security of personal information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business.

If we are unable to obtain adequate reimbursement from third-party payors or governmental agencies for CyPath® Lung or other diagnostic tests or therapeutic products under development or if new restrictive legislation is adopted, market acceptance of our tests or products may be limited, and we may not achieve expected revenues.

The continuing efforts of government and insurance companies, health maintenance organizations ("HMOs"), and other payors of healthcare costs to contain or reduce costs may affect our future revenues and profitability, as well as the future revenues and profitability of our potential customers, suppliers, and collaborative partners and the availability of capital. For example, in certain international markets, pricing or profitability of diagnostic tests and therapeutic products is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of medical devices, tests, and prescription pharmaceuticals, and Medicare and Medicaid reforms. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition, and results of operations.

Our ability to commercialize our tests or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our tests or products are obtained by governmental authorities, private health insurers, and other organizations such as HMOs. Governmental agencies and third-party payors are increasingly challenging the prices charged for medical tests, drugs, and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services, diagnostics, and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of our tests or products.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, vendors, and agents acting on behalf of us or our affiliates. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to (1) comply with the regulations of the FDA or foreign health authorities; (2) provide true, complete, and accurate information to the FDA or foreign health authorities; (3) comply with manufacturing standards we have established; (4) comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (5) report financial information or data accurately or to disclose unauthorized activities to us.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation, ordering, and prescription of any diagnostic tests or therapeutic products for which we obtain marketing approval. Our operations and current and future arrangements with investigators, healthcare professionals, customers, and third-party payors are subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, and the Physician Payments Sunshine Act and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing, and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell, and distribute our diagnostic tests or therapeutic products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory, and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants, or stock options as compensation for services provided to us, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the delay, reduction, termination, or restructuring of our operations. Further, defending against any such actions can be costly and time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We face intense competition in the biotechnology and pharmaceutical industries.

The biotechnology and pharmaceutical industries are intensely competitive. We face direct competition from U.S. and foreign companies focusing on diagnostic tests and pharmaceutical products, which are rapidly evolving. Our competitors include major multinational diagnostic and pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs, and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial tests or products based on technology developed at such institutions. Our competitors may succeed in developing or licensing technologies, tests, and products that are more effective or less costly than ours or succeed in obtaining CAP/CLIA validation or FDA or other regulatory approvals for diagnostic test and therapeutic product candidates before we do. Acquisitions of, or investments in, competing diagnostic, pharmaceutical, or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

The market for our proposed tests and products is competitive and rapidly changing, and new diagnostic technologies which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The diagnostic, pharmaceutical, and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our proposed tests or products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from diagnostic, pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase.

As a company engaged in the development of diagnostic technology with limited revenue generated to date, our resources are limited, and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar diagnostic efficacy compared to our proposed tests or products. Our competitors may develop diagnostic technologies that are more effective or less costly than our proposed tests or products and therefore present a serious competitive threat.

The potential widespread acceptance of diagnostic tests or therapies that are alternatives to ours may limit market acceptance of our proposed tests or products, even if commercialized. Many of our targeted diseases and conditions can also be detected by other tests or treated by other medications. These tests and treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive technologies may limit the potential for our technologies, formulations, tests, and products to receive widespread acceptance if commercialized.

Healthcare cost containment initiatives and the growth of managed care may limit our returns.

Our ability to commercialize our diagnostic tests and therapeutic products successfully may be affected by the ongoing efforts of governmental and third-party payors to contain the cost of healthcare. These entities are challenging prices of healthcare products and services, denying or limiting coverage and reimbursement amounts for new diagnostic tests and therapeutic products, CAP/CLIA-validated LDTs, and FDA-approved diagnostic tests and therapeutic products considered experimental or investigational or which are used for disease indications without FDA marketing authorization. Even if we succeed in bringing any tests or products to the market, they may not be considered cost effective, and governmental or third-party reimbursement might not be available or sufficient. If adequate governmental or third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and development for new tests and products. In addition, legislation and regulations affecting the pricing of diagnostic tests, pharmaceuticals, or healthcare services may change in ways adverse to us before or after any of our proposed tests and products are approved for marketing.

Our internal information technology systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our diagnostic tests' or therapeutic product candidates' development programs, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party clinical research organizations and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, extortion, account takeover attacks, degradation of service attacks, denial-of-service attacks, "phishing," or social engineering and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure or lead to data leakage. We have technology security initiatives and disaster recovery plans in place to mitigate our risk to these vulnerabilities, but these measures may not be adequately designed or implemented to ensure that our operations are not disrupted or that data security breaches do not occur. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs, and the development of our diagnostic tests and therapeutic product candidates could be delayed. In addition, the loss of clinical trial data for our diagnostic tests and therapeutic product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Like all businesses we may be increasingly subject to ransomware or other malware that could significantly disrupt our business operations or disable or interfere with necessary access to essential data or processes. Numerous recent attacks of this nature have also involved exfiltration and disclosure of sensitive or confidential personal or proprietary information, or intellectual property, when victim companies have not paid the cyber criminals substantial ransom payments. For example, any such event that leads to unauthorized access, use, disclosure, unavailability, or compromised integrity of personal or other sensitive or essential information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, increase the costs we incur to protect against such information security breaches, such as increased investment in technology, render key personnel unable to perform duties or communicate throughout the organization, and otherwise subject us to fines and other liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

The costs of mitigating cybersecurity risks are significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; and costs related to maintaining redundant networks, data backups and other damage-mitigation measures. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim.

Declining general economic or business conditions, including tariff and customs regulations, may have a negative impact on our business.

Continuing concerns over the U.S. healthcare system and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the U.S. and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence, could precipitate an economic slowdown and recession. Additionally, political changes in the U.S. and elsewhere in the world have created a level of uncertainty in the markets. If the economic climate deteriorates, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition, and results of operations.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development, and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition, and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners. Tariffs, economic sanctions, and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the U.S. or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the U.S. and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition, and results of operations.

Further, due to increasing inflation, operating costs for many businesses have increased and, in the future, could impact demand or pricing manufacturing of our drug candidates or services providers. Inflation rates, particularly in the U.S., have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including employee wages), reduced liquidity, and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Actual events involving reduced or limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

In addition, the global macroeconomic environment could be negatively affected by, among other things, a resurgence of COVID-19 or other pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, the war in the Middle East and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations. These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

Global climate change and related regulations could negatively affect our business.

The effects of climate change, such as extreme weather conditions, create financial risks to our business. For example, the demand for our products may be affected by unseasonable weather conditions. The effects of climate change could also disrupt our operations by impacting the availability and cost of materials needed for manufacturing and could increase insurance and other operating costs. We could also face indirect financial risks passed through the supply chain and disruptions that could result in increased prices for our products and the resources needed to produce them.

Risks Related to the Operation of a CAP/CLIA Laboratory

The operations of PPLS will depend in part upon prior relationships with existing customers and our ability to continue such relationships with these customers.

PPLS' future success will depend in part upon the continued relationships with existing customers, many of whom have developed professional relationships with pathologists who have established relationships with our customers. In particular, Roby Joyce, M.D. who is the Medical Director of PPLS and a member of our Board of Directors, has a long-term relationship with certain PPLS clients. We cannot be assured that we will be able to retain his services. Although we have entered into a three-year employment agreement with him, there can be no assurance that the agreement will not be terminated prior to its expiration. We do not have an insurance policy on the life of Dr. Joyce, and we do not have "key person" life insurance policies for any of our other officers or advisors. The loss of employees who have established business relationships with our clients could result in delays in services, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results.

PPLS may be unable to effectively maintain equipment or generate revenue when its equipment is not operational.

Timely, effective service is essential to maintaining the reputation and high use rates of our CAP/CLIA laboratory, PPLS. Although it has agreements with a third-party equipment service providers pursuant to which such service providers maintain and repair its equipment, the agreement does not compensate it for loss of revenue when its systems are not fully operational, and its business interruption insurance may not provide sufficient coverage for the loss of revenue. Also, third-party equipment service providers may not be able to perform repairs or supply needed parts in a timely manner, which could result in a loss of revenue. Therefore, if PPLS experiences more equipment malfunctions than anticipated or if it is unable to promptly obtain the service necessary to keep its equipment functioning effectively, or where its business or data is compromised on account of equipment malfunctions or a cybersecurity-related attack, PPLS's ability to provide services and to fulfill its contractual arrangements would be adversely affected and our revenue could decline.

If our sole laboratory facility becomes damaged or inoperable, loses its accreditation, or is required to vacate the facility, PPLS' ability to sell its products or provide diagnostic assays and pursue its research and development efforts may be jeopardized.

PPLS' facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding, and power outages, which may render it difficult or impossible for it to provide pathology services or perform our diagnostic assays for some period of time. The inability to of PPLS to perform its services for customers if PPLS' facility is inoperable for even a short period of time may result in the loss of customers or harm to its reputation or relationships with its customers, and it may be unable to regain those customers or repair its reputation in the future. Furthermore, PPLS' facilities and the equipment it uses to perform its services could be costly and time-consuming to repair or replace.

Further, if PPLS' current or future CLIA-certified, CAP-accredited, and state-licensed laboratory becomes inoperable or unqualified in any way, it may not be able to license or transfer its technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which its current assays and its planned future assays could be performed. Even if PPLS finds a facility with such qualifications to perform its assays, it may not be available to PPLS on commercially reasonable terms.

To date, substantially all of our revenue has been derived from the operations of the laboratory. The inability of PPLS to perform its services for its customers if PPLS' facility is inoperable would significantly impact our ability to generate revenue.

PPLS relies on commercial courier delivery services to transport sputum samples for processing the CyPath® Lung test in a timely and cost-efficient manner, and if these delivery services are disrupted, its business will be harmed.

PPLS' business depends on its ability to quickly and reliably deliver test results to its customers. Sputum samples are received overnight within the U.S. for analysis at the laboratory facility located in San Antonio, Texas. Disruptions in delivery service, whether due to bad weather, natural disaster, terrorist acts or threats, or for other reasons could adversely affect specimen integrity and its ability to process samples in a timely manner and to service its customers, and ultimately its reputation and its business. In addition, if PPLS is unable to continue to obtain expedited delivery services on commercially reasonable terms, its operating results may be adversely affected.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to PPLS' business or prevent it from accessing critical information and expose it to liability, which could adversely affect its business and reputation.

In the ordinary course of its business, PPLS collects and stores sensitive data, including legally protected health information, credit card information, and personally identifiable information, such as data collected in connection with the CyPath® Lung laboratory test results. PPLS also stores sensitive intellectual property and other proprietary business information, including that of its customers, payors, and collaboration partners. PPLS manages and maintains its applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information, and business and financial information. PPLS is highly dependent on information technology networks and systems, including the internet, to securely process, transmit, and store this critical information. Although its policies and practices adhere to the requirements of HIPAA and PPLS employs measures to protect sensitive information from unauthorized access or disclosure, its information technology and infrastructure, and that of its third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm PPLS' reputation, compel PPLS to comply with state breach notification laws, subject PPLS to mandatory corrective action, require PPLS to verify the correctness of database contents and otherwise subject PPLS to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If PPLS is unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, its operations could be disrupted, and it may suffer loss of reputation, financial loss, and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise PPLS' networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such interruption in access, improper access, disclosure, modification of, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss, or dissemination could also disrupt PPLS' operations, including its ability to perform tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about tests, educate patients and clinicians about services, and manage the administrative aspects of its business, any of which could damage its reputation and adversely affect our business. Any such breach could also result in the compromise of PPLS' trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of health-related, privacy, and data protection laws in the U.S., Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with PPLS' practices. If so, this could result in government-imposed fines or orders requiring that it change its practices, which could adversely affect our business and its reputation. Complying with these various laws could cause us to incur substantial costs or require PPLS to change its business practices and compliance procedures in a manner adverse to our business.

If PPLS uses hazardous chemicals in a manner that causes injury, PPLS could be liable for damages.

PPLS' activities currently require the controlled use of potentially harmful chemicals. PPLS cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, PPLS could be held liable for any resulting damages, and any liability could exceed its resources or any applicable insurance coverage it may have. Additionally, PPLS is subject to, on an ongoing basis, federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on its, and therefore our, financial condition, results of operations, and cash flows. In the event of an accident or if PPLS otherwise fails to comply with applicable regulations, it could lose its permits or approvals or be held liable for damages or penalized with fines.

If PPLS is unable to successfully scale its operations to support demand for CyPath® Lung, its business could suffer.

As test volume of CyPath® Lung grows, PPLS will need to continue to ramp up its testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements, and expand its internal quality assurance program and technology platform to support testing on a larger scale. PPLS will also need additional equipment and certified laboratory personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements, and quality assurance will be successfully implemented by PPLS or that equipment and appropriate personnel will be available. As additional tests are developed, PPLS may need to bring new equipment on-line, implement new systems, technology, controls and procedures, and hire personnel with different qualifications.

The value of CyPath® Lung depends, in large part, on PPLS' ability to perform the tests accurately and on a timely basis and on its reputation for such timeliness and accuracy. Failure to implement necessary procedures or to hire the necessary personnel could impact its ability to meet market demand. There can be no assurance that it will be able to perform tests on a timely basis at a level consistent with demand, that its efforts to scale its commercial operations will not negatively affect the quality of test results, or that it will be successful in responding to the growing complexity of testing operations.

In addition, PPLS' growth may place a significant strain on its management, operating and financial systems, and its sales, marketing, and administrative resources. As a result of its growth, PPLS' operating costs may escalate even faster than planned, and some of its internal systems may need to be enhanced or replaced. If we cannot effectively manage PPLS' expanding operations and its costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

Billing for PPLS' services is complex, and PPLS must dedicate substantial time and resources to the billing process to be paid.

Billing for clinical laboratory services is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, PPLS bills various payors, including Medicare, insurance companies, and patients, all of which have different billing requirements. It generally bills third-party payors for its diagnostic assays and pursues reimbursement on a case-by-case basis where pricing contracts or Medicare reimbursement is not in place. To the extent laws or contracts require it to bill patient co-payments or co-insurance, PPLS must also comply with these requirements. PPLS may also face increased risk in its collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect its business, results of operations, and financial condition.

Several factors make the billing process complex, including:

- the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes and/or coverage policies that apply to PPLS' assays;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

PPLS uses standard industry billing codes, known as Current Procedural Terminology ("CPT") codes, to bill for its diagnostic assays. These codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission, or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on PPLS' revenues. There can be no assurance that payors will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems will not result in errors, delays in payments, and a related increase in accounts receivable balances.

As PPLS introduces new assays, PPLS will need to add new codes to its billing process as well as its financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect its collection rates, revenue, and cost of collecting.

Additionally, PPLS' billing activities require its third-party billing provider to implement compliance procedures and oversight, train and monitor its employees, challenge coverage and payment denials, assist patients in appealing claims, and require PPLS to undertake audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that PPLS may be required to return some portion of prior payments it has received. These billing complexities and the related uncertainty in obtaining payment for its assays could negatively affect its revenue and cash flow, its ability to achieve profitability, and the consistency and comparability of its, and therefore our, results of operations.

PPLS relies on a third-party billing provider and an in-house billing function to transmit claims to payors, and any delay in transmitting claims could have an adverse effect on its revenue.

While PPLS manages the overall processing of claims, it relies on a third-party billing provider to transmit the actual claims to payors based on the specific payor billing format. Claims processing could be delayed if its third-party provider makes changes to its invoicing system. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payors on a timely basis or are erroneously submitted, or if PPLS is required to switch to a different provider to handle claim submissions, it may experience delays in its ability to process these claims and receipt of payments from payors, or possibly denial of claims for lack of timely submission, which would have an adverse effect on its, and therefore our, revenue and business.

Risks Related to Intellectual Property Rights

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make diagnostic tests and therapeutic product candidates that are the same as or similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- it is possible that noncompliance with the U.S. Patent and Trademark Office ("USPTO") and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment, and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests and products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that are directed to our diagnostic tests and product candidates or uses thereof in the U.S. or foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing diagnostic tests and product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; and
- if enforced, a court may not hold that our patents are valid, enforceable, and infringed.

If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business.

We may in the future require licenses to third-party technology and materials. Such licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We may in the future rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to future in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Even if we acquire the right to control the prosecution, maintenance, and enforcement of the licensed and sublicensed intellectual property relating to our diagnostic tests or therapeutic product candidates, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance, and enforcement of such patent rights dependent on third-party licenses will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our diagnostic tests or therapeutic product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our diligence, development and commercialization timelines, milestone payments, royalties, insurance, and other obligations under our license agreements, we may lose our patent rights with respect to such agreement, which would affect our patent rights worldwide.

