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, 2025.

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, 2025, 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 4,498,675 as of March 13, 2026.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to the 2026 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, 2025 (the "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 ("IP") protection for our diagnostic and therapeutic inventions or future diagnostic and therapeutic inventions to expand our product offerings;
- our ability to protect our IP rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our IP rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their IP rights and that we may incur substantial costs and be required to devote substantial time defending against such claims;
- our reliance on third parties;
- the success of competing 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, conflict 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.
- We are unable to precisely estimate when we will begin to generate significant profit from Precision Pathology Laboratory Services ("PPLS").

Risks Related to Development and Commercialization of Our Diagnostic Tests

- Delays or difficulties in the enrollment of patients in our clinical trials could delay greater adoption by physicians of our commercial test.
- Clinical trials are expensive, time-consuming, and may not be successful.
- 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 our subsidiary, 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.
- 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.
- Global climate change and related regulations could negatively affect our business.

Risks Related to the Operation of Our Commercial Laboratory Accredited by the College of American Pathologists ("CAP") and the U.S. Centers for Medicare and Medicaid ("CMS") in Accordance with the Clinical Laboratory Improvements Amendments of 1988 ("CLIA").

- 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 commercialization of tests in the research and development stage 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 delays associated with 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 IP 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 IP.
- Diagnostic tests and therapeutic products we develop could be subject to infringement claims.
- We may become involved in lawsuits to protect or enforce our IP.

- 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

- Failure to comply with applicable laws pertaining to our commercial test 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.
- We may never obtain approval of 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 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.
- 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.

PART I

Item 1. Business

Business Overview

We develop noninvasive diagnostic laboratory tests to detect early-stage lung cancer and other diseases of the lung using flow cytometry and automated analysis informed by machine learning, a form of artificial intelligence (AI). Our first commercial diagnostic test, CyPath® Lung, identifies and analyzes cell populations using flow cytometry, including cancer and cancer-related cells, that indicate a malignancy in the lung.

CyPath® Lung addresses the need for noninvasive detection of early-stage lung cancer with the proven ability to detect the leading cancer killer at its curative Stage 1A. 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 or those patients who are likely without lung cancer and should continue screening in accordance with guidelines. For patients with small pulmonary nodules less than 20 millimeters (mm), CyPath® Lung has shown 92% sensitivity and 87% specificity with 88% accuracy in a clinical trial, offering the potential to increase the overall diagnostic accuracy of lung cancer testing, which could lead to increased survival, fewer unnecessary invasive procedures, reduced patient anxiety, and lower medical costs.

CyPath® Lung is performed and offered by our wholly owned subsidiary PPLS, a clinical anatomic and pathology laboratory which we acquired by purchasing the assets of Village Oaks Pathology Services, P.A., a Texas professional association. PPLS is a CAP-accredited and CLIA-certified commercial laboratory that has been in operation for more than 18 years.

In addition to CyPath® Lung, we are advancing development of our flow cytometry+AI platform for companion diagnostic tests targeted at asthma and chronic obstructive pulmonary disease ("COPD"). Diagnostics under development are designed to quantify the extent and type of inflammation in the lung associated with disease and further detect specific receptors in sputum that may determine the effectiveness of new and emerging therapies for asthma and COPD that have proved to effectively treat specific types of inflammation. Therapeutics for these lung diseases that are on the market or in development can help some but not all patients, and often it is unknown before use whether a drug will be effective. Our tests in development are designed to help determine the most effective use of new and emerging therapies for asthma and COPD and lessen the need for a trial-and-error approach to proscribing treatment.

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, we have conducted research that has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells. We continue to advance research and development for use of this technology for topical treatment of squamous cell skin cancer. We expect to present our findings at conferences and publish our research in peer-reviewed journals in the near future. We intend to seek strategic partners to develop our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future.

Research and optimization of our platform technologies are conducted in laboratories at our wholly owned subsidiary PPLS and leased laboratory space at The University of Texas at San Antonio (UTSA). UTSA provided notice in January 2026 that our lease would not be renewed, and as a result we will relocate our research operations from UTSA to privately owned laboratory space.