Our inability to secure any future license agreements necessary for development of our products would reduce or eliminate our rights under these agreements on which we rely that include license provisions and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other diagnostic tests or therapeutic product candidates that are dependent on third-part license agreements which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our diagnostic tests or therapeutic product candidates may be materially harmed.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated

We currently own intellectual property directed to our diagnostic tests, therapeutic product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our diagnostic tests or therapeutic product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our product candidates, such licenses may not be available to us on commercially reasonable terms or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing diagnostic tests or therapeutic products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our competitive position depends on protection of our intellectual property.

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, or if competitors develop technologies incorporating the same or similar technologies that already are in the public domain, those competitors may be able to develop similar technologies to our own. Our success depends in part on our ability to obtain patent protection for our diagnostic tests, therapeutic products, or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on our proprietary rights.

Since patent applications in the U.S. are maintained in secrecy for at least portions of their pendency periods (published on U.S. patent issuance or, if earlier, 18 months from earliest filing date for most applications) and since other publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we are or will be the first to make the inventions to be covered by our patent applications. The patent position of biopharmaceutical and biotechnology firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

The patent applications we file, including applications that will follow the filing of provisional patents, may not issue as patents or the claims of any issued patents may not afford meaningful protection for our technologies, tests, or products. In addition, patents issued to us or to any future licensors may be challenged and subsequently narrowed, invalidated, or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights.

Although we have executed assignment of invention agreements with current scientific and technical employees and in the future will require our scientific and technical employees and consultants to enter into broad assignment of invention agreements, and require all of our employees, consultants, and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

Diagnostic tests and therapeutic products we develop could be subject to infringement claims asserted by others.

We cannot assure that diagnostic tests and therapeutic products based on our patents or intellectual property that we license from others will not be challenged by a third-party claiming infringement of its proprietary rights. If we are not able to successfully defend patents that may be issued to us, that we may acquire, or that we may license in the future, we may have to pay substantial damages or licensing fees, possibly including treble damages, for past infringement.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we intend to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology, we also intend to rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We have executed and will continue to seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also have executed and will continue to seek to enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests and therapeutic product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a "first inventor to file" system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be titled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our diagnostic tests and therapeutic product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees, and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our diagnostic tests or therapeutic product candidates, our competitive position would be adversely affected.

Patent terms may be inadequate to protect our competitive position on our diagnostic tests or therapeutic product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the U.S., provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our diagnostic tests and therapeutic product candidates, when the terms of all patents covering a diagnostic test or therapeutic product expire, our business may become subject to competition from competitive diagnostics or therapeutics. Given the amount of time required for the development, testing, and regulatory review and approval of new diagnostic test or therapeutic product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests and therapeutic products similar or identical to ours.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or a licensee initiate legal proceedings against a third party to enforce a patent covering one of our diagnostic tests or therapeutic product candidates, the defendant could counterclaim that the patent covering our diagnostic tests or therapeutic product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (i.e., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our diagnostic tests or therapeutic product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or therapeutic product candidates. Such a loss of patent protection could have a material adverse impact on our business.

If we do not obtain patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our diagnostic tests or therapeutic product candidates, our business may be harmed.

In the U.S., a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration, and conditions of FDA marketing authorization of our diagnostic tests or therapeutic product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which permits a patent term extension of up to five years for a patent covering an approved diagnostic test or therapeutic product as compensation for effective patent term lost during diagnostic test or therapeutic product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of diagnostic test or therapeutic product approval, and only claims covering such approved diagnostic test or drug product, a method for using it, or a method for manufacturing it may be extended. In Europe, our diagnostic test or therapeutic product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Even if we are granted such an extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened, and our competitors may obtain approval to market competing diagnostic tests or products sooner. The resulting reduction of years of revenue from applicable diagnostic tests or products could be substantial.

We enjoy only limited geographical protection with respect to certain patents, and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents covering our diagnostic tests and therapeutic product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than it is in the U.S. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. In-licensing patents covering our diagnostic tests and therapeutic product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting, and defending patents even in only those jurisdictions in which we develop or commercialize our diagnostic tests and therapeutic product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own diagnostic tests and therapeutic products and further may export otherwise infringing products to territories where we and our licensors have patent protection, but where enforcement is not as strong as that in the U.S. or Europe. These diagnostic tests and products may compete with our diagnostic tests and therapeutic product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, or other forms of intellectual property, particularly those relating to biotechnology tests and products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing tests and products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic tests and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our diagnostic tests and product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

In some jurisdictions, including European countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented, declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions.

Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and tradenames to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and tradenames may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our therapeutic product candidate in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA, or an equivalent administrative body in a foreign jurisdiction, objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulations

CyPath® Lung is currently being offered as an LDT by PPLS. Should the FDA disagree that CyPath® Lung is an LDT, or if the FDA's regulatory approach to LDTs should change in the future, our commercialization strategy may be adversely affected, which would negatively affect our results of operations and financial condition.

The FDA considers an LDT to be a test that is developed, validated, and performed within a single laboratory. The FDA has historically asserted its authority to regulate LDTs as medical devices under the FDCA, but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, *de novo* classification, or clearance of LDTs, it has generally chosen not to enforce those requirements. The FDA has, on occasion, sent warning letters to laboratories offering LDTs that the agency believed were not eligible for enforcement discretion because of how they were developed, validated, performed, or marketed and consequent risks to the public.

On May 6, 2024, FDA promulgated a final rule phasing out over four years its enforcement discretion over LDTs. The agency states it will expect compliance with premarket review and quality system requirements for LDTs marketed after May 6, 2024. The FDA states that the agency will generally not enforce premarket review requirements for LDTs that were marketed before May 6, 2024, if they are not modified in certain ways. In particular, the rule states that the LDT is exempt if marketed before May 6, 2024, and is not modified in a way that changes its indications for use; does not alter its operating principle; does not include significantly different technology; and, the LDT does not adversely change its performance or safety specifications. The Company has no expectation or intention to modify CyPath® Lung in any manner that will change its indications for use, alter its operating principal or include different technology, or change its performance or safety specifications.

Although we do intend to conduct clinical trials in order to receive *de novo* classification from the FDA as a Class II in vitro diagnostic, there can be no assurance that the trial will have favorable results or that it will generate the results necessary to obtain such clearance.

Delay by or failure of the FDA to grant our request for* de novo *classification, or failure on our part to comply with applicable requirements, would adversely affect our business, results of operations, and financial condition.

The FDCA requires that medical devices introduced to the U.S. market, unless exempted by regulation, be authorized by the FDA pursuant to either the premarket notification pathway, known as 510(k) clearance, the *de novo* classification pathway, or the premarket approval ("PMA") pathway. We plan to seek *de novo* classification for the CyPath® Lung test in fiscal year 2028. The FDA may not agree that CyPath® Lung meets the criteria for *de novo* classification, in which case we would be required to submit a PMA to obtain marketing authorization, which would require manufacturing information and a pre-approval inspection of the manufacturing facilities and could require review by an FDA advisory panel comprised of experts outside the FDA. Any delay by or failure of the FDA to grant our *de novo* request or PMA could adversely affect our consolidated revenues, results of operations, and financial condition.

Additionally, obtaining FDA marketing authorization, approval, or *de novo* classification for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices can take several years and require detailed and comprehensive scientific and clinical data. In addition, medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review. Ongoing compliance with FDA regulations increases the cost of conducting our business and subjects us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Failure by our laboratory to comply with applicable laws pertaining to LDTs or IVDs could adversely affect our business, results of operations, and financial condition.

The clinical laboratory testing sector is highly regulated in the U.S. PPLS, our laboratory, is accredited by CAP and holds a CLIA certificate of accreditation. Any failure by our laboratory licensee to comply with CAP/CLIA requirements could result in adverse findings on inspection that, if not timely corrected, could result in loss of accreditation and the inability to perform laboratory testing.

Additionally, certain states, including California, Maryland, Nevada, Pennsylvania, and Rhode Island, require laboratories testing specimens from their jurisdictions to hold an out-of-state laboratory license or permit. New York is exempt from, and imposes requirements in addition to, CLIA, including a requirement for test-specific permits of LDTs before they can be used to test specimens from patients in New York. The failure of our laboratory to obtain state licenses or permits, where required, could interfere with our strategy for a national rollout of CyPath® Lung.

ICU Medical is providing the Acapella® Choice Blue device to assist patients in expelling sputum out of the lungs into a collection cup noninvasively. This device is 510(k) cleared as a positive expiratory pressure device to help mobilize lung secretions in people with certain lung conditions. The device does not have a cleared indication for use as a specimen collection device. Promotion of the device by us or our partners for use of the device for specimen collection could cause the FDA to consider the device to be adulterated or misbranded in violation of the FDCA and to require a 510(k) clearance for a specimen collection indication as a condition of distributing the device. Any disruption to our ability to distribute the Acapella® Choice Blue could interfere with our ability to collect adequate patient samples necessary for CyPath® Lung.

CyPath® Lung also relies on a proprietary algorithm to develop and validate software integrated into the test procedure that generates the quantitative and qualitative diagnostic results that are included in the laboratory report. Certain types of standalone diagnostics software are subject to FDA regulation as a medical device (specifically, software as a medical device or "SaMD"). Some types of SaMD are subject to premarket authorization requirements. If the FDA were to conclude that we are required to obtain premarket authorization for the software, our ability to offer CyPath® Lung as an LDT could be delayed or prevented, which would adversely affect our business.

The third-party licensors of our future therapeutic products, when ready, may be unable to obtain regulatory approval. The denial or delay of any such approval would delay commercialization of our future therapeutic products and have a material adverse effect on our potential to generate revenue, our business, and our results of operations.

We plan to license our therapeutic candidates to third parties for development, including clinical testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import. These activities that are to be undertaken by third-party licensees of our future therapeutic products are subject to extensive regulation by the FDA and by foreign health authorities in other countries. These regulations differ from country to country. In the U.S., we are not permitted to market our therapeutic product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following research and development and thereafter the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. For our licensors to gain approval to market our product candidates, they must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. We or any third party has not yet obtained regulatory approval to market any of our product candidates in the U.S. or any other country. Our business depends upon licensing our therapeutic products to third-party pharmaceutical companies that would obtain these regulatory approvals. The FDA can delay, limit, or deny approval of these product candidates for many reasons, including:

- the inability of our licensors to satisfactorily demonstrate that the product candidates have acceptable safety and efficacy profiles for the requested indication;
- the FDA's disagreement with the trial designs of our licensors or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- the licensors' inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the formulation, labeling, or specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes, drug product characteristics, or facilities of third-party manufacturers with which we or the third-party licensors contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering clinical data related to any therapeutic product candidate insufficient for approval.

Even if clinical testing approval of any regulatory filing for our product candidates eventually is completed, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than the third party originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If the FDA requires the licensors to narrow the indications to smaller patient subsets, the market opportunities for our product candidates, if approved, and the ability to generate revenues and royalties may be materially limited. To the extent the licensors seeks regulatory approval in foreign countries, they may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

Obtaining and maintaining regulatory approval of our diagnostic tests or therapeutic product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the U.S., to market and sell our diagnostic tests and therapeutic products in the EU, many Asian countries, and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Clearance by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing authorization of a diagnostic test or therapeutic product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the diagnostic test or therapeutic product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a diagnostic test or therapeutic product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our diagnostic tests or therapeutic products is also subject to approval. A diagnostic test or therapeutic product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the U.S. on a timely basis, if at all.

We may also submit marketing applications in other countries, such as countries in Europe or Asia. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our diagnostic tests or therapeutic products in any jurisdiction. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of diagnostic tests or therapeutic product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our diagnostic tests or therapeutic products in certain countries. We do not have any diagnostic tests or therapeutic product candidates approved for sale in any foreign jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our diagnostic tests or therapeutic product candidates by regulatory or payor authorities in the EU, Asia, or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that diagnostic test or therapeutic product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our diagnostic tests or therapeutic product candidates will be harmed.

Even if we obtain FDA clearance of any of our diagnostic tests or therapeutic product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any diagnostic test or therapeutic product outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional diagnostic and therapeutic product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties, and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our diagnostic tests or therapeutic products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any diagnostic test or therapeutic product candidate approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our diagnostic tests or therapeutic products will be harmed.

The impact of changes to healthcare law and guidance, as well as other changes in the healthcare industry, and changes in healthcare spending is currently unknown and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry, and new laws, regulations, judicial decisions, or new interpretations of existing laws, regulations, or decisions related to healthcare availability, the method of delivery, or payment for healthcare tests, products, and services could negatively impact our business, operations, and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future, including future challenges or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations, and other payors to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our diagnostic tests or therapeutic product candidates, if we or our licensors obtain regulatory approval;
- the ability to set a price that we believe is fair for our diagnostic tests and therapeutic products;
- the ability to obtain coverage and reimbursement approval for a diagnostic test and therapeutic product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Risks Related to Ownership of Our Common Stock and Warrants

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

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

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

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, the stockholder's equity requirement, or the minimum closing bid price requirement, The Nasdaq Capital Market may take steps to de-list our Common Stock or Tradeable Warrants. Such a de-listing or even notification of failure to comply with such requirements would likely have a negative effect on the price of our Common Stock and Tradeable Warrants and would impair the ability to sell or purchase our Common Stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with The Nasdaq Capital Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price, improve the liquidity of our Common Stock, prevent our Common Stock from dropping below The Nasdaq Capital Market minimum bid price requirement, or prevent future non-compliance with The Nasdaq Capital Market's listing requirements.

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

We do not expect to pay dividends in the foreseeable future. Any return on investment may be limited to the value of our Common Stock.

We do not anticipate paying cash dividends on our Common Stock in the foreseeable future. The payment of dividends on our Common Stock will depend on earnings, financial condition, and other business and economic factors affecting it at such time as our Board of Directors (our "Board") may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will occur only if our stock price appreciates.

Our Common Stock market price may never exceed the exercise price of our outstanding warrants.

Each Tradeable Warrant and Non-Tradeable Warrant that we issued in our initial public offering has an exercise price of $3.0625. Our other outstanding warrants have exercise prices ranging from $1.50 to $7.35. In the event our Common Stock price does not exceed the exercise price of the warrants during the period when they are exercisable, the warrants may not have any value.

Holders of warrants have no rights as stockholders other than as set forth in the warrants until such holders exercise their warrants and acquire our shares of Common Stock.

Until holders of our warrants acquire shares of Common Stock upon exercise thereof, such holders will have no rights with respect to the shares of Common Stock underlying the Warrants other than as set forth in the Warrants. Upon exercise of the warrants, the holders will be titled to exercise the rights of a stockholder only as to matters for which the record date occurs after the date they were entered in the register of members of the Company as a stockholder.

The warrant certificates governing our warrants designate the state and federal courts of the State of New York sitting in the City of New York, Borough of Manhattan, as the exclusive forum for actions and proceedings with respect to all matters arising out of the warrants, which could limit a warrant holder's ability to choose the judicial forum for disputes arising out of the warrants.

The warrant certificates governing our warrants provide that all legal proceedings concerning the interpretations, enforcement, and defense of the transactions contemplated by the warrant certificate (whether brought against a party to the warrant certificate or their respective affiliates, directors, officers, shareholders, partners, members, employees, or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. The warrant certificates further provide that we and the warrant holders irrevocably submit to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan, for the adjudication of any dispute under the warrant certificate or in connection with it or with any transaction contemplated by it or discussed in it. Furthermore, we and the warrant holders irrevocably waive, and agree not to assert in any suit, action, or proceeding, any claim that we or they are not personally subject to the jurisdiction of any such court, that such suit, action, or proceeding is improper or is an inconvenient venue for such proceeding. With respect to any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder, we note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in the warrant certificates expressly does not apply to suits brought to enforce any duty or liability created by the Exchange Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our warrants shall be deemed to have notice of and consented to the foregoing provisions. Although we believe this exclusive forum provision benefits us by providing increased consistency in the application of the governing law in the types of lawsuits to which it applies, the exclusive forum provision may limit a warrant holder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, officers, other employees, stockholders, or others which may discourage lawsuits with respect to such claims. Our warrant holders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of this exclusive forum provision. Further, in the event a court finds the exclusive forum provision contained in our warrant certificates to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

Our failure to file a registration statement to register the shares of Common Stock issuable upon exercise of the warrants that we issued in February 2025 will result in a breach of the terms of the warrant inducement agreement.

Pursuant to the terms of the warrant inducement agreement that we entered into with certain investors in February 2025, we are obligated to file a registration statement to register the shares of Common Stock issuable upon exercise of the new warrants within 45 days of the date of such agreement and to use commercially reasonable efforts to keep the registration statement effective at all times while the investors own any warrants or shares of Common Stock issuable upon exercise of the warrants. The failure to take any of these actions will constitute a default under the warrant inducement agreement.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that we provide herein or our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, regulatory issues, economic, market, and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from those contained in the projections.

Our stock price has fluctuated in the past, has recently been volatile, and may be volatile in the future, and as a result, investors in our Common Stock could incur substantial losses.

Investors should consider an investment in our Common Stock risky and invest only if they can withstand a significant loss and wide fluctuations in the market value of their investment. Investors who purchase our Common Stock may not be able to sell their shares at or above the purchase price. Our stock price has been volatile and may be volatile in the future. The stock market in general has been, and the market price of our Common Stock or Tradeable Warrants in particular, will likely be subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our Common Stock or Tradeable Warrants may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our diagnostic tests and therapeutic products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts;
- development of technological innovations or new competitive diagnostic tests or therapeutic products by others;
- announcements of technological innovations or new diagnostic tests or therapeutic products by us;
- our failure to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced diagnostic tests or therapeutic products and the generation of sales from those diagnostic tests and therapeutic products;
- developments concerning intellectual property rights, including our involvement in litigation;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified diagnostic tests or therapeutic products;
- changes in the amounts that we spend to develop, acquire, or license new diagnostic tests or therapeutic products, technologies, or businesses;
- changes in our expenditures to promote our diagnostic tests or therapeutic products;
- our sale or proposed sale, or the sale by our significant shareholders, of our Common Stock or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our Common Stock; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our Common Stock or Tradeable Warrants and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

Our Common Stock has often been thinly traded, so investors may be unable to sell at or near ask prices or at all if investors need to sell shares to raise money or otherwise desire to liquidate their shares.

To date, there have been many days on which limited trading of our Common Stock took place. We cannot predict the extent to which investors' interests will lead to an active trading market for our Common Stock or whether the market price of our Common Stock will be volatile. If an active trading market does not develop, investors may have difficulty selling our Common Stock. We are likely to be too small to attract the interest of many brokerage firms and analysts. We cannot give investors any assurance that an active public trading market for our Common Stock will develop or be sustained. The market price of our Common Stock could be subject to wide fluctuations in response to quarterly variations in our revenues and operating expenses, announcements of new products or services by us, significant sales of our Common Stock, including "short" sales, the operating and stock price performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets or general economic conditions.

An investment in our Company may involve tax implications, and you are encouraged to consult your own advisors as neither we nor any related party is offering any tax assurances or guidance regarding our Company or your investment.

An investment in our Company generally, involves complex federal, state, and local income tax considerations. Neither the Internal Revenue Service nor any state or local taxing authority has reviewed the transactions described herein and may take different positions than the ones contemplated by management. You are strongly urged to consult your own tax and other advisors prior to investing, as neither we nor any of our officers, directors, or related parties can offer tax or similar advice, nor are any such persons making any representations and warranties regarding such matters.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including the completion of any offering taken together with other transactions we may consummate in the succeeding three-year period. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability.

Our Certificate of Incorporation permits "blank check" Preferred Stock, which can be designated by our Board without stockholder approval.

We are authorized to issue 20,000,000 shares of Preferred Stock. The shares of our Preferred Stock may be issued from time to time in one or more series, each of which shall have a distinctive designation or title as is determined by our Board prior to the issuance of any shares thereof. The Preferred Stock may have such voting powers, full, enhanced or limited, or no voting powers, and such preferences and relative, participating, optional, or other special rights and such qualifications, limitations, or restrictions thereof as adopted by the Board, which may include enhanced dividend rights, rights of redemption, sinking funds to pay dividends, liquidation, and other rights that would be different than, and preferential to, the rights of the Common Stockholders. Because our Board is able to designate the powers and preferences of the Preferred Stock without the vote of a majority of our stockholders, Common Stockholders will have no control over what designations and preferences our Preferred Stock will have. If Preferred Stock is designated and issued, then depending upon the designation and preferences, the holders of the Preferred Stock may exercise voting control. As a result, our stockholders would have no control over the operations of our Company.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation, as amended (our "Charter") and amended and restated bylaws ("A&R Bylaws") may discourage, delay, or prevent a merger, acquisition, or other change in control, that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- provide that the Board is expressly authorized to adopt, amend, alter, or repeal our bylaws;
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
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- authorize our Board to issue Preferred Stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board.

Any provision in our Charter or A&R Bylaws that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our Common Stock and could also affect the price that some investors are willing to pay for our Common Stock.

Certain provisions of the DGCL may have anti-takeover effects that could delay, defer, or discourage another party from acquiring control of the Company, prevent changes in our Board or management, and make certain transactions more challenging that stockholders might otherwise believe to be in their best interests.

We are subject to the provisions of Section 203 of the DGCL, which generally prohibits us from engaging in a "business combination," meaning a merger, asset sale, or other transaction resulting in a stockholder's financial benefit, with an "interested stockholder" for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a manner prescribed by Section 203. Section 203 defines an "interested stockholder" as a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of a corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing changes in control of our Company and of averting changes in our Board or management. They are expected to discourage certain types of coercive takeover practices and inadequate takeover bids, and as a consequence, they might also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Our Charter designates a state or federal court located within the state of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our Charter provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, stockholders, or employees to us or our stockholders, or (3) any action asserting a claim arising pursuant to any provision of the DGCL, our Charter, or our A&R Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Charter and our A&R Bylaws contain a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find the exclusive forum provision in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

Certain limitation-of-liability and indemnification provisions in our Charter and A&R Bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties, may reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit the Company and other stockholders, and may adversely impact stockholders' investments to the extent that the Company pays the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Our Charter contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our Charter and our A&R Bylaws require us to indemnify our directors and officers and allow us to indemnify other employees and agents to the fullest extent permitted by the DGCL. Subject to certain limitations and limited exceptions, our Charter and A&R Bylaws also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

While we believe that including the limitation-of-liability and indemnification provisions in our Charter, A&R Bylaws, and indemnification agreements is necessary to attract and retain qualified persons such as directors, officers, and key employees, those provisions may discourage stockholders from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

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

Based on the provisions for determining beneficial ownership in accordance with Rule 13d-3 and Item 403 of Regulation S-K under the Exchange Act, immediately after this Offering, our officers and directors will own or exercise control of approximately 24% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

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

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

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our Company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our Common Stock would be negatively affected. If one or more of the analysts who cover us downgrade our Common Stock or publish inaccurate or unfavorable research about our business, our Common Stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Stock could decrease, which might cause our Common Stock price and trading volume to decline.

If we fail to establish and maintain an effective system of internal control or disclosure controls and procedures are not effective, we may not be able to report our financial results accurately and timely or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our Common Stock.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") requires us to evaluate and report on our internal controls over financial reporting and, depending on our future growth, may require our independent registered public accounting firm to annually attest to our evaluation, as well as issue its own opinion on our internal controls over financial reporting. The process of implementing and maintaining proper internal controls and complying with Section 404 is expensive and time consuming. We cannot be certain that the measures we will undertake will ensure that we will maintain adequate controls over our financial processes and reporting in the future. Furthermore, if we are able to rapidly grow our business, the internal controls that we will need may become more complex, and significantly more resources will be required to ensure our internal controls remain effective. Failure to implement required controls or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting obligations. If we or our auditors discover a material weakness in our internal controls, the disclosure of that fact, even if the weakness is quickly remedied, could diminish investors' confidence in our financial statements and harm our stock price. In addition, non-compliance with Section 404 could subject us to a variety of administrative sanctions, including the suspension of trading, ineligibility for future listing on one of the Nasdaq Stock Markets or national securities exchanges, and the inability of registered broker-dealers to make a market in our Common Stock, which may reduce our stock price.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We maintain a cyber risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

The underlying processes and controls of the bioAffinity cyber risk management program incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF").

In addition, bioAffinity maintains policies over areas, such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect bioAffinity IT assets, data, and services from threats and vulnerabilities. bioAffinity partners with industry-recognized cybersecurity providers leveraging third-party technology and expertise. These cybersecurity partners, including consultants and other third-party service providers, are a key part of bioAffinity's cybersecurity risk management strategy and infrastructure and provide services including maintenance of an IT assets inventory, periodic vulnerability scanning, identity access management controls including restricted access to privileged accounts, network integrity safeguarded by web-based software, including endpoint protection, endpoint detection and response, and remote monitoring management on all devices, industry-standard encryption protocols, critical data backups, infrastructure maintenance, incident response, cybersecurity strategy, and cyber risk advisory, assessment and remediation.

bioAffinity's management team, in conjunction with third-party IT and cybersecurity service providers, is responsible for oversight and administration of the cyber risk management program and informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes and relies on threat intelligence as well as other information obtained from governmental, public, or private sources.

The Audit Committee of the Board of Directors oversees bioAffinity cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. The cybersecurity stakeholders, including member(s) of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services, brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of the cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on bioAffinity processes to prevent, detect, and mitigate cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board of Directors at least annually, as part of the Company's corporate risk oversight processes.

bioAffinity faces risks from cybersecurity threats that could have a material adverse effect on its business, financial condition, results of operations, cash flows, or reputation. bioAffinity acknowledges that the risk of cyber incident is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. However, prior cybersecurity incidents have not had a material adverse effect on our business, financial condition, results of operations, or cash flows. The Company proactively seeks to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject the Company to additional liability and reputational harm. In response to such risks, the Company has implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan. For more information on cybersecurity risks see Item 1A. "Risk Factors – Our internal information technology systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our diagnostic tests' or therapeutic product candidates' development programs, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business."

Item 2. Properties.

In June 2015, we were accepted into the "New Venture Incubator Program," which was established by The University of Texas at San Antonio ("UTSA") to foster research by assisting technology-based businesses and entrepreneurs. Pursuant to the terms of a license agreement, UTSA grants us a license for the temporary use of approximately 1,250 square feet of laboratory and office space in room SRL 1.424 inside the Science Research Laboratories on UTSA's campus. In exchange, we pay a licensing fee of $5,300 per month. The license agreement has a one-year term that we can extend by requesting a term extension from UTSA. Since 2016, UTSA has granted each of our annual requests for a license extension.

PPLS leases a premises in San Antonio, Texas, used in connection with operation of the CAP-accredited, CLIA-certified clinical pathology laboratory. The rent is currently $10,144 per month, and the term of the lease expires in October 2027.

We rent additional corporate office space located near the PPLS lease. The rent is currently $2,970 per month, and the term of the lease expires in August 2030.

Management believes that the combination of our rented and licensed office and laboratory spaces are adequate to meet our current needs and expected level of operations. We do not own any real property.

Item 3. Legal Proceedings.

We are not currently a party to any current or pending material legal proceedings. From time to time, however, the Company may be involved in various disputes and litigation matters that arise in the ordinary course of business. The Company may face claims brought by third parties, or, from time to time, the Company may make claims or take legal actions to assert our rights. Regardless of the outcome, any such claims or legal proceedings could adversely impact our business, reputation, operating results, and financial condition because of defense and settlement costs, diversion of resources, and other factors. Results of actual and potential litigation are inherently uncertain, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock, par value $0.007 per share (the "Common Stock") trades under the symbol "BIAF." Our tradeable warrants, each to purchase one share of Common Stock (collectively, the "Tradeable Warrants"), trade under the symbol "BIAFW." Our Common Stock and Tradeable Warrants trade on The Nasdaq Capital Market.

Holders of Record

As of March 17, 2025, there were approximately 92 holders of record of shares of our Common Stock. This number does not reflect the beneficial holders of our Common Stock who hold shares in street name through brokerage accounts or other nominees.

Dividends

We have never declared or paid any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business prospects, and other factors our Board of Directors may deem relevant.

Unregistered Sales of Equity Securities

We did not sell any equity securities during the quarter ended December 31, 2024, in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2024, with respect to shares of our Common Stock that may be issued under our equity incentive plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights	Weighted-average exercise price of outstanding options, warrants, and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2024 Equity Incentive Plan	519,792	$ 2.00	1,480,208
2014 Equity Incentive Plan	380,132	$ 5.78	—
Equity compensation plans not approved by security holders	—	—	—
Total	899,924	$ 3.59	1,480,208

Item 6. [Reserved.]

Item 7. 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 Annual Report. 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 Annual Report and in the "Risk Factors" in this Annual Report.

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 year ended December 31, 2024, to the year ended December 31, 2023.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Estimates* – Accounting estimates are those estimates made in accordance with U.S. generally accepted accounting principles ("GAAP") that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

Company Overview

Business

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

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

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

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

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

Current Year Financial Highlights

Key financial results for the year ended December 31, 2024 include:

- Consolidated revenue increased approximately 270% to $9.4 million as compared to $2.5 million for the year ended December 31, 2023, primarily as a result of the acquisition of PPLS in September 2023.
- CyPath® Lung testing revenue increased approximately 1,400% to $0.5 million as compared to $35 thousand for the year ended December 31, 2023, due to an increase in total test results delivered of more than 600 for the current year.
- Raised approximately $6.9 million in gross proceeds from equity transactions to fund operating activities.

Recent Financial Developments

Targeted Strategic Actions

In March 2025, we announced targeted strategic actions to improve financial performance and accelerate the commercial growth of CyPath® Lung, taking steps to deliver approximately $4 million in annual cost savings at our subsidiary PPLS, while increasing resources to expand CyPath® Lung sales in high-potential national markets. Specifically, cost savings are a result of labor cost reductions, operational efficiency enhancements, and discontinuing certain pathology services with suboptimal profit margins to focus on high-margin services such as CyPath® Lung and by discontinuing certain pathology services with suboptimal profit margins.

Public and Private Offerings

On February 26, 2025, pursuant to the terms of the February Inducement Agreement certain holders of existing warrants exercised for cash (i) October Warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock, at the reduced exercise price of $0.58 per share, and (ii) August Warrants to purchase an aggregate of up to 1,136,391 shares of Common Stock, at the reduced exercise price of $0.58 per share. We received aggregate gross proceeds of approximately $1.4 million, before deducting advisory fees and other expenses payable by us. In consideration of the immediate exercise of the October Warrants and August Warrants by the holders thereof in accordance with the February Inducement Agreement, we issued unregistered common warrants (the "February Warrants") to purchase an aggregate of up to 2,926,166 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the October Warrants and August Warrants) to such holders.

We agreed in the February Inducement Agreement to file a registration statement to register the resale of the shares of Common Stock (the "February Warrant Shares") issuable upon exercise of the February Warrants (the "Resale Registration Statement") as soon as practicable (and in any event within 45 calendar days following the date of the Inducement Agreement), and to use commercially reasonable efforts to have the Resale Registration Statement declared effective by the SEC and to keep such registration statement effective at all times until the Holders no longer own any February Warrants or February Warrant Shares.

On October 21, 2024, we issued to certain institutional investors (i) in a registered direct offering, 2,048,294 shares of our Common Stock, and (ii) in a concurrent private placement (the "October Private Placement"), common warrants to purchase an aggregate of 2,662,782 shares of Common Stock, with an exercise price of $1.50, pursuant to a securities purchase agreement, dated October 18, 2024, that we entered into with such institutional investors, and received aggregate gross proceeds from the offerings of approximately $2.7 million, before deducting placement agent fees and other offering expenses. The common warrants issued in the October Private Placement became exercisable on December 20, 2024, the date that our stockholders approved the issuance of the shares of Common Stock issuable upon exercise of such warrants, and expire on December 19, 2029.

Financial

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

We have never been profitable, and as of December 31, 2024, we had a working capital deficit of $0.4 million and an accumulated deficit of approximately $53.6 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and advance our diagnostic tests through clinical trials; however, we do expect revenue to increase due to accelerating sales of CyPath® Lung and cost-saving measures we recently instituted at PPLS. We intend to seek strategic partners for our therapeutic discoveries related to selective broad-spectrum cancer treatments through pre-clinical and clinical development.

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

Year Ended December 31, 2024 Compared to the Year Ended December 31, 2023

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future. Net loss for the year ended December 31, 2024 was approximately $9.0 million, compared to a net loss of approximately $7.9 million for the year ended December 31, 2023, resulting from the operational activities described below.

Revenue

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

	Year Ended December 31,	
	2024	2023
Patient service fees[1]	$ 8,175,670	$ 2,199,558
Histology service fees	1,103,751	272,660
Medical director fees	66,576	19,324
Department of Defense observational studies	8,654	19,442
Other revenues	7,371	21,515
Total net revenue	$ 9,362,022	$ 2,532,499

[1]Patient services fees includes direct billing for CyPath® Lung diagnostic test of approximately $516,000 and $35,000 for the years ended December 31, 2024 and 2023, respectively.

Operating Expenses

	Year Ended December 31,		Change in 2024 Versus 2023	
	2024	2023	$	%
Operating expenses:				
Direct costs and expenses	$ 5,983,475	$ 1,740,884	$ 4,242,591	244%
Research and development	1,461,227	1,467,936	(6,709)	0%
Clinical development	321,655	256,661	64,994	25%
Selling, general and administrative	9,943,473	6,790,654	3,152,819	46%
Depreciation and amortization	605,637	249,592	356,045	143%
Total operating expenses	$ 18,315,467	$ 10,505,727	$ 7,809,740	74%

Operating expenses totaled $18.3 million and $10.5 million for the years ended December 31, 2024 and 2023, respectively. The increase in operating expenses is the result of the following factors.