Current Year Financial Highlights

Key financial results for the year ended December 31, 2025, include:

- Primarily as a result of the Company's targeted strategic actions to discontinue unprofitable pathology services, reduce costs through operational efficiency, and drive sales growth for CyPath® Lung, consolidated revenue decreased approximately 34% to $6.2 million as compared to $9.4 million for the year ended December 31, 2024. While these actions contributed to lower consolidated revenue in the short term, they improved operating focus and cost structure and are intended to position our noninvasive lung cancer diagnostic for scalable growth and improved long-term margin potential.
- CyPath® Lung testing revenue increased approximately 87% to $963,000 as compared to $516,000 for the year ended December 31, 2024, due to a 99% increase for a total of more than 1,200 test results delivered for the current year.
- Raised approximately $16.9 million in gross proceeds from equity transactions to fund operating activities.

Recent Developments

The Start of Our Longitudinal Clinical Study

In March 2026, we enrolled our first patient in our clinical trial entitled "Detection of Early-Stage Lung Cancer in Sputum using Flow Cytometry and an Automated Analysis Pipeline" (NCT07168993). The John P. Murtha Cancer Center Research Program (MCCRP), a research program within the Department of Surgery at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, is providing support and funding associated with the trial at three collection sites – Brooke Army Medical Center in San Antonio, Texas, Walter Reed Medical Center in Bethesda, Maryland, and the South Texas Audie L. Murphy Memorial Veterans Medical Center.

The approved trial protocol calls for enrollment of up to 2,063 patients at 17 VA, military, academic and private medical centers who are at high risk for lung cancer with one or more indeterminate pulmonary nodules between 6 mm to less than 30 mm. Patients enrolled in the trial will be followed until the patient receives either a diagnosis of cancer or noncancer, with patients followed up to two years. The clinical trial will evaluate the clinical performance of the test as a sensitive and specific noninvasive diagnostic to identify the presence of lung cancer in high-risk individuals who have indeterminate pulmonary nodules as determined by CT imaging. To differentiate the investigational use of our CyPath® Lung test that is offered for commercial sale and use, we use the name "FlowPath™ Lung" in protocol documents and on collection kits provided to sites.

Continuation of Research Studies with the Military

Following the sale of tests to Brooke Army Medical Center ("BAMC") beginning in the fourth quarter of 2023 and through 2024 as part of an observational study, we began a collaboration with BAMC in the fourth quarter 2025 to collect and validate the clinical utility of using CyPath® Lung to analyze sputum samples obtained by tracheal and bronchial suctioning for early detection of lung cancer. Bronchoscopy is used commonly in the United States, with approximately 500,000 procedures performed annually. The CyPath® Lung study with BAMC will explore an approach that could expand the utility of bronchoscopy-collected samples for earlier, noninvasive lung cancer detection.

In the first quarter of 2026, we began a research collaboration with BAMC to advance the development of companion diagnostic tests targeted at asthma and COPD. The initial research study is designed to quantify the extent and type of inflammation in the lung associated with disease and further determine the ability of our diagnostic platform to detect specific receptors in sputum that determine the effectiveness of new and emerging therapies for asthma and COPD that have been proved to effectively treat specific types of inflammation.

Positive Research Findings Advance Company's Pipeline Tests for Asthma

In March 2026, the Company presented positive research findings for its platform technology's ability to identify antibody drug receptors in sputum, including receptors for dupilumab, a leading therapy for asthma and chronic obstructive pulmonary disease ("COPD"), and benralizumab, another asthma therapy. The research, presented at the American Academy of Allergy, Asthma and Immunology's annual conference, advances the Company's pipeline tests aimed at guiding personalized treatment decisions and improving disease monitoring for asthma and COPD sufferers.

Appointment of Nationally Recognized Lung Cancer Authorities to its Medical and Scientific Advisory Board

In February 2026, we announced the appointment of David Ost, MD, MPH, Chief of Pulmonary, Critical Care and Sleep Medicine at the University of Texas MD Anderson Cancer Center, Daniel Sterman, MD, Chief of the Division of Pulmonary, Critical Care and Sleep Medicine at New York University Langone Medical Center, and J. Scott Ferguson, MD, Director of Interventional Pulmonology at the University of Wisconsin School of Medicine and Public Health, to our Medical and Science Advisory Board that includes recognized leaders in the field of lung cancer.