Direct Costs and Expenses

Our direct costs and expenses are primarily direct labor for pathology services, laboratory supplies and reagents, laboratory equipment and allocated shared facilities. Direct costs and expenses totaled approximately $6.0 million and $1.7 million during 2024 and 2023, respectively. The increase of approximately $4.3 million, or 244%, was primarily attributable to the laboratory operations of PPLS being owned for the full fiscal year 2024, compared to approximately 3.5 months in fiscal year 2023.

Research and Development

Our research and development expenses consist primarily of expenditures for lab operations, preclinical studies, compensation, and consulting costs. Research and development expenses remained consistent year-over-year, totaling $1.5 million for the years ended December 31, 2024 and 2023.

Clinical Development

Clinical development expenses totaled $321,655 and $256,661 for the years ended December 31, 2024 and 2023, respectively. The increase of $64,994, or 25% was primarily attributable to an increase in compensation costs and benefits as we added clinic development personnel.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately $9.9 million and $6.8 million for the years ended December 31, 2024 and 2023, respectively. The increase of approximately $3.1 million, or 46% was primarily attributable to the laboratory operations of PPLS being owned for the full fiscal year 2024, compared to approximately 3.5 months in fiscal year 2023. Additionally, the increase was due to the expansion of sales efforts for CyPath® Lung, partially offset by a reduction in legal and professional fees.

Other Income (Expense)

	Year Ended December 31,		Change in 2024 Versus 2023	
	2024	2023	$	%
Interest (expense) income, net	$ (74,865)	$ 85,006	$ 159,871	(188)%
Other income (expense), net	129	(27,796)	(27,925)	(100)%
Total other (expense) income	$ (74,736)	$ 57,210	$ 131,946	231%

Other net income (expense) totaled $129 and $(27,796) for the years ended December 31, 2024 and 2023, respectively, an increase of approximately $28,000, or 100%. The net other expense for the year ended December 31, 2023 related to the loss on the disposal of an asset and other non-operating costs. The net other income for the year ended December 31, 2024 related to approximately a $9,000 gain on a sale of an asset and offset by property taxes.

Interest income (expense)

We had net interest (expense) income of approximately $(74,865) and $85,006 for the years ended December 31, 2024 and 2023, respectively. The prior year amount related to approximately $120,000 interest earned from money market account partially offset by interest paid in financing lease for laboratory equipment. The current year amount related to approximately $18,000 interest earned from money market account offset by interest paid in financing lease for laboratory equipment.

Liquidity and Capital Resources

To date, we have funded our operations primarily through our IPO, exercise of warrants, and the sale of our equity and debt securities, resulting in gross proceeds of approximately $42.7 million. We have evaluated whether there are conditions and events that raise substantial doubt about our ability to continue as a going concern for at least one year after the date the consolidated financial statements are issued.

Recent Financings

February 2025 Warrant Inducement

On February 26, 2025, pursuant to the terms of the February Inducement Agreement certain holders of existing warrants exercised for cash (i) October Warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock, at the reduced exercise price of $0.58 per share, and (ii) August Warrants to purchase an aggregate of up to 1,136,391 shares of Common Stock, at the reduced exercise price of $0.58 per share. We received aggregate gross proceeds of approximately $1.4 million, before deducting advisory fees and other expenses payable by us. In consideration of the immediate exercise of the October Warrants and August Warrants by the holders thereof in accordance with the February Inducement Agreement, we issued unregistered common warrants to purchase an aggregate of up to 2,926,166 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the October Warrants and August Warrants) to such holders.

October 2024 Registered Direct Offering and Concurrent Private Placement

On October 21, 2024, we issued to certain institutional investors (i) in a registered direct offering, 2,048,294 shares of our Common Stock, and (ii) in a concurrent private placement, common warrants to purchase an aggregate of 2,662,782 shares of Common Stock, with an exercise price of $1.50, pursuant to a securities purchase agreement, dated October 18, 2024, that we entered into with such institutional investors, and received aggregate gross proceeds from the offerings of approximately $2.7 million, before deducting placement agent fees and other offering expenses.

August 2024 Warrant Inducement, Registered Director Offering and Concurrent Private Placement

On August 5, 2024, pursuant to the terms of the August Inducement Agreement, certain holders of existing warrants, exercised for cash March Warrants to purchase an aggregate of up to 1,041,667 shares of Common Stock, at the reduced exercise price of $1.25 per share. We received aggregate gross proceeds of approximately $1.3 million, before deducting advisory fees and other expenses payable by us. In consideration of the immediate exercise of the March Warrants by the holders thereof in accordance with the August Inducement Agreement, we issued unregistered common warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the March Warrants) to such holders.

On August 5, 2024, we also issued to an institutional investor (i) in a registered direct offering, 360,000 shares of Common Stock, and (ii) in a concurrent private placement, warrants to purchase an aggregate of 450,000 shares of Common Stock, with an exercise price of $1.50. We received aggregate gross proceeds from the offerings of approximately $450,000, before deducting fees payable to the placement agent and other estimated offering expenses.

March 2024 Registered Direct Offering and Concurrent Private Placement

On March 8, 2024, we issued to certain investors, pursuant to a Securities Purchase Agreement (1) 1,600,000 shares of Common Stock in a registered direct offering, and (2) warrants to purchase an aggregate of 1,600,000 shares of Common Stock with an exercise price of $1.64, in a concurrent private placement. The direct offering resulted in gross proceeds of $2.5 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. During 2024 and 2023, we had net losses of $9.0 million and $7.9 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately $53.6 million as of December 31, 2024. Based on our current expected level of operating expenditures and the cash on hand of approximately $390 thousand at the time of this filing, management concludes that there is substantial doubt about our ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that our cash resources are sufficient to continue operations through April 2025.

Cash and cash equivalents were approximately $1.1 million as of December 31, 2024, which does not take into account the gross proceeds of $1.4 million that we received in February 2025. We need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or through exercised outstanding warrants to support our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. There can be no assurance that we will be successful in accomplishing these objectives.

Cash Flows

The following information reflects cash flows for the years presented:

	Year Ended December 31,	
	2024	**2023**
Cash and cash equivalents at beginning of year	$ 2,821,570	$ 11,413,749
Net cash used in operating activities	(7,264,795)	(6,037,806)
Net cash used in investing activities	(79,083)	(2,209,399)
Net cash provided by (used in) financing activities	5,627,599	(344,984)
Cash and cash equivalents at end of year	$ 1,105,291	$ 2,821,570

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $7.3 million and $6.0 million for the years ended December 31, 2024 and 2023, respectively. The increase of approximately $1.3 million in cash used by operations was primarily attributable to the laboratory operations of PPLS being owned for the full fiscal year 2024, compared to approximately 3.5 months in fiscal year 2023. Additionally, the increase was due to the expansion of sales efforts for CyPath® Lung.

Net Cash Used in Investing Activities

We used approximately $79,000 in investing activities for the year ended December 31, 2024, compared to $2.2 million used for the year ended December 31, 2023. The significant decrease of $1.4 million in cash used in investing activities was primarily due to equipment purchases in the current year, and the investing activities in the prior year related to the acquisition of PPLS.

Net Cash Provided by Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $5.5 million as compared to net cash used in financing activities of $0.3 million during 2023, representing an increase of approximately $5.9 million. During the year ended December 31, 2024, net cash provided by financing activities was primarily due to net proceeds of approximately $5.8 million from issuance of Common Stock and, option and warrant exercises, partially offset by financing payments.

Critical Accounting Estimates

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

Patient Fee Revenues

We follow ASC 606, *Revenue from Contracts with Customers*, which requires revenue recognition in the period in which the service was performed. To be able to report timely net revenues for the period, estimates are used for a portion of uncollected balances. The Company follows a standard process, which considers historical denial and collection experience and other factors (including the period of time that the receivables have been outstanding), to estimate contractual allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation.

Patient Fee Receivables and Considerations for Credit Losses

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

Discount Rate for Finance Leased Equipment

We follow *Leases* ("ASC 842"). In February 2016, the FASB issued Topic ASC 842, under which a lessee is required to recognize most leases on its balance sheet. The Company has elected to apply a third-party valuation incremental borrowing rate ("IBR") as the discount rate by class of underlying assets when the rate is not implicit in the lease.

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.

Assessment of Goodwill and Intangible Assets

Our indefinite-lived assets include Goodwill and Intangible Assets resulting from the acquisition of PPLS. Goodwill represents the purchase price in excess of fair values assigned to the underlying identifiable net assets of the acquired business. Goodwill and Intangible Assets are reviewed annually for impairment unless circumstances dictate the need for more frequent assessment.

In performing impairment tests for our Goodwill in 2024, in accordance with *ASC 350 - Intangibles – Goodwill and Other*, we opted to complete a quantitative assessment at the PPLS level as opposed to relying on a qualitative assessment as permitted in the guidance. This quantitative assessment required that the estimated fair value of PPLS' net assets, including Goodwill, be calculated and compared to the carrying amount. If that estimated fair value is in excess of the carrying amount, no impairment is recognized. We performed this assessment as of December 31, 2024. We estimated the fair value of the net assets tested using a discounted cash flow model. The income-based approach required significant judgment to estimate future cash flows, including revenue growth inclusive of long-term growth rate assumptions and the discount rate. Significant changes in our estimates and assumptions could affect our fair value calculations. Our estimate of fair value exceeded the carrying amount and therefore resulted in no impairment.

Going Concern

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our consolidated financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of our diagnostic tests and therapeutic products are inherently subject to uncertainty.

Off-Balance Sheet Arrangements

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data.

The information required by this item is presented at the end of this Annual Report beginning on page F-1 and is incorporated herein by reference. An index of those financial statements is found in Part IV, Item 15, Exhibit and Financial Statement Schedules, of this Annual Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report, is collected, recorded, processed, summarized, and reported within the time periods specified under the rules of the SEC. As of December 31, 2024, the end of the period covered by this Annual Report, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our "disclosure controls and procedures," as defined in Rule 13a-15(e) under the Exchange Act\. The Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based on their assessment, they have concluded that, as of December 31, 2024, our disclosure controls and procedures are effective.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with GAAP. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures and our internal control processes will prevent all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2024.

As of December 31, 2024, we are a non-accelerated filer, and our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting**.**

Item 9B. Other Information.

During the three months ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this item of this Annual Report will be included under the caption "Directors, Executive Officers, and Corporate Governance" in our 2025 Proxy Statement, and is incorporated by reference herein.

Item 11. Executive Compensation.

The information required by this item of this Annual Report will be included under the caption "Executive and Director Compensation" in our 2025 Proxy Statement, and is incorporated by reference herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item of this Annual Report will be included in our 2025 Proxy Statement and is incorporated by reference herein.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item of this Annual Report will be included under the captions "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance – Director Independence" in our 2025 Proxy Statement and is incorporated by reference herein.

Item 14. Principal Accountant Fees and Services.

The information required by this item of this Annual Report will be included in our 2025 Proxy Statement and is incorporated by reference herein.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a) Financial Statements and Schedules.

See "Index to Consolidated Financial Statements" beginning on page F-1 following the signature page as required by Part II, Item 8 of this Annual Report.

(b) Exhibits.

Exhibit Number	Description
3.1	Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (incorporated by reference as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
3.2	Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on June 16, 2022)
3.3	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016 (incorporated by reference as Exhibit 3.3 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
3.4	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.5	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021 (incorporated by reference as Exhibit 3.5 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
3.6	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.7	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)
3.8	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 5, 2024 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 5, 2024)
3.9	Amendment to Amended and Restated By-Laws of bioAffinity Technologies Inc., dated October 17, 2024 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
4.1	Form of Registrant's Common Stock Certificate (Incorporated by reference as Exhibit 4.1 to the Registrant's Form S-1/A filed with the SEC on June 16, 2022)
4.2	Common Stock Purchase Warrant issued to San Antonio Economic Development Corporation dated March 17, 2017 (Incorporated by reference as Exhibit 4.2 to the Registrant's Form S-1/A filed with the SEC on May 25, 2022).
4.3	Form of Common Stock Purchase Warrant issued to Holders of the Registrant's Convertible Promissory Notes (Incorporated by reference as Exhibit 4.3 to the Registrant's Form S-1/A filed with the SEC on May 25, 2022)
4.4	Form of Placement Agent's Warrant issued to WallachBeth Capital, LLC (Incorporated by reference as Exhibit 4.4 to the Registrant's Form S-1/A filed with the SEC on August 5, 2022)
4.5	Form of Representative's Warrant issued to WallachBeth Capital, LLC, in connection with the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.5 to the Registrant's Form S-1/A filed with the SEC on July 28, 2022).

4.6	Form of (Tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 6, 2022)
4.7	Form of Warrant Agent Agreement for the Warrants issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on September 6, 2022)
4.8	Form of (Non-tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 6, 2022)
4.9	Form of Amendment to Common Share Purchase Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
4.10	Form of Amendment to Initial Public Offering Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
4.11	Form of Warrant to Purchase Common Stock (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 8, 2024)
4.12	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on March 8, 2024)
4.13*	Description of Securities
4.14	Form of Purchase Warrant (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
4.15	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
4.16	Form of Common Warrant (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
4.17	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
4.18	Form of New Warrant (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)
4.19	Form of Advisor Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)
10.1+	2014 Equity Incentive Plan of Registrant, as amended. (Incorporated by reference as Exhibit 10.1 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)
10.2+	Executive Chairman Employment Agreement dated January 1, 2020, by and between Registrant and Steven Girgenti, as amended. (Incorporated by reference as Exhibit 10.2 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)

10.3+	Employment Agreement dated February 1, 2015, by and between Registrant and Maria Zannes. (Incorporated by reference as Exhibit 10.3 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)
10.4+	Employment Agreement dated April 4, 2016, by and between Registrant and Vivienne Rebel, as amended. (Incorporated by reference as Exhibit 10.4 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)
10.5+	Employment Agreement dated February 1, 2015, by and between Registrant and Timothy Zannes. (Incorporated by reference as Exhibit 10.5 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)
10.6+	Consulting Agreement dated May 25, 2017, by and between Registrant and Michael Edwards, as amended. (Incorporated by reference as Exhibit 10.6 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.7	License Agreement to Participate in the UTSA New Venture Incubator Program dated June 15, 2015, by and between Registrant and the University of Texas at San Antonio. (Incorporated by reference as Exhibit 10.9 to the Registrant's Form S-1 filed with the SEC on April 25, 2022)
10.8	Joint Development Agreement dated October 1, 2018, by and between the Registrant and Village Oaks Pathology Services, P.A. d/b/a Precision Pathology Services (Incorporated by reference as Exhibit 3.2 to the Registrant's Form S-1/A filed with the SEC on July 27, 2022)
10.9	Agreement dated October 17, 2020, by and between Registrant and GO2 Partners (Incorporated by reference as Exhibit 10.9 to the Registrant's Form S-1/A filed with the SEC on July 27, 2022)
10.10	Form of Note Purchase Agreement used by the Registrant in its private offering of Convertible Promissory Notes issued between October 2021 and January 2022 (Incorporated by reference as Exhibit 10.10 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.11+	Offer Letter between bioAffinity Technologies, Inc. and Michael Dougherty dated April 11, 2023 (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 1, 2023)
10.12+	bioAffinity Technologies, Inc. Amended and Restated 2014 Equity Incentive Plan Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)
10.13+	Amendment, effective as of August 1, 2023, to Employment Agreement, dated February 1, 2015, by and between bioAffinity Technologies, Inc. and Maria Zannes (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on July 28, 2023)
10.14	Asset Purchase Agreement, effective September 18, 2023, by and among, Precision Pathology Laboratory Services, LLC, Dr. Roby P. Joyce and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.15	Subscription Agreement, dated September 18, 2023, by and between The Joyce Living Trust, dated March 19, 2013, and bioAffinity Technologies, Inc. (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.16	Management Services Agreement, effective as of September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)

10.17	Succession Agreement, effective September 18, 2023, by and among, Precision Pathology Laboratory Services, LLC, Dr. Roby P. Joyce and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.18	Professional Services Agreement, effective as of September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.19+	Executive Employment Agreement, dated September 18, 2023, by and between the Registrant and Roby Joyce, M.D. (Incorporated by reference as Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.20	Assignment and Assumption of Lease Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.21	Office Lease, dated July 31, 2019, by and between Village Oaks Pathology Services, P.A. and 343 West Sunset, LLC (Incorporated by reference as Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.22	Assignment and Assumption Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.23	Equipment Usage Attachment, dated effective as of August 9, 2019, by and between Gen-Probe Sales & Service, Inc., together with its subsidiaries and affiliates and Village Oaks Pathology Services, P.A. d/b/a Precision Pathology, as amended by that certain Amendment No. 1 to Equipment Usage Attachment dated November 2, 2020, as further amended by that certain Amendment No. 2 to Equipment Usage Attachment dated November 2, 2020, and as further amended by that certain Amendment No. 3 to Equipment Usage Attachment dated December 21, 2022 (Incorporated by reference as Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.24	Master Agreement, dated as of January 29, 2015, by and between Leica Microsystems, Inc. and Precision Pathology, as amended by Amendment No. 1 to the Master Agreement, dated on or about April 4, 2018, as further amended by that certain Amendment No. 2 to Master Agreement, dated March 23, 2021 (Incorporated by reference as Exhibit 10.11 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.25	Strategic Relationship License Agreement, dated December 1, 2022, by and between Pathology Watch, Inc. and Precision Pathology Services (Incorporated by reference as Exhibit 10.12 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.26	Bill of Sale signed by Village Oaks Pathology Services, P.A., effective as of September 18, 2023 (Incorporated by reference as Exhibit 10.13 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)

10.27	Jamie Platt Offer Letter (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on December 5, 2023)
10.28+	bioAffinity Technologies, Inc. Management Incentive Bonus Plan (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 31, 2024)
10.29+	Amendment to Michael Dougherty Offer Letter (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 31, 2024)
10.30	Form of Securities Purchase Agreement, dated as of March 6, 2024, by and among the Company and the investors parties thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 8, 2024)
10.31	Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on March 8, 2024)
10.32+	bioAffinity Technologies, Inc. 2024 Incentive Compensation Plan (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 5, 2024)
10.33	Form of Securities Purchase Agreement, dated as of August 2, 2024, by and among the Company and the investor listed on the signature page thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.34	Form of Warrant Inducement Agreement (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.35	Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.36+	Consulting Agreement, dated August 21, 2024, by and between bioAffinity Technologies, Inc. and Michael Edwards (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 23, 2024)
10.37+	Employment Agreement between bioAffinity Technologies, Inc. and Michael Edwards, dated as of October 9, 2024 (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 10, 2024)
10.38	Form of Securities Purchase Agreement, dated as of October 18, 2024, by and between the Company and the purchasers listed on the signature pages thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
10.39	Form of Support Agreement (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
10.40+	Amendment No. 2 to Employment Agreement with Maria Zannes (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 14, 2025)
10.41	Form of Warrant Inducement Agreement (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)

14.1	Code of Business Conduct of the Registrant (Incorporated by reference as Exhibit 14.1 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
19.1*	Amended and Restated Insider Trading Policy of the Registrant
21.1	List of Subsidiaries of the Registrant (incorporated by reference as Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
23.1*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm
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 pursuant to Section 906 of Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002
97.1	Clawback Policy (incorporated by reference as Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on the 31st day of March, 2025.

bioAffinity Technologies, Inc.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Maria Zannes Maria Zannes	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 31, 2025
/s/ J. Michael Edwards J. Michael Edwards	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025
/s/ Steven Girgenti Steven Girgenti	Executive Chairman and Director	March 31, 2025
/s/ Robert Anderson Robert Anderson	Director	March 31, 2025
/s/ Stuart Diamond Stuart Diamond	Director	March 31, 2025
/s/ Peter S. Knight Peter S. Knight	Director	March 31, 2025
/s/ Gary Rubin Gary Rubin	Director	March 31, 2025
/s/ Roby Joyce, M.D. Roby Joyce	Director	March 31, 2025
/s/ Jamie Platt Jamie Platt	Director	March 31, 2025

bioAffinity Technologies, Inc.
Index to the Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
bioAffinity Technologies, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of bioAffinity Technologies, Inc. (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with principles generally accepted in the United States of America.

Substantial Doubt Regarding the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant losses and negative cash flows from operations since inception, has an accumulated deficit, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2021.

New York, New York
March 31, 2025

PCAOB ID Number 100

bioAffinity Technologies, Inc.
Consolidated Balance Sheets
as of December 31, 2024 and 2023

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,105,291	$ 2,821,570
Accounts and other receivables, net	1,139,204	811,674
Inventory	27,608	18,484
Prepaid expenses and other current assets	422,995	321,017
Total current assets	2,695,098	3,972,745
Non-current assets:		
Property and equipment, net	375,385	458,633
Operating lease right-of-use asset, net	463,011	370,312
Finance lease right-of-use asset, net	780,872	1,165,844
Goodwill	1,404,486	1,404,486
Intangible assets, net	775,139	833,472
Other assets	19,676	16,060
Total assets	$ 6,513,667	$ 8,221,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 987,311	$ 604,789
Accrued expenses	1,398,722	1,149,811
Unearned revenue	24,404	33,058
Operating lease liability, current portion	127,498	94,708
Finance lease liability, current portion	395,301	365,463
Notes payable, current portion	171,669	—
Total current liabilities	3,104,905	2,247,829
Non-current liabilities		
Operating lease liability, net of current portion	342,098	283,001
Finance lease liability, net of current portion	444,448	835,467
Notes payable, net of current portion	20,180	—
Total liabilities	3,911,631	3,366,297
Commitments and contingencies (See Note 11)		
Stockholders' equity:		
Preferred stock, no shares issued or outstanding at December 31, 2024 and 2023, respectively	—	—
Common stock, par value $0.007 per share; 100,000,000 shares authorized; 15,576,674 and 9,394,610 shares issued and outstanding as of December 31, 2024 and 2023, respectively	106,593	65,762
Additional paid-in capital	56,139,753	49,393,972
Accumulated deficit	(53,644,310)	(44,604,479)
Total stockholders' equity	2,602,036	4,855,255
Total liabilities, and stockholders' equity	$ 6,513,667	$ 8,221,552

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

bioAffinity Technologies, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2024 and 2023

	2024	2023
Net Revenue	$ 9,362,022	$ 2,532,499
Operating expenses:		
Direct costs and expenses	5,983,475	1,740,884
Research and development	1,461,227	1,467,936
Clinical development	321,655	256,661
Selling, general and administrative	9,943,473	6,790,654
Depreciation and amortization	605,637	249,592
Total operating expenses	18,315,467	10,505,727
Loss from operations	(8,953,445)	(7,973,228)
Other income (expense):		
Interest income	17,610	122,131
Interest expense	(92,475)	(37,125)
Other income	10,323	3,325
Other expense	(10,194)	(31,121)
Loss before income taxes	(9,028,181)	(7,916,018)
Income tax expense	(11,650)	(20,993)
Net loss	$ (9,039,831)	$ (7,937,011)
Net loss per common share, basic and diluted	$ (0.75)	$ (0.91)
Weighted average common shares outstanding	12,125,029	8,747,509

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

bioAffinity Technologies, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2024 and 2023

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2022	—	—	8,381,324	$ 58,669	$ 47,652,242	$ (36,667,468)	$ 11,043,443
Stock-based compensation	—	—	448,314	3,138	745,685	—	748,823
Stock issued in connection with the acquisition	—	—	564,972	3,955	996,045	—	1,000,000
Net loss	—	—	—	—	—	(7,937,011)	(7,937,011)
Balance at December 31, 2023	—	—	9,394,610	$ 65,762	$ 49,393,972	$ (44,604,479)	$ 4,855,255
Stock-based compensation	—	—	549,917	3,849	985,832	—	989,681
Exercise of stock options	—	—	208,031	1,456	73,443	—	74,899
Exercise of stock warrants	—	—	1,066,767	7,467	1,363,680	—	1,371,147
Sale of common stock	—	—	4,008,294	28,059	5,584,724	—	5,612,782
Offering costs	—	—			(1,261,898)	—	(1,261,898)
Net loss	—	—	—	—	—	(9,039,831)	(9,039,831)
Balance at December 31, 2024	—	—	15,227,619	$ 106,593	$ 56,139,753	$ (53,644,310)	$ 2,602,036

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

bioAffinity Technologies, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2024 and 2023

	2024	2023
Cash flows from operating activities		
Net loss	$ (9,039,831)	$ (7,937,011)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	605,637	249,592
Stock-based compensation expense	989,681	748,823
Changes in operating assets and liabilities:		
Accounts and other receivables	(327,530)	311,366
Inventory	(9,124)	(12,944)
Prepaid expenses and other assets	(105,594)	214,402
Accounts payable	382,521	(14,501)
Accrued expenses	248,911	362,012
Unearned revenue	(8,654)	33,058
Accrued interest	—	—
Operating lease right-of-use asset	(812)	7,397
Net cash used in operating activities	(7,264,795)	(6,037,806)
Cash flows from investing activities		
Purchase of property and equipment	(79,083)	(22,902)
Acquisition, net of cash acquired	—	(2,186,497)
Net cash used in investing activities	(79,083)	(2,209,399)
Cash flows from financing activities		
Proceeds from issuance of common stock from direct offering, net of underwriting discounts, commissions, and offering expenses of $1,334,811	4,350,885	—
Proceeds from exercised stock options	74,899	—
Proceeds from exercise of warrants	1,371,147	—
Payment on loans payable	—	(251,746)
Proceeds from loans payable	191,849	—
Principal repayments on finance leases	(361,181)	(93,238)
Net cash provided by (used in) by financing activities	5,627,599	(344,984)
Net decrease in cash and cash equivalents	(1,716,279)	(8,592,189)
Cash and cash equivalents at beginning of year	2,821,570	11,413,759
Cash and cash equivalents at end of year	$ 1,105,291	$ 2,821,570
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	$ 11,650	$ 20,993
Interest paid	17,610	37,125
Noncash investing activities:		
Stock issuance in connection with the acquisition	$ —	$ 1,000,000
Noncash financing activities:		
Fair value of warrants issued to placement agents	$ 74,281	—

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

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

Description of Business

bioAffinity Technologies, Inc., a Delaware corporation (the "Company," or "bioAffinity Technologies"), addresses the need for noninvasive diagnosis of lung cancer at early stage and other diseases of the lung. bioAffinity Technologies' proprietary platform uses flow cytometry and automated data analysis built by machine learning, a form of artificial intelligence, to preferentially target cancer cell populations and other cell populations indicative of a diseased state. The Company's first diagnostic test, CyPath® Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. CyPath® Lung is offered for sale to physicians by the Company's subsidiary, Precision Pathology Laboratory Services, LLC ("PPLS"). The Company also conducted and intends to seek strategic partners to advance therapeutic discoveries that could in the future result in broad-spectrum cancer treatments. Research and optimization of the Company's proprietary platform technologies are conducted in laboratories at PPLS and laboratory space leased at The University of Texas at San Antonio.

Organization

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

Basis of Presentation

The consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC").

Liquidity and Capital Resources

In accordance with Accounting Standards Update ("ASU") 2014-15, *Presentation of Financial Statements – Going Concern* (Subtopic 205-40), the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern for at least one year after the date the 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 $53.6 million at December 31, 2024. The Company's cash and cash equivalents at December 31, 2024, were approximately $1.1 million. Based on the Company's current expected level of operating expenditures and the cash and cash equivalents on hand at December 31, 2024, management concludes that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that the Company's cash resources are sufficient to continue operations through April 2025. The Company may need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations, if revenue from operations does not significantly increase. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan may be curtailed. Furthermore, an alternative source of funding to the sale of additional equity or debt securities is the exercise of outstanding warrants for which there can be no guarantee. No adjustments have been made to the presented consolidated financial statements as a result of this uncertainty.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Principles of Consolidation

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

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

Business Combination

On September 18, 2023, the Company, in connection with the Asset Purchase Agreement it entered into with Village Oaks and Roby P. Joyce, M.D., dated September 18, 2023, acquired substantially all the assets and assumed certain liabilities of Village Oaks in exchange for total consideration of $3,500,000, which consists of: (1) $2.5 million in cash paid at closing and (2) 564,972 shares of the Company's Common Stock valued at $1 million. The assets purchased included a clinical pathology laboratory regulated by the Centers for Medicare and Medicaid Services ("CMS") and accredited by the College of American Pathologists ("CAP") and certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). The primary reason for the acquisition was control of the laboratory in which CyPath® Lung is ordered and processed.

The Company recognized goodwill of $1,404,000 arising from the acquisition. The acquisition is being accounted for as a business combination in accordance with ASC 805. The Company has determined the fair values of the accounts receivable, accounts payable, and accrued expenses that make up the majority of the net working capital assumed in the acquisition.

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

Cash	$	2,500,000
Common Stock		1,000,000
Total purchase consideration	$	3,500,000
Assets		
Net working capital (including cash)	$	912,000
Property and equipment		326,000
Other assets		8,000
Customer relationships		700,000
Trade names and trademarks		150,000
Goodwill		1,404,000
Total net assets	$	3,500,000

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

The Company incurred and expensed approximately $811,000 in acquisition costs.

Cash and Cash Equivalents

For the purpose of the consolidated statement of cash flows, the Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at cost, which approximates market value because of the short maturity of these instruments.

Concentration of Risk

The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Advertising Expense

The Company expenses all advertising costs as incurred. Advertising expenses were approximately $267,201 and $88,832 for the years ended December 31, 2024 and 2023, respectively.

Loss Per Share

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

The following potentially dilutive securities have been excluded from the computations of weighted average shares of Common Stock outstanding as of December 31, 2024 and 2023, as they would be anti-dilutive:

	As of December 31,	
	2024	2023
Shares underlying options outstanding	304,125	683,695
Shares underlying warrants outstanding	12,298,124	—
Shares underlying unvested restricted stock outstanding	349,057	4,649,952
Anti-dilutive securities	12,951,306	5,333,647

Revenue Recognition

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

Post-acquisition of PPLS, additional revenue streams have been consolidated starting September 19, 2023. PPLS generates three sources of revenue: (1) patient service fees, (2) histology service fees, and (3) medical director fees. The Company recognizes as revenue the amount that reflects the consideration to which it expects to be entitled in exchange for goods sold or services rendered primarily upon completion of the testing process (when results are reported) or when services have been rendered.

The Company follows a standard process, which considers historical denial and collection experience and other factors (including the period of time that the receivables have been outstanding), to estimate contractual allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation.

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

	Year Ended December 31,	
	2024	2023
Patient service fees[1]	$ 8,175,670	$ 2,199,558
Histology service fees	1,103,751	272,660
Medical director fees	66,576	19,324
Department of Defense observational studies	8,654	19,442
Other revenues	7,371	21,515
Total net revenue	$ 9,362,022	$ 2,532,499

1 Patient services fees include direct billing for CyPath® Lung diagnostic test of approximately $516,000 and $35,000 for the years ended December 31, 2024 and 2023.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. Any reclassifications had an immaterial effect on the Company's consolidated financial statements and had no effect on prior periods net income or stockholders' equity.

Property and Equipment, Net

In accordance with ASC 360-10, *Accounting for the Impairment of Long-Lived Assets (*"ASC 360"*)*, the Company periodically reviews the carrying value of its long-lived assets, such as property, equipment, and definite lived intangible assets, to test whether current events or circumstances indicate that such carrying value may not be recoverable. When evaluating assets for potential impairment, the Company compares the carrying value of the asset to its estimated undiscounted future cash flows. If an asset's carrying value exceeds such estimated cash flows (undiscounted and with interest charges), the Company records an impairment charge for the difference. The Company did not record any impairment for the years ended December 31, 2024 or 2023.

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

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

Intangible Assets

The Company's acquisition of PPLS on September 18, 2023 identified Goodwill and intangible assets. Goodwill represents the purchase price in excess of fair values assigned to the underlying identifiable net assets of the acquired business. The intangible assets and their respective useful lives are as follows: trade names and trademarks (18 years) and customer relationships (14 years). Intangible assets, net of accumulated amortization, are summarized as follows as of December 31, 2024 and 2023:

	December 31,	
	2024	2023
Cost		
Goodwill	$ 1,404,486	$ 1,404,486
Trade names and trademarks	150,000	150,000
Customer relationships	700,000	700,000
	2,254,486	2,254,486
Accumulated amortization		
Goodwill	—	—
Trade names and trademarks	(10,694)	(2,361)
Customer relationships	(64,167)	(14,167)
	(74,861)	(16,528)
Intangible assets, net	$ 2,179,625	$ 2,237,958

For the year ended December 31, 2024, amortization of intangible assets totaled $58,333 compared to $16,528 in the prior year comparative period.

Goodwill is reviewed annually for impairment in accordance with *ASC 350 - Intangibles – Goodwill and Other*, and intangible assets are reviewed annually for impairment in accordance with ASC 360 unless circumstances dictate the need for more frequent assessment. The Company elected to perform a quantitative impairment analysis as of December 31, 2024. The annual quantitative assessment of the intangible assets was performed utilizing a discounted cash flow analysis ("income approach"). The income approach measures the fair value of an interest in a business by discounting expected future cash flows to present value. The results of the annual quantitative impairment analysis indicated that the fair value exceeded the carrying value of the reporting unit and therefore resulted in no impairment needed.