New Patient Case Studies Add to Real-World Evidence of CyPath® Lung Reducing Diagnostic Burden

In February 2026, we announced two additional patient case studies where a CyPath® Lung result of "Unlikely Malignancy" relieved patient anxiety and supported the physician's decision to continue repeat imaging rather than subjecting patients to invasive, risky and costly biopsies. The case studies add to a growing number of reported cases where CyPath® Lung has made a decisive positive impact on patient care.

PPLS Continues to Meet Highest Standards for Laboratory Operations

In January 2026, we announced that PPLS maintained its accreditation across all laboratory service lines from the College of American Pathologists (CAP), considered the gold standard for excellence. CAP accreditation signifies that a laboratory meets high standards of quality, accuracy and patient safety through comprehensive peer-based inspections conducted every two years.

Public and Private Offerings

In October 2025, we entered into definitive agreements for the purchase and sale of 720,000 shares of common stock, par value $0.007 per share, at a purchase price of $2.50 per share in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds from the offering were approximately $1.8 million before deducting placement agent fees and other offering expenses payable by us.

On September 29, 2025, we consummated a best efforts public offering of an aggregate of (i) 1,047,694 shares of Common Stock and (ii) pre-funded warrants to purchase up to 874,067 shares of Common Stock in lieu of shares of Common Stock. Each share was sold at a public offering price of $2.50. Each pre-funded warrant was sold at a public offering price of $2.493. The total gross proceeds for the transaction were approximately $4.8 million.

On August 13, 2025, we entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell in a private placement (i) 990 shares of our newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share, for gross proceeds to us of $990,000, which were initially convertible into 143,476 shares of our Common Stock at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of our Common Stock at an exercise price of $10.56 per share of Common Stock.

On May 7, 2025, we completed a public offering of securities for gross proceeds of $3.25 million, before deducting agent fees and other estimated expenses payable by us. The offering consisted of 338,541 shares of our Common Stock, of which 79,044 were pre-funded warrants, together with warrants to purchase up to 507,812 shares of Common Stock, at a combined offering price for each share of Common Stock (or pre-funded warrant) and accompanying warrant of $9.60 per share. The warrants have an exercise price of $10.56 per share and have certain provisions that allow for additional shares to be issued in the event of a reverse split of Common Stock. Additionally, the warrants include an anti-dilution adjustment which is subject to stockholder approval.

On February 26, 2025, pursuant to the terms of a warrant inducement agreement (the "February Inducement Agreement"), we entered into with certain holders of existing warrants dated February 25, 2025, such holders exercised for cash (i) warrants to purchase an aggregate of up to 43,402 shares of Common Stock issued on August 5, 2024 (the "August Warrants"), at the reduced exercise price of $17.40 per share, and (ii) warrants to purchase an aggregate of up to 37,878 shares of Common Stock issued on October 21, 2024 (the "October Warrants"), at the reduced exercise price of $17.40 per share. We 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, we issued unregistered common warrants to purchase an aggregate of up to 97,538 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.

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*. Lung cancer is the leading cause of cancer deaths in the European Union with an estimated 17 to 34 million people at high risk, according to Cancer Epidemiology. China reported 1,060,600 cases of lung cancer in 2022. The American Lung Association ("ALA") estimated that 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 10-year survival rate of 92%, as compared to the current overall five-year survival rate in the U.S. of 29.7% as reported by the ALA in its 2025 "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. If half of the individuals at high risk 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 proven to detect curative Stage 1A 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. Physicians receive a CyPath® Lung test result within three days of the sample arriving at the laboratory that identifies patients who should undergo more aggressive follow-up procedures to confirm a suspected lung cancer or guide and support a physician's decision to monitor the patient using LDCT or CT imaging.

The results of a clinical trial using CyPath® Lung, "Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning," published in *Respiratory Research* on January 21, 2023, reported 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 millimeters or smaller or no nodules detected by imaging, this trial resulted in 92% sensitivity, 87% specificity, 99% negative predictive value, and 88% accuracy. This 150-patient test validation trial analyzed sputum from people at high risk for lung cancer including patients with the disease (N=28) and those who were cancer-free (N=122). In the 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.

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 privately insured patients with a positive lung cancer screening for total cost 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., 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. Economists John E. Schneider, Ph.D., and Maggie L. Do Valle, Master of Public Health, of Avalon Health Economics also were authors on 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. A patented algorithm developed using machine learning, a form of AI, automatically analyzes a patient's flow cytometry data to generate a physician's report within minutes after data acquisition that stratifies patients into one of two risk groups. A "Likely"

result means cancer has been detected. An "Unlikely" result means cancer has not been detected. The physician's report also provides a numerical probability score between 0.1 to 1.0, with 0.1 to less than 0.5 being a negative result and more than 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.

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."

CyPath® Lung evaluates sputum for the presence of cancer without the opportunity to introduced 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 Food and Drug Administration ("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 to produce a physician's report in less than 20 minutes using integrated software for high-throughput, user-friendly standardized analysis.

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 in 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. The Current Procedural Terminology ("CPT") Proprietary Laboratory Analysis ("PLA") code specifically for use with CyPath® Lung, is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [\4- carboxyphenyl porphyrin TCPP, CD206, onveniCD66b, CD3, CD19), algorithm reported as likelihood of lung cancer."

We have an agreement with Cardinal Health for logistical services assisting in the delivery of collection kits and return of patient samples to PPLS. 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 using 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.

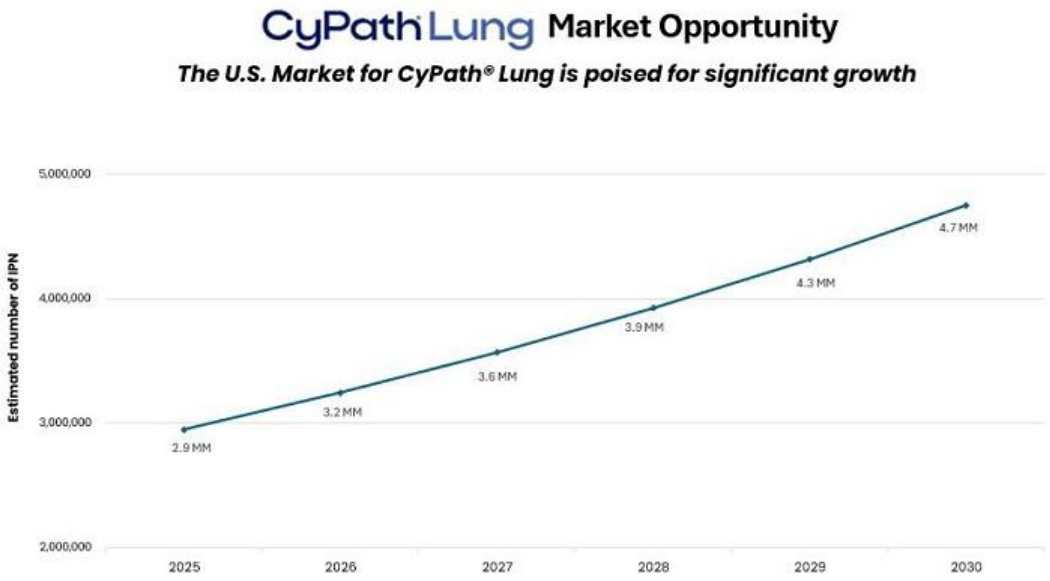
The Cancer Diagnostics Market and CyPath® Lung

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.