Recent Accounting Pronouncements

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

The Company adopted FASB issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* on December 31, 2024, on a retrospective basis. The Company used the five steps to ASC 280 to evaluate what, if any, segment reporting would be beneficial for shareholders. These five steps included: 1) evaluate operating segments for aggregation, 2) perform quantitative threshold tests, 3) evaluate remaining operating segments for aggregation, 4) ensure that 75% of revenue is reported, and 5) consider practical limit. Based on the analysis above against those five steps, management concludes that segment reporting is required for two segment operations: 1) diagnostic R&D and 2) laboratory services (See Note 2).

The FASB issued Accounting Standards Update ("ASU") No. ASU 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* which requires public business entities to disclose annually a tabular rate reconciliation, including specific items such as state and local income tax, tax credits, nontaxable or nondeductible items, among others, and a separate disclosure requiring disaggregation of reconciling items as described above which equal or exceed 5% of the product of multiplying income from continuing operations by the applicable statutory income tax rate. The ASU is effective for all public business entities for annual periods beginning after December 15, 2024. The adoption of this standard is not expected to have a material effect on the Company's operating results or financial condition.

Income Taxes

Income taxes are accounted for under the asset and liability method. 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. 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. The Company includes interest and penalties related to uncertain tax positions as part of income tax expense, if any. No such interest or penalties were recognized during the years ended December 31, 2024 and 2023, and the Company had no accruals for interest and penalties at December 31, 2024 or 2023.

Segment Information

The Company is organized in two operating segments, Diagnostic Research and Development ("R&D") and Laboratory Services, whereby its chief operating decision maker ("CODM") uses operating income as the primary measure of segment profit or loss to assess performance and make resource allocation decisions, in addition to monitoring revenue growth and research and development progress. The CODM is the Chief Executive Officer.

Diagnostic R&D includes research and development and clinical development of diagnostic tests. Any revenues assigned to Diagnostic R&D are proceeds received from observational studies. Laboratory services include all the operations from Village Oaks and PPLS in addition to sales and marketing costs of CyPath® Lung from bioAffinity.

	As of December 31,	
	2024	2023
Net revenues:		
Diagnostic R&D	$ 8,654	$ 19,442
Laboratory services	9,353,368	2,513,057
Total net revenues	9,362,022	2,532,499
Operating expenses:		
Diagnostic R&D	(1,782,882)	(1,724,597)
Laboratory services	(9,946,452)	(3,769,783)
General corporate activities	(6,586,133)	(5,011,347)
Total operating loss	(8,953,445)	(7,973,228)
Non-operating income (expense), net	(74,736)	57,210
Net loss before income taxes	(9,028,181)	(7,916,018)
Income tax expense	(11,650)	(20,993)
Net loss	$ (9,039,831)	$ (7,937,011)

Research and Development

Research and development costs are charged to expense as incurred. The Company's research and development expenses consist primarily of expenditures for laboratory operations, preclinical studies, compensation, and consulting costs.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by service providers, which include preclinical studies. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses in the accompanying consolidated balance sheets and within research and development expense in the accompanying consolidated statements of operations.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with service providers. The Company makes significant judgments and estimates in determining the accrued expenses balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Regulatory Matters

Regulations imposed by federal, state, and local authorities in the U.S. are a significant factor in providing medical care. In the U.S., drugs, biological products, and medical devices are regulated by the federal Food, Drug and Cosmetic Act, which is administered by the FDA and CMS. The Company has not yet obtained marketing authorization from the FDA but is able to market its CyPath® Lung test as a laboratory developed test sold by Precision Pathology Laboratory Services, a CAP-accredited, CLIA-certified clinical pathology laboratory and wholly owned subsidiary.

Note 3. ACCOUNTS AND OTHER RECEIVABLES, NET

Accounts and other receivables at December 31, 2024 and 2023, are summarized below:

	December 31,	
	2024	2023
Patient service fees	$ 915,488	$ 657,717
Histology service fees	190,648	121,301
Medical director fees	5,194	3,103
Other receivables	27,874	29,553
Total accounts and other receivables, net	$ 1,139,204	$ 811,674

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2024 and 2023, are summarized below:

	December 31,	
	2024	2023
Prepaid insurance	$ 248,364	$ 171,855
Legal and professional	27,448	24,476
Other	147,183	124,686
Total prepaid expenses and other current assets	$ 422,995	$ 321,017

Note 5. PROPERTY AND EQUIPMENT, NET

Property and equipment at December 31, 2024 and 2023, are summarized below:

	December 31,	
	2024	2023
Lab equipment	$ 662,747	$ 647,214
Computers and software	81,433	68,682
Leasehold improvements	19,353	9,941
Vehicles	148,103	105,919
	911,636	831,756
Less: accumulated depreciation and amortization	(536,251)	(373,123)
Total property and equipment, net	$ 375,385	$ 458,633

Total property and equipment depreciation and amortization expense was $162,332 and $233,064 for the years ended December 31, 2024 and 2023, respectively.

Note 6. ACCRUED EXPENSES

Accrued expenses at December 31, 2024 and 2023, are summarized below:

	December 31,	
	2024	2023
Compensation	$ 1,079,839	$ 857,037
Legal and professional	98,477	257,926
Clinical	160,371	15,350
Other	60,035	19,498
Total accrued expenses	$ 1,398,722	$ 1,149,811

Note 7. UNEARNED REVENUE

The Company engaged in an observational study of CyPath® Lung with the DOD. A total of 70 CyPath® Lung units were ordered and shipped. However, in compliance with FASB ASC 606, the performance obligation was complete for only 40 units as of December 31, 2024. The performance obligation is deemed complete after samples have been collected and processed and results analyzed. The unearned revenue balance amounted to $24,404 and $33,058 as of December 31, 2024 and 2023, respectively.

Note 8. FAIR VALUE MEASUREMENTS

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

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

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

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

Note 9. LEASES

The Company has one operating lease for its real estate and office space for the CAP/CLIA laboratory, as well as multiple finance leases for lab equipment in Texas that were acquired through the September 18, 2023 acquisition. Additionally, the Company entered into another operating lease on September 1, 2024 with regard to office space. The Company has operating leases consisting of office space with remaining lease terms ranging from 3.1 to 5.9 years as of December 31, 2024. The Company has finance leases consisting of office and lab equipment with remaining lease terms ranging from approximately 1.25 to 3.0 years as of December 31, 2024, for which the Company has determined that it will use the equipment for a major part of its remaining economic life.

The lease agreements generally do not provide an implicit borrowing rate. Therefore, the Company used a benchmark approach as of the date of inception of the leases to derive an appropriate incremental borrowing rate to discount remaining lease payments. The Company benchmarked itself against other companies of similar credit ratings and comparable quality and derived imputed interest rates ranging from 7.41% to 8.03% for the lease term lengths.

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

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

The components of lease expense, which are included in selling, general and administrative expense and depreciation and amortization for the year ended December 31, 2024, and 2023 are as follows:

Components of lease expense:	**2024**	**2023**
Amortization of right-of-use assets - finance lease	$ 384,971	$ 128,324
Interest on lease liabilities - finance lease	83,041	33,838
Operating lease cost	93,029	39,887
Total lease cost	$ 561,041	$ 202,049
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 361,181	$ 93,238
Operating cash flows from operating leases	133,605	32,489

Operating leases:	**2024**	**2023**
Operating lease right-of-use, assets	$ 463,011	$ 370,312
Operating lease liability, current	127,498	94,708
Operating lease liability, non-current	342,098	283,001
Total operating lease liabilities	$ 469,596	$ 377,709

Financing leases:	**2024**	**2023**
Financing lease right-of-use assets, gross	$ 1,294,168	$ 1,294,168
Accumulated amortization	(513,296)	(128,324)
Finance lease right-of-use assets, net	$ 780,872	$ 1,165,844
Financing lease liability, current	395,301	365,463
Financing lease liability, non-current	444,448	835,467
Total finance lease liabilities	$ 839,749	$ 1,200,930

Weighted-average remaining lease term:	**2024**	**2023**
Operating leases (in years)	4.21	3.58
Finance leases (in years)	2.39	3.25

Weighted-average discount rate:	**2024**	**2023**
Operating leases	7.41%	8.07%
Finance leases	8.03%	8.01%

	Operating Leases	Finance Leases
2025	$ 157,837	$ 448,505
2026	159,282	270,395
2027	110,063	202,970
2028	40,616	—
2029	42,252	—
2030 and thereafter	28,919	—
Total undiscounted cash flows	538,969	921,870
Less discounting	(69,373)	(82,121)
Present value of lease liabilities	$ 469,596	$ 839,749

Note 10. NOTES PAYABLE

Toyota Corolla - 2024

On March 18, 2024, the Company entered into a finance agreement to purchase a 2024 Toyota Corolla for $33,620 with a maturity date of February 18, 2030. The loan bears fixed interest at a rate of 5.99% per annum, with monthly payments of $467, which is comprised of principal and interest. This loan is collateralized by the underlying vehicle. The balance of this loan as of December 31, 2024, and 2023 was $24,849 and $0, respectively. The current portion of the balance of this loan as of December 31, 2024, and 2023 was $5,603 and $0, respectively.

Directors and Officers Insurance Policy – 2024

In September 2024, the Company obtained short-term financing of approximately $0.26 million with 11 monthly payments of approximately $24,000 and interest at a 6.7% fixed annual rate for director and officer insurance policies. The current portion of the balance of this loan as of December 31, 2024, and December 31, 2023, was $167,000 and $0, respectively.

Note 11. COMMITMENTS AND CONTINGENCIES

Legal Matters

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

Note 12. COMMON STOCK

The Company has authorized a total of 100,000,000 shares of Common Stock, $0.007 par value per share. On June 4, 2024, the Company received stockholder approval to increase the number of authorized shares of Common Stock from 25,000,000 shares to 100,000,000 shares, and on June 5, 2024, the Company filed an amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the increase. The Company has issued 15,576,674 shares of Common Stock, of which 349,057 are unvested restricted stock awards as of December 31, 2024, and 9,505,255 shares of Common Stock, of which 110,645 are unvested restricted stock awards as of December 31, 2023.

Note 13. STOCK-BASED COMPENSATION

The Company granted options and restricted stock awards under its 2014 Equity Incentive Plan (the "2014 Plan"). Under the 2014 Plan, the Company was authorized to grant options or restricted stock for up to 2,000,000 shares of Common Stock. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 1,142,857 to 2,000,000. Options or restricted stock awards may be granted to employees, the Company's board of directors, and external consultants who provide services to the Company. Options and restricted stock awards granted under the 2014 Plan have vesting schedules with terms of one to three years and become fully exercisable based on specific terms imposed at the date of grant. The 2014 Plan expired according to the respective 10-year term of the 2014 Plan in March 2024. A new 2024 Incentive Compensation Plan (the "2024 Plan") was approved at the Annual Meeting of Shareholders on June 4, 2024.

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

	2024	2023
Research and development	$ 99,174	$ 37,131
Selling, general and administrative	890,507	711,692
Total stock-based compensation expense	$ 989,681	$ 748,823

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

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2023	683,695	$ 3.99	2.9	$ 158,332
Granted	—	—	—	—
Exercised	(208,031)	1.16	—	—
Forfeited	(171,539)	2.16	—	—
Outstanding at December 31, 2024	304,125	$ 6.95	4.20	$ —
Vested and exercisable at December 31, 2024	304,125	$ 6.95	4.20	$ —

As of December 31, 2024, there was no unrecognized compensation cost related to non-vested stock options.

During the year ended December 31, 2024, 208,031 options were exercised at an exercise price of $1.155, of which 143,183 options were from a cashless exercise, and 137,854 options were forfeited due to a cashless exercise.

Restricted Stock Awards

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

	Number of restricted stock awards (RSA)	Weighted-average grant price	FMV on grant date	As of December 31, 2024	
				Vested number of RSA	Unvested number of RSA
Balance at December 31, 2023	540,969	$ 2.24	$ 1,209,400	462,298	78,671
Granted	865,423	1.81	1,570,834	517,941	347,482
Forfeited	(77,096)	1.80	(139,173)	—	(77,096)
Balance at December 31, 2024	1,329,296	$ 2.24	$ 2,641,061	980,239	349,057

During the year ended December 31, 2024, the Company issued restricted stock awards ("RSAs") for 865,423 shares of Common Stock to employees, non-employees, and the Board of Directors. The shares vest in equal monthly installments over terms of between immediately up to three years, subject to the employees and non-employees providing continuous service through the vesting date. During the year ended December 31, 2024, 31,973 shares vested from RSAs granted prior to January 1, 2024, and 517,943 shares vested from RSAs granted during the year ended December 31, 2024.

During the year ended December 31, 2023, the Company issued RSAs for 431,028 shares of Common Stock to employees and non-employees. The shares vest in equal monthly installments over terms of between immediately up to one year, subject to the employees and non-employees providing continuous service through the vesting date. During the year ended December 31, 2023, 59,051 shares vested from RSAs previously issued.

Note 14. WARRANTS

The Company's outstanding Common Stock warrants are equity classified. As of December 31, 2024 and 2023, the Company had 12,298,124 and 4,649,952 warrants outstanding, respectively, to purchase one share of the Company's Common Stock for each warrant at a weighted average exercise price of $2.95 and expire at various dates through October 2029. During the year ended December 31, 2024, a total number of 1,066,767 warrants were exercised into an equivalent number of shares of Common Stock as compared to no warrants being exercised during the year ended December 31, 2023. The proceeds of the exercised warrants for the year ended December 31, 2024, was $1,343,390, compared to no proceeds during the year ended December 31, 2023.

On March 8, 2024, the Company issued to certain investors (1) in a registered direct offering, 1,600,000 shares of the Company's Common Stock and (2) in a concurrent private placement, warrants to purchase an aggregate of 1,600,000 shares of Common Stock, with an exercise price of $1.64 (collectively, the "Transaction"), which Transaction constitutes a Dilutive Issuance under the terms of the warrants. In addition, the placement agent was granted warrants to purchase 32,000 shares of Common Stock, with an exercise price of $1.64.

On August 5, 2024, the Company entered into warrant exercise agreements with three existing accredited investors to exercise certain outstanding warrants to purchase an aggregate of 1,041,667 of the Company's shares of Common Stock (the "Existing Warrants"). The exercising holders received in a private placement new unregistered warrants (the "New Warrants") to purchase up to an aggregate of 1,302,082 shares of Common Stock with an exercise price of $1.50 per share, which are initially exercisable on the date that stockholder approval of the exercise of the New Warrants is obtained and will expire five years from the date of such approval. In connection with the exercise of the Existing Warrants, the Company agreed to reduce the exercise price of the Existing Warrants from $1.64 to $1.25 per share. The exercise of the Existing Warrants and the issuance of the New Warrants occurred on August 5, 2024. The change in the exercise price of the Existing Warrants resulted in a fair value adjustment of $27,757 which was recorded to Additional paid-in capital for the exercised warrants.

On August 5, 2024, the Company also entered into a securities purchase agreement with an institutional investor (the "Purchaser"), pursuant to which the Company issued to the Purchaser, (1) in a registered direct offering, 360,000 shares of Common Stock, and (2) in a concurrent private placement, warrants (the "Private Warrants") to purchase an aggregate of 450,000 shares of Common Stock (the "Private Warrant Shares"), with an exercise price of $1.50 (collectively, the "Offering"). In addition, designees of the placement agent for the Offering were granted warrants to purchase an aggregate of up to 49,862 shares of Common Stock, with an exercise price of $1.50.

On October 21, 2024, the Company issued (1) in a registered direct offering, 2,048,294 shares (the "Shares") of the Company's Common Stock, par value $0.007 per share, and (2) in a concurrent private placement, common warrants (the "Common Warrants") to purchase an aggregate of 2,662,782 shares of Common Stock (the "Common Warrant Shares"), with an exercise price of $1.50, pursuant to a securities purchase agreement, dated October 18, 2024 with institutional investors (the "Purchasers"). Such registered direct offering and concurrent private placement are collectively referred to as the "Offerings." In addition, designees of the placement agent for the Offering were granted warrants to purchase an aggregate of up to 61,448 shares of Common Stock, with an exercise price of $1.50.

As of December 31, 2024, and prior to the Offering, there were tradeable warrants to purchase up to an aggregate of 1,601,255 shares of Common Stock outstanding and non-tradeable warrants to purchase an aggregate of up to 2,704,458 shares of Common Stock outstanding.