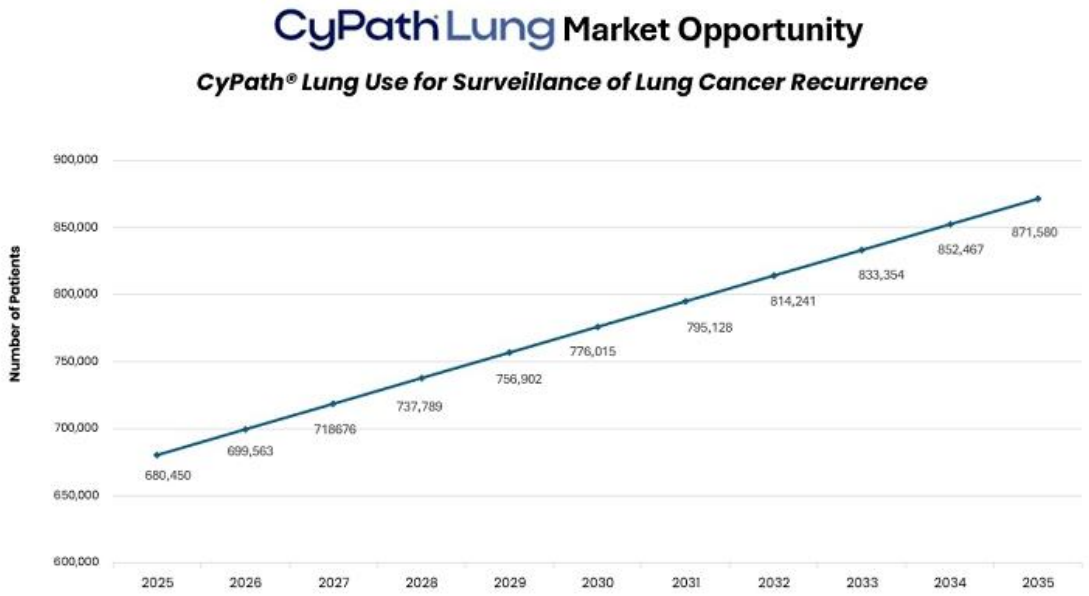
In particular, we believe the market for CyPath® Lung is poised for significant growth. The test is most often ordered by physicians who need better clarity when patients present with small pulmonary nodules that are considered indeterminate, leaving both physician and patient without a clear diagnostic path forward. In Gould et al. (2015), researchers reported that imaging increasingly finds indeterminate pulmonary nodules with difficult choices: "watchful waiting" with serial CT scans or invasive procedures. According to the National Lung Screening Trial Research Team (2011), lung cancer screening using low dose CT can detect lung cancer at an early stage, but it has low specificity. Only about four out of 100 patients with a suspicious finding will have lung cancer. In addition, Gould et al. observed that indeterminate pulmonary nodules are increasingly found incidentally when imaging for other reasons.

Projected Number of Indeterminate Pulmonary Nodules in the U.S.

As shown below, the total number of indeterminate pulmonary nodules detected by lung cancer screening and incidentally is projected to increase by 62% from 2.9 million in 2025 to 4.7 million in 2030, representing an estimated market of greater than $4.7 billion for CyPath® Lung. The forecast is based on a percentage of 2024 reported cases of suspicious pulmonary nodules and assumes a 10% compound annual growth for the 2024-2030 period based on 1) an increase in lung cancer screening from 18.1% in 2023 to close to 50% by 2030 due to growing adoption and awareness with improved access, and 2) improved ability to detect indeterminate nodules through greater adherence to guideline recommendations and use of AI.



In addition, CyPath® Lung's ability to be used for surveillance of cancer survivors after they have completed treatment represents an estimated market of $870 million over the next ten years. The total number of people living with lung cancer is projected to increase by 28% from 680,450 survivors in 2025 to 871,580 in 2035.



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

Diagnostic Test or Procedure	Intended Patient	Sensitivity	Specificity	Procedural Risk	Source
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 favorably compared to current Standards of Care, including more invasive and riskier diagnostic procedures. 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.

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 three phases of strategic expansion in the U.S. and the European Union ("EU") and Asia that are timed to maximize our resources and minimize market risk.

In January 2025, we reported successful results from 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. Our test marketing approach allowed us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market. In 2025, we more than doubled the number of tests sold and tripled our revenues. We expanded our sales team in the second half of 2025 to enter the Mid-Atlantic market.