	Number of warrants issued	Weighted-average exercise price	Number of warrants exercised	Number of warrants outstanding
Pre-IPO convertible notes	2,900,904	$ 5.31	—	2,900,904
IPO tradeable	2,326,835	3.06	(725,580)	1,601,255
IPO non-tradeable	3,015,464	3.06	(311,006)	2,704,458
Direct offering March 8, 2024	1,600,000	1.64	(1,066,667)	533,333
Placement agent direct offering March 8, 2024	32,000	1.64	—	32,000
Inducement/direct offering August 5, 2024	1,752,082	1.50	—	1,752,082
Placement agent direct offering August 5, 2024	49,862	1.50	—	49,862
Direct offering October 21, 2024	2,662,782	1.50	—	2,662,782
Placement agent direct offering October 21, 2024	61,448	1.50	—	61,448
Balance at December 31, 2024	14,401,377	$ 2.95	(2,103,253)	12,298,124

Note 15. INCOME TAXES

Deferred tax assets and valuation allowance

The Company had, subject to limitation, approximately $31 million of net operating loss carryforwards at December 31, 2024, of which approximately $0.67 million will begin expiring in 2034. The remaining balance of approximately $30 million will carry forward indefinitely. A 100% valuation allowance has been provided for the deferred tax benefits resulting from the net operating loss carryover due to a lack of earnings history. In addressing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. The valuation allowance increased by approximately $2.0 million and $3.0 million for the years ended December 31, 2024 and 2023, respectively. Significant components of deferred tax assets are as follows:

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryover	$ 8,185,845	$ 6,479,696
Stock compensation	247,574	325,320
Capitalized R&E costs	662,855	525,463
Bad debt expense	203,323	145,777
Other	107,538	58,236
Operating lease liabilities	274,962	79,319
Tax credits	480,724	332,690
Total deferred tax assets	10,162,821	7,946,501
Deferred tax liability:		
Right-of-use asset tax liability	$ (261,215)	$ (77,766)
Depreciation and amortization	(50,463)	(59,248)
Total deferred tax liability	(311,678)	(137,014)
Less: valuation allowance	(9,851,143)	(7,809,487)
	$ —	$ —

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2024 and 2023, was as follows:

	December 31,	
	2024	2023
Tax at federal statutory rate	-21.00%	-21.00%
Permanent differences	0.1%	0.03%
Research and development credits	-0.8%	-0.83%
Deferred balance true-up	0.00%	-16.07%
Change in valuation allowance	21.7%	37.87%
Effective income tax rate	0.00%	0.00%

Unrecognized tax benefits

As of December 31, 2024, and 2023, the Company has unrecognized tax benefits related to tax credits of $281,207 and $249,516, respectively. None of the unrecognized tax benefits as of December 31, 2024, if recognized, would impact the effective tax rate due to the valuation allowance, and no interest or penalties have been recognized. A reconciliation of the beginning and ending balance of unrecognized tax benefits is as follows:

	December 31,	
	2024	2023
Beginning balance	$ 249,516	$ 190,228
Deductions based on tax positions related to the prior year	—	30,897
Additions based on tax positions related to the current year	31,691	28,391
Ending balance	$ 281,207	$ 249,516

Note 16. SUBSEQUENT EVENTS

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

On February 26, 2025, pursuant to the terms of a warrant inducement agreement (the "February Inducement Agreement"), dated February 25, 2025 that the Company entered into with certain holders of existing warrants, such holders exercised for cash (i) warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock issued on October 21, 2024 (the "October Warrants"), at the reduced exercise price of $0.58 per share, and (ii) warrants to purchase an aggregate of up to 1,136,391 shares of Common Stock issued on August 5, 2024 (the "August Warrants"), at the reduced exercise price of $0.58 per share. The Company received aggregate gross proceeds of approximately $1.4 million, before deducting advisory fees and other expenses payable by it. In consideration of the immediate exercise of the October Warrants and August Warrants by the holders thereof in accordance with the February Inducement Agreement, the Company issued unregistered common warrants to purchase an aggregate of up to 2,926,166 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the October Warrants and August Warrants) to such holders.

Exhibit 4.13

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

bioAffinity Technologies, Inc. (the "Company," "we," "us," and "our") has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our common stock, par value $0.007 per share (the "Common Stock"), and tradeable warrants each to purchase one share of our Common Stock (the "Tradeable Warrants").

Common Stock

General

The following is a description of the material terms of our Common Stock. This is a summary only and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Charter"), and our Amended and Restated Bylaws (the "A&R Bylaws"), each of which are incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K. We encourage you to read our Charter, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

Authorized Capital Stock

We are currently authorized to issue up to 100,000,000 shares of Common Stock.

Voting Rights

Holders of our Common Stock are entitled to cast one vote for each share held of record on all matters presented to the stockholders. Holders of our Common Stock have no cumulative voting rights.

Dividend Rights

The Board is not obligated to declare a dividend, has never declared or paid cash dividends on its Common Stock, and does not anticipate paying dividends on our Common Stock for the foreseeable future.

Rights upon Liquidation

In the event of our liquidation, dissolution, or winding up, either voluntary or involuntary, subject to the rights and preferences that may apply to any shares of Preferred Stock outstanding at the time, the assets or surplus funds legally available for distribution to our stockholders would be distributable ratably among the Common Stockholders based on the number of shares of Common Stock held by each such holder, subject to prior satisfaction of all outstanding debt and liabilities.

No Preemptive or Similar Rights

Holders of our Common Stock are not entitled to preemptive rights to subscribe to additional shares if issued. Our Common Stock is not subject to any redemption or sinking-fund provisions. All outstanding shares of our Common Stock are fully paid and non-assessable.

Exchange Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "BIAF."

Tradeable Warrants

General

The following summary of certain terms and provisions of the Tradeable Warrants is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement between us and VStock Transfer, LLC, as Warrant Agent, and the form of Tradeable Warrant, all of which are filed as exhibits to our most recent Annual Report on Form 10-K. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the annexes thereto, and form of Tradeable Warrant.

Exercisability

The Tradeable Warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. If a registration statement registering the issuance of the shares of Common Stock underlying the Tradeable Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder of a Tradeable Warrant may, in its sole discretion, elect to exercise the Tradeable Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the Tradeable Warrant.

Exercise Limitation

A holder of a Tradeable Warrant will not have the right to exercise any portion of the Tradeable Warrant if the holder (together with its affiliates and any other person or entity acting as a group) would beneficially own more than 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Tradeable Warrants. However, upon notice from the holder to us, the holder may waive such limitation up to a percentage, not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following delivery of such notice from the holder to us.

Exercise Price

The exercise price per whole share of Common Stock purchasable upon exercise of the Tradeable Warrants was initially $7.35 per share, which had been reduced to $3.0625 pursuant to the terms thereof The exercise price of the Tradeable Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, or similar events affecting our Common Stock) and also upon any distributions of assets, including cash, stock, or other property to our stockholders.

Cashless Exercise

If at the time of exercise there is no effective registration statement registering the Warrant Shares, then the holder of a Tradeable Warrant may, in its sole discretion, exercise in whole or in part, and in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, elect instead to exercise the Tradeable Warrant on a cashless basis. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments or net cash settlement to the Tradeable Warrant holder in lieu of delivery of the Warrant Shares. Upon a "cashless exercise," the Tradeable Warrant holder shall be entitled to receive the number of Warrant Shares equal to the quotient obtained by dividing (A-B) (X) by (A), where:

(A) = the last VWAP immediately preceding the date of exercise giving rise to the applicable "cashless exercise," as set forth in the applicable Election to Purchase (as defined in the Warrant Agent Agreement) (to clarify, the "last VWAP" will be the last VWAP as calculated over an entire trading day such that, in the event that the Tradeable Warrant is exercised at a time that the trading market is open, the prior trading day's VWAP shall be used in this calculation);

(B) = the Exercise Price then in effect for the applicable Warrant Shares at the time of the exercise of the Tradeable Warrant, as adjusted as set forth herein; and

(X) = the number of Warrant Shares that would be issuable upon exercise of the Tradeable Warrant in accordance with the terms of the Tradeable Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

Fractional Shares

No fractional shares of Common Stock will be issued upon exercise of the Tradeable Warrants. If, upon exercise of a Tradeable Warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the next whole share.

Transferability

Subject to applicable laws, the Tradeable Warrants may be offered for sale, sold, transferred, or assigned without our consent.

Exchange Listing

The Tradeable Warrants are listed on The Nasdaq Capital Market under the symbol "BIAFW."

Warrant Agent; Global Certificates

The Tradeable Warrants are issued in registered form under a Warrant Agent Agreement between the Warrant Agent and us. The Tradeable Warrants shall initially be represented only by one or more global warrants deposited with the Warrant Agent, as custodian on behalf of The Depository Trust Company ("*DTC*") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. Our transfer agent, VStock Transfer, LLC, serves as our Warrant Agent.

Fundamental Transactions

In the event of a fundamental transaction, as described in the Tradeable Warrants and generally including any reorganization, recapitalization, or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or the acquisition of more than 50% of our outstanding Common Stock, the holders of the Tradeable Warrants are entitled to receive upon exercise of the Tradeable Warrants the kind and amount of securities, cash, or other property that the holders would have received had they exercised the Tradeable Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the Tradeable Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a Tradeable Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Tradeable Warrant.

Governing Law; and Exclusive Forum

The Tradeable Warrants and the Warrant Agent Agreement are governed by New York law. The warrant certificates governing the Tradeable Warrants provide that all legal proceedings concerning the interpretations, enforcement, and defense of the transactions contemplated by the warrant certificate (whether brought against a party to the warrant certificate or their respective affiliates, directors, officers, shareholders, partners, members, employees, or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York, Borough of Manhattan. The warrant certificates further provide that we and the Tradeable Warrant holders irrevocably submit to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan, for the adjudication of any dispute under the warrant certificate or in connection with it or with any transaction contemplated by it or discussed in it. Furthermore, we and the Tradeable Warrant holders irrevocably waive, and agree not to assert in any suit, action or proceeding, any claim that we or they are not personally subject to the jurisdiction of any such court, that such suit, action, or proceeding is improper or is an inconvenient venue for such proceeding. With respect to any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder, we note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in the Tradeable Warrant certificates expressly does not apply to suits brought to enforce any duty or liability created by the Exchange Act. We irrevocably waive any right we may have to, and agree not to request, a jury trial for the adjudication of any dispute under, in connection with, or arising out of the Tradeable Warrant or any transaction contemplated by the Tradeable Warrant.

Anti-Takeover Effects of Delaware Law and Provisions of Our Charter and A&R Bylaws

Certain provisions of the DGCL, our Charter, and our A&R Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our Board. These provisions might also have the effect of preventing changes in our Board or management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our Common Stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the corporation's board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by the corporation's board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include mergers, asset sales, and other transactions resulting in financial benefit to a stockholder, and an "interested stockholder" as a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing changes in control of our Company.

Provisions of Our Charter and A&R Bylaws

Our Charter and A&R Bylaws include a number of provisions that may have the effect of delaying, deferring, or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board rather than pursue non-negotiated takeover attempts. These provisions will include the items described below.

Director Vacancies

Our A&R Bylaws authorize the Board to fill vacant directorships and provide that the number of directors constituting our Board may be set by resolution of the incumbent directors.

Special Meetings of Stockholders

Our A&R Bylaws provide that special meetings of our stockholders may only be called pursuant to a resolution approved by the Board. The only business that may be conducted at a special meeting of our stockholders is the matter or matters set forth in the notice of such special meeting.

Prohibition of Stockholder Action by Written Consent

Our Charter and A&R Bylaws prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders.

Advance Notice Requirements

Our A&R Bylaws establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. To be timely, a stockholder's notice will need to be received by the Company secretary at our principal executive offices (x) not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the anniversary date of the immediately preceding annual meeting of stockholders (if such meeting is to be held on a day which is not more than 30 days in advance of the anniversary of the previous year's annual meeting or not later than 60 days after the anniversary of the previous year's annual meeting), or (y) with respect to any other annual meeting of stockholders, including in the event that no annual meeting was held in the previous year, not earlier than the close of business on the 120th day prior to the annual meeting and not later than the close of business on the later of: (1) the 90th day prior to the annual meeting and (2) the close of business on the tenth day following the first date that the date of such meeting was disclosed in a press release reported by the Dow Jones News Services, the Associated Press, or a comparable national news service or in a document filed by the Company with the SEC pursuant to the Exchange Act. Our A&R Bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Amendment to Charter and Bylaws

As required by the DGCL, any amendment of our Charter must first be approved by a majority of our Board, and if required by law or our Charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our A&R Bylaws provide for amendment of the A&R Bylaws by a majority of our Board or by a majority of the outstanding shares entitled to vote on the amendment.

Exclusive Forum

Both our Charter and our A&R Bylaws contain exclusive forum provisions that provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder to bring (1) any derivative action or proceeding brought on behalf of the Company, (2) any action asserting a claim of breach of fiduciary duty owed by any current or former director, officer, employee or agent of the Company to the Company or the Company's stockholders, (3) any action asserting a claim arising pursuant to the DGCL, our Charter or A&R Bylaws (as either may be amended or restated) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (4) any action asserting a claim governed by the internal affairs doctrine of the State of Delaware. These provisions expressly do not apply to claims arising under the Exchange Act, or for any other federal securities laws which provide for exclusive federal jurisdiction. However, these exclusive forum provisions provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Therefore, this provision could apply to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and that asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such an exclusive forum provision with respect to claims under the Securities Act. Stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock shall be deemed to have notice of and consented to the exclusive forum provisions in our Charter and A&R Bylaws. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, employees, or agents, which may discourage lawsuits against us and our directors, officers, employees, and agents.

Limitations on Liability and Indemnification of Officers and Directors

Our Charter contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our Charter and our A&R Bylaws require us to indemnify our directors and officers, and allow us to indemnify other employees and agents, to the fullest extent permitted by the DGCL. Subject to certain limitations and limited exceptions, our Charter and A&R Bylaws also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We believe that including the limitation of liability and indemnification provisions in our Charter, A&R Bylaws, and indemnification agreements is necessary to attract and retain qualified persons such as directors, officers, and key employees. Those provisions may discourage stockholders from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Transfer Agent

The transfer agent and registrar for our Common Stock and Warrant Agent for our Tradeable Warrants is VStock Transfer, LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598.

Exhibit 19.1

BIOAFFINITY TECHNOLOGIES, INC.
AMENDED AND RESTATED INSIDER TRADING POLICY
and Guidelines with Respect to Certain Transactions in Company Securities
As Adopted by the Board of Directors on March 27, 2025

I. PURPOSE

It is illegal for any employee, officer or director of bioAffinity Technologies, Inc. or any subsidiary thereof (the "Company") to trade in the securities of the Company while in the possession of material nonpublic information about the Company. It is also illegal for any employee, officer or director of the Company to give material nonpublic information to others who may trade on the basis of that information.

In order to comply with U.S. securities laws governing (i) trading in Company securities while in the possession of material nonpublic information concerning the Company and (ii) tipping or disclosing material nonpublic information to outsiders, and in order to prevent the appearance of improper trading or tipping, the Company has adopted this policy for all of its employees, officers and directors.

II. SCOPE

A. This policy covers all employees, officers and directors of the Company. If this policy applies to you, it also applies to family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings, in-laws and adoptive relationships) or are financially dependent on you, and also includes other family members whose transaction in securities are directed by you or are subject to your influence or control (collectively referred to as "Family Members"). This policy also applies to any other person who lives in your household and to any legal entities (such as a corporation, partnership or trust) that are influenced or controlled by you (collectively referred to as "Controlled Entities").

   Transactions by your Family Members, household members and Controlled Entities should be treated for the purposes of this Policy as if they were for your own account. Accordingly, all references to you with regard to all trading restrictions and pre-clearance procedures in this Policy also apply to your Family Members, household members and Controlled Entities. You are personally responsible for the actions of your Family Members, household members and Controlled Entities.

B. This policy applies to any and all transactions in the Company's securities, including its shares of common stock and options to purchase shares of common stock (as described in more detail in Section V.F below), and any other type of securities that the Company may issue, such as preferred shares, convertible debentures, warrants and exchange-traded options or other derivative securities.

C. This policy will be delivered to all employees, officers or directors upon its adoption by the Company, and to all new employees, officers or directors at the start of their employment or relationship with the Company. Upon first receiving a copy of this policy or any revised versions, each employee, officer or director must sign a certification attached hereto as Appendix A that he or she has received a copy and agrees to comply with the terms of this policy. This certification and agreement will constitute consent for the Company to impose sanctions for violation of this policy and to issue any necessary stop-transfer orders to the Company's transfer agent to enforce compliance with this policy. As discussed in Section VI.B, sanctions for individuals may include demotion or other disciplinary actions, up to and including termination of employment, if the Company has a reasonable basis to conclude that its policy has been violated.

D. This policy allows for trades by employees, officers and directors made in compliance with Rule 10b5-1 ("Rule 10b5-1") promulgated by the U.S. Securities and Exchange Commission under the Securities Exchange Act of 1934 (the "Exchange Act").Entry into a Rule 10b5-1 trading program (a "Rule 10b5-1 Plan") must comply with the requirements set forth in Section V. D below.

E. The Company may change these procedures or adopt such other procedures in the future as the Company considers appropriate in order to carry out the purposes of its policy.

III. INSIDER TRADING COMPLIANCE OFFICER

The Company has designated Timothy Zannes, the Company's Executive Vice President, Secretary and General Counsel (or his successor in that position), as its Insider Trading Compliance Officer (the "Compliance Officer") and in the event of the General Counsel's unavailability, Maria Zannes, the Company's President and Chief Executive Officer (or her successor in that position), shall be authorized to serve as Compliance Officer in the interim. The duties of the Compliance Officer will include the following:

A. Administering and interpreting this policy and monitoring and enforcing compliance with all policy provisions and procedures.

B. Responding to all inquiries relating to this policy and its procedures, including the preclearance of transactions in Company securities.

C. Designating and announcing special trading blackout periods during which no designated employees, officers or directors may trade in Company securities.

D. Providing copies of this policy and other appropriate materials to all current and new employees, officers and employees, and such other persons who the Compliance Officer determines may have access to material nonpublic information concerning the Company.

E. Administering, monitoring and enforcing compliance with all US insider trading laws and regulations, including without limitation the Exchange Act and the rules and regulations promulgated thereunder, the Securities Act of 1933, as amended (the "Securities Act"); and assisting in the preparation and filing of all required SEC reports relating to insider trading in Company securities.

F. Revising the policy as necessary to reflect changes in insider trading laws and regulations.

G. Maintaining as Company records originals or copies of all documents required by the provisions of this policy or the procedures set forth herein, and copies of all required SEC reports relating to insider trading.

The Compliance Officer may designate one or more individuals who may perform the Compliance Officer's duties in the event that the Compliance Officer is unable or unavailable to perform such duties.

IV. DEFINITION OF "MATERIAL NONPUBLIC INFORMATION"

A. "MATERIAL" INFORMATION

Information about the Company is "material" if it would be expected to affect the investment or voting decisions of a reasonable shareholder or investor, or if the disclosure of the information would be expected to alter significantly the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. A determination as to whether information is material depends on all of the related facts and circumstances. Material information is not limited to historical facts but may also include projections and forecasts. Materiality is based on an assessment of all the facts and circumstances and is often evaluated by courts and enforcement authorities with the benefit of hindsight. While it is not possible to identify all information that would be deemed "material," the following types of information ordinarily would be considered material:

i. Financial performance, especially quarterly and year-end earnings, and significant changes in financial performance or liquidity.

ii. Potential material mergers and acquisitions or material sales of Company assets or subsidiaries.

iii. Stock splits, public or private securities/debt offerings, or changes in Company dividend policies or amounts.

iv. Significant changes in senior management.

v. New major contracts or customers, or the loss of a major customer.

vi. Pending or threatened significant litigation, or the resolution of such litigation..

B. "NONPUBLIC" INFORMATION

Information that has not been disclosed to the public is generally considered to be non-public information. Information is considered to be public when it has been released in a manner that is reasonably designed to provide broad, non-exclusionary distribution (e.g., by means of a press release or an SEC filing) and after enough time has elapsed to permit the investment market to absorb and evaluate the information. . For the purposes of this policy, information will be considered public, i.e., no longer "nonpublic," at the opening of trading on the third full trading day following the Company's widespread public release of the information. Note that the information disseminated must be some form of "official" announcement. In other words, the fact that rumors, speculation, or statements attributed to unidentified sources are public is insufficient to be considered broadly distributed even when the information is accurate.

C. CONSULT THE COMPLIANCE OFFICER FOR GUIDANCE

Employees, officers or directors who are unsure whether the information that they possess is material or nonpublic should consult the Compliance Officer for guidance before trading in any Company securities.

V. STATEMENT OF COMPANY POLICY AND PROCEDURES

A. PROHIBITED ACTIVITIES

i. No employee, officer or director may trade in Company securities while possessing material nonpublic information concerning the Company (except as permitted by Section V.C). It does not matter that there is an independent, justifiable reason for a purchase or sale, if the employee, officer or director has material nonpublic information, the prohibition still applies.

ii. No employee, officer or director may trade in Company securities outside of the applicable "trading windows" described in Section V.B below (except as permitted by Section V.C). and no employee, officer or director may trade in the Company securities during any special trading blackout periods designated by the Compliance Officer that are applicable to such employee, officer or director (except as permitted by Section V.C).

iii. No employee, officer or director may disclose material nonpublic information concerning the Company to any outside person (including family members, analysts, individual investors and members of the investment community and news media), unless required as part of the regular duties of such employee, director or officer for the Company or authorized by the Compliance Officer. In any instance in which such information is disclosed to outsiders, the Company will take such steps as are necessary to preserve the confidentiality of the information, including requiring the outsider to agree in writing to comply with the terms of this policy and/or to sign a confidentiality agreement. All inquiries from outsiders regarding material nonpublic information about the Company must be forwarded to the Compliance Officer.

iv. No employee, officer or director may give trading advice of any kind about the Company to anyone while possessing material nonpublic information about the Company, except that employees, officers or directors should advise others not to trade if doing so might violate the law or this policy. The Company strongly discourages all employees, officers or directors from giving trading advice concerning the Company to third parties even when the directors, officers and employees do not possess material nonpublic information about the Company.

v. No employee, officer or director may trade in any interest or position relating to the future price of Company securities, such as a put, call or short sale (including a short sale "against the box").

vi. Except as permitted by Section V.C, no employee, officer or director may give or make any other transfer of securities without consideration during a period when that employee, officer or director is not permitted to trade.

vii. No director, officer or employee may participate, in any manner other than passive observation, in any of the investment or stock-related Internet "chat" rooms or message boards relating to the Company.

viii. No employee, officer or director may (a) trade in the securities of any other public company while possessing material nonpublic information concerning that company obtained in the course of service as an employee, officer or director, (b) "tip" or disclose such material nonpublic information concerning any other public company to anyone, or (c) give trading advice of any kind to anyone concerning any other public company while possessing such material nonpublic information about that company.

B. TRADING WINDOWS AND BLACKOUT PERIODS

i. *Trading Windows*. Employees, officers and directors may trade in Company securities only during the period beginning at the opening of trading on the third full trading day following the Company's widespread public release of quarterly or year-end operating results, and ending at the close of trading two weeks before the end of the then-current quarter, as long as they are not in possession of material nonpublic information or subject to any special trade blackout.

ii. *No Trading Even During Trading Windows While in the Possession of Material Nonpublic Information*. No employee, officer or director possessing material nonpublic information concerning the Company may trade in Company securities even during applicable trading windows.

iii. *No Trading During Blackout Periods*. No director, officer or employee may trade in Company securities outside of the applicable trading windows or during any special blackout periods that the Compliance Officer may designate. No director, officer or employee may disclose to any outside third party that a special blackout period has been designated.

C. EXCEPTION FOR TRANSFERS PURSUANT TO RULE 10b5-1

The trading restrictions in this policy shall not prohibit transfers of Company securities made pursuant to a Rule 10b5-1 Plan. Implementation of a Rule 10b5-1 Plan under the Exchange Act provides an affirmative defense (which must be proven) from insider trading liability under Rule 10b-5. A Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material non-public information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party. Entry into a Rule 10b5-1Plan must comply with the requirements set forth in "Rule 10b5-1 Plans" below.

D. PROCEDURES FOR APPROVING TRADES UNDER RULE 10B5-1 PLANS.

Entry into a Rule 10b5-1 Plan requires the prior written approval of the Compliance Officer (which approval may include an email confirmation). Any Rule 10b5-1 Plan must be submitted for approval five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required. You may not adopt a Rule 10b5-1 Plan outside of a trading window or during any special blackout periods that the Compliance Officer may designate, or at a time when you are aware of material non-public information. For purposes of this section V. D., the term "Officer" shall mean the individuals classified by the Company as officers for purposes of SEC rules under Section 16 of the Exchange Act.The following requirements apply to all Rule 10b5-1 Plans:

i. directors and Officers may not commence sales under a Rule 10b5-1 plan until the later of (i) 90 days following the date of adoption or modification of such plan; or (ii) two business days following the disclosure of the Company's financial results in a Form 10-K or Form 10-Q relating to the fiscal quarter in which the Rule 10b5-1 plan was adopted or modified (but not to exceed 120 days following plan adoption or modification);

ii. all persons other than directors and Officers, may not commence sales under a Rule 10b5-1 plan until 30 days following the date of adoption or modification of such plan;

iii. directors and Officers must provide a representation in the Rule 10b5-1 plan certifying that, on the date of adoption or modification of the plan, they (i) are not aware of material nonpublic information about the Company or its securities; and (ii) are adopting or modifying the plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5;

iv. subject to the limited exceptions set forth in Rule 10b5-1, you may not maintain multiple, overlapping plans;

v. subject to the limited exceptions set forth in Rule 10b5-1, you can utilize only one single-trade plan (i.e. a plan designed to effect only a single transaction) during any 12 month period; and

vi. you must act in good faith with respect to the Rule 10b5-1 plan, not just in connection with entering into the plan.

The Company may impose additional restrictions on Rule 10b5-1 Plans, including without limitation:

- requiring that all plans be managed by an administrator selected by the Company;
- restrictions on termination or modification of plans;
- prohibition on entry into new plans for extended periods following termination of an existing plan; and
- prescribed periods during which persons may enter into plans.

Modification or termination of Rule 10b5-1 Plans are generally discouraged absent compelling circumstances. Any modification to any Rule 10b5-1 Plan is treated as the entry into a new plan and must comply with all of the above requirements.

E. PRE-CLEARANCE PROCEDURES

The Company requires that all directors, officers and employees, as well as their respective Family Members, household members and Controlled Entities, obtain prior written approval from the Compliance Officer (which approval may include an email confirmation) before engaging in any transaction in Company securities. A request for pre-clearance should be submitted to the Compliance Officer at least two business days in advance of the proposed transaction. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance, and may determine not to permit the transaction. If a person seeks pre-clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company securities, and should not inform any other person of the restriction. If approved, the transaction must be completed within five business days, but in no event outside of a trading window or during any special blackout periods that the Compliance Officer may designate, or at a time when you are aware of material non-public information. If the transaction does not occur during the five business day period, pre-clearance of the transaction must be re-requested. A form of "Request for Approval" is attached as Appendix B hereto and should be used to request approval hereunder, unless otherwise notified by the Compliance Officer.

The Compliance Officer's approval of a transaction submitted for pre-clearance does not constitute legal advice, does not constitute confirmation that you do not possess material non-public information and does not relieve you of any of your legal obligations.

The Compliance Officer may not trade in our securities unless the Chief Executive Officer has approved the Compliance Officer's trade(s) in accordance with this policy's procedures.

F. STOCK OPTION PLANS

The trading prohibitions and restrictions of this policy apply to all sales of securities acquired through the exercise of stock options granted by the Company, but not to the acquisition of securities through such exercises.

G. PRIORITY OF STATUTORY OR REGULATORY TRADING RESTRICTIONS

The trading prohibitions and restrictions set forth in this policy will be superseded by any greater prohibitions or restrictions prescribed by securities laws and regulations.

VI. POTENTIAL CIVIL, CRIMINAL AND DISCIPLINARY SANCTIONS

A. CIVIL AND CRIMINAL PENALTIES

The consequences of prohibited insider trading or tipping can be severe. Persons violating insider trading or tipping rules may be required to pay over to the Company the profit made or the loss avoided by trading, pay the loss suffered by the persons who purchased securities from or sold securities to the insider tippee, pay civil penalties up to three times the profit made or loss avoided, pay a criminal penalty of up to $1 million and serve a jail term of up to 10 years. The Company and/or the supervisors of the person violating the rules may also be required to pay major civil or criminal penalties and could under certain circumstances be subject to private lawsuits by contemporaneous traders for damages suffered as a result of illegal insider trading or tipping by persons under the Company's control.

B. COMPANY DISCIPLINE

Violation of this policy or federal or state insider trading or tipping laws by any employee, officer or director may subject a director to dismissal proceedings and an officer or employee to disciplinary action by the Company up to and including termination for cause. A violation of the Company's policy is not necessarily the same as a violation of law. In fact, for the reasons indicated above, the Company's policy is intended to be broader than the law. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether its policy has been violated. The Company may determine that specific conduct violates its policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

C. REPORTING OF VIOLATIONS

Any employee, officer or director who violates this policy or any federal or state laws governing insider trading or tipping, or knows of any such violation by any other employee, officer or director, must report the violation immediately to the Compliance Officer. Upon learning of any such violation, the Compliance Officer, in consultation with the Company's legal counsel, will determine whether the Company should release any material nonpublic information, or whether the Company should report the violation to the SEC or other appropriate governmental authority.

VII. COMPANY TRANSACTIONS

From time to time, the Company may engage in transactions in its own securities. It is the Company's policy to comply with all insider trading laws, rules and regulations, and any applicable listing standards when engaging in transactions in its own securities.

VIII. INQUIRIES

Please direct all inquiries regarding any of the provisions or procedures of this policy to the Compliance Officer.

Appendix A

bioAffinity Technologies, Inc.
Amended and Restated Insider Trading Policy

Acknowledgement

I have read the procedures outlined in this policy. I understand that while this is not an employment contract I am bound to abide by the policies set herein. I further understand that bioAffinity Technologies may modify, revise and update policy at any time. I am also aware that this updating may include additions or deletions. I also certify that I have had ample time to discuss this policy and its contents with a bioAffinity Technologies representative, and I fully understand the contents.

Employee signature _____

Employee name _____

Date _____

bioAffinity Technologies reserves the right to make changes to this policy for the purpose of modifying, revising and updating Company policy. Notice of changes will be provided to the employee electronically and become a part of this policy. Violation of any Company policy may result in immediate termination.

APPENDIX B

REQUEST FOR APPROVAL TO TRADE COMPANY SECURITIES

Number of Securities (e. g., shares): _____

Type of Security [check all applicable boxes]

- ☐ Common stock
- ☐ Restricted stock
- ☐ Stock Option
- ☐ Debt Securities
- ☐ Other _____

Type of Transaction [check all applicable boxes]

- ☐ Stock option exercise (must complete applicable exercise form)
- ☐ Purchase
- ☐ Sale
- ☐ Gift (Name of Donnee)
- ☐ Rule lOb5-1 Plan (attach a copy of the 10b5-1 Plan to this request form)
- ☐ Sale under benefit plans
- ☐ Other _____

Broker Contact Information

Company Name_____
Contact Name_____
Telephone_____
Fax_____
Account Number_____
Social Security or other Tax Identification Number_____

Status (check all applicable boxes and complete blanks)

- ☐ Employee – Citizenship_____, Country in which you are based _____
- ☐ Board Member

I am not currently in possession of any material non-public information relating to bioAffinity Technologies, Inc. (the "Company"). I hereby certify that the statements made on this form are true and correct. I have also discussed any questions I had with respect to the Company's insider trading policy and its applicability to the transactions contemplated hereby with the Compliance Officer.

Signature _____ Print
Name _____
Date: _____ Telephone Number

(office use only)
Request Approved (transaction must be completed within 5 business days after approval)
Request Denied
Request Approved with the following modification:

Signature & Date_____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-275608) and Form S-8 (Nos. 333-279963, POS-333-275073, and 333-271332) of bioAffinity Technologies, Inc. of our report dated March 31, 2025, which includes an explanatory paragraph regarding the substantial doubt about the Company's ability to continue as a going concern, relating to the consolidated financial statements of bioAffinity Technologies, Inc. as of and for the years ended December 31, 2024 and 2023, which appear in this Form 10-K.

/s/ WithumSmith+Brown, PC
New York, New York
March 31, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14 AND 15d-14 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Maria Zannes, certify that:

1. I have reviewed this annual report on Form 10-K 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14 AND 15d-14 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Michael Edwards, certify that:

1. I have reviewed this annual report on Form 10-K 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

/s/ J. Michael Edwards
J. 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 Annual Report on Form 10-K for the year ended December 31, 2024 of bioAffinity Technologies, Inc. (the "Registrant"), pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Maria Zannes, the Chief Executive Officer of the Registrant hereby certifies, to my knowledge, that:

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 Registrant as of and for the year ended December 31, 2024 (the last date of the period covered by the Report).

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer
Date: March 31, 2025

Exhibit 32.2

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 Annual Report on Form 10-K for the year ended December 31, 2024 of bioAffinity Technologies, Inc. (the "Registrant"), pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, J. Michael Edwards, the Chief Financial Officer of the Registrant hereby certifies, to my knowledge, that:

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 Registrant as of and for the year ended December 31, 2024 (the last date of the period covered by the Report).

/s/ J. Michael Edwards
J. Michael Edwards
Chief Financial Officer
Date: March 31, 2025