In 2026, we will enter Phase 2 of our business plan with expansion into broader strategic markets aimed at providing national coverage, including increasing our sales force and strategic partners in the Mid-Atlantic and entering the South Atlantic, Southeast, Northeast, Midwest, West and federal markets. Phase 2 includes launching our longitudinal clinical trial that will provide additional validation and further evidence of CyPath® Lung's ability to detect early-stage lung cancer.

In Phase 3 of our business plan, we expect to have achieved a national sales footprint upon which we can build and secure strategic partners in the EU and Asia who can support entry into those markets. We also foresee establishing CyPath® Lung as a Standard of Care for the federal and VA healthcare systems which can propel CyPath® Lung for adoption as a Standard of Care for the entire U.S. healthcare system.

We will continue to execute on strategic marketing and promotional collaborations that can accelerate growth, including collaboration with strategic partners that provide greater market access, marketing resources, and opportunities to leverage existing relationships with physicians and their patients.

We have developed messaging and marketing programs that will continue to grow both in size and scope as we penetrate the U.S. market, including executing strategies that take advantage of practicing physicians who find significant benefits from using CyPath® Lung. To date, we have published more than a dozen patient case studies. Peer-to-peer communication has been a driver for sales which is supported by attending major conferences and presentations by key opinion leaders ("KOLs") of case studies, digital marketing, social media presence, and advertising to create an "inbound" lead generation mechanism that delivers our message to our target audience.

The Competition for CyPath® Lung

CyPath® Lung has not been tested directly against its competitors' products, but a comparison of the published performance numbers provides evidence that 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. Processing and analysis procedures are easy to perform. Our competitive analysis reviewed published research that was sufficient to provide a scientific basis for evaluation.

Low dose computer tomography (LDCT) is recommended as a screening test with eligibility driven by age and smoking history, but its low positive predictive value (PPV) can lead to unnecessary invasive procedures on benign nodules. CyPath® Lung is recommended for adults at high risk of lung cancer, particularly those with small or indeterminate pulmonary nodules discovered by LDCT, to assist doctors in deciding whether to recommend invasive procedures such as biopsy or continue monitoring by LDCT. CyPath® Lung and competing tests that assist in making such decisions may be categorized as (1) rule-out tests (2) rule-in tests, and (3) balanced tests. Rule-out tests are designed to have high sensitivity and negative predictive value (NPV) to determine that the patient is unlikely to have lung cancer and exclude the patient from unnecessary follow-up procedures. However, these tests also have lower specificity and produce a greater number of false positives results. Rule-in tests by contrast have high specificity but lower sensitivity, providing higher positive predictive value (PPV) so that a positive result predicts the patient does have lung cancer. The positive result may lead to more aggressive follow-up procedures but with higher false-negative rates that can result in more invasive procedures on benign nodules. Balanced tests are designed to achieve high sensitivity and specificity to both exclude patients without cancer from unnecessary follow-up diagnostic procedures and accurately detect patients with early-stage cancer who can proceed to more aggressive procedures to confirm diagnosis.

CyPath® Lung is a balanced test, having demonstrated a sensitivity of 92% and a specificity of 87% and a NPV of 99% for patients with nodules under 20 mm in a population with lung cancer prevalence of 18% (Lemieux 2023, Morris 2024). The high sensitivity and specificity of CyPath® Lung make it a balanced test. In our analysis we will classify competitors as balanced tests, rule-out tests and rule-in tests.

- A balanced test called LungLB (sold by LungLife AI in the US) is commercially available as a laboratory developed test and has an insurance reimbursement code. LungLB has reported sensitivity and specificity of 77% and 72%, respectively, in a population with 74.2% malignant lung lesions (Tahvilivan 2023). The sensitivity and specificity of LungLB are lower than for CyPath® Lung. Furthermore, the LungLB study was conducted on a population with a much higher prevalence of disease than the intended high-risk patient population with a reported prevalence of 1.1%. (NLCST) Moreover, LungLB is a fluorescence in *situ* hybridization (FISH)-based blood test that requires a significant amount of expertise to conduct.
- Biodesix offers two tests for patients with intermediate nodules. The tests are commercially available as laboratory developed tests and have insurance reimbursement codes. Nodify XL2 is a rule-out test with a sensitivity of 97%, specificity of 44% and a NPV of 99% in patients with solid pulmonary nodule 8–30 mm and a probability of lung cancer ≤50% by the Mayo Clinic solitary pulmonary nodule calculator (Kheir 2023). About 55% of patients with lung nodules that physicians considered indeterminate, namely lung nodules sized between 8-30 mm, were excluded from the study. Nodify CDT is a rule-in test with specificity of 98% and PPV of 78% validated for patients with an 8–30 mm nodule and pre-test risk ≤65% by the Mayo calculator (Chapman 2012, Massion 2017, Biodesix website). In contrast with Biodesix, CyPath® Lung can provide a balanced result with both high sensitivity and specificity with a single test. Furthermore, Nodify's tests cannot be used by patients who have received a cancer diagnosis in the past five years. CyPath® Lung does not have such a restriction and can be used as surveillance for lung cancer survivors.
- The Percepta nasal swab test offered by Veracyte is an RNA-based gene expression test. The test is commercially available as a laboratory developed test and has an insurance reimbursement code. Percepta Nasal Swab is recommended for current or former smokers who have a pulmonary nodule detected on CT equal to or less than 30 mm. Test performance is different for patients determined to be in one of two risk categories. In a 2023 test validation trial (Lamb 2023), the sensitivity and specificity for individuals who are considered at low risk for lung cancer was 97% and 40%, respectively. The sensitivity and specificity for the high-risk classification were 57% and 92%, respectively. Similar to LungLB, patients in the study had a high cancer prevalence of 54% as compared to the overall

high-risk population that has an estimated lung cancer prevalence of 1.1%. (NLCST) 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 (1) sputum is in close contact with the tumor and pre-cancerous areas that shed cancer and pre-cancerous cells directly into the sputum, (2) can be obtained noninvasively, and (3) can be transported easily. Moreover, sputum contains immune cell populations associated with the presence of a tumor. Second, our proprietary technology is straightforward. CyPath® Lung uses well-established flow cytometry techniques to investigate cells contained in the sputum for characteristics that indicate the likelihood of lung cancer, unlike molecular tests which can use labile genetic materials. Sample processing is well established, 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 demonstrated 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.

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. Tests that perform well are most useful to a physician and their 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 after a CyPath® Lung results in a "likely malignancy" or to follow a more conservative approach when the CyPath® Lung test result is "unlikely malignancy".

Building on our Flow Cytometry Platform to Develop Asthma and COPD Companion Diagnostics

We are conducting research studies that expand our platform technology to detect the type and severity of inflammation in the lung and design precision diagnostics that identify patients who will benefit from effective but often expensive commercial therapies treating asthma and chronic obstruction pulmonary disease ("COPD"). Major pharmaceutical companies offer very effective treatments for asthma and COPD that work well for some sufferers but not all. Many patients must try a series of different types of treatments before finding an effective therapy. Our tests under development leverage our expertise in using our proprietary flow cytometry platform equipped with automated AI analysis to develop tests that match asthma and COPD patients with the most appropriate biologic therapies and monitor their ongoing conditions.

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 begin patient studies 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 continue to advance research for use of this technology as a topical treatment of squamous cell skin cancer. We expect to present our findings at conferences and publish our research in peer-reviewed journals in the near future. We intend to seek strategic partners to develop our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future.

Our therapeutic discoveries 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. 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%.

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, 2025, we and our OncoSelect® subsidiary have a patent estate that includes 19 issued U.S. and non-U.S. counterpart patents including three U.S. patents and 16 counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, 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 non-U.S. patents directed at diagnostic

applications expire in 2030, three non-U.S. patents directed at a diagnostic application for lung cancer prediction expires in 2039, and one non-U.S. patent directed to an automated diagnostic lung cancer prediction assay expires in 2042. One U.S. patent directed to siRNA therapeutic compounds and method of use for treating cancer expires in 2042, one counterpart non-U.S. patent expires in 2039, and one U.S. patent and two counterpart non-U.S. patents directed to therapeutic porphyrin conjugate compounds and method of use for treating cancer expire in 2037.

With regard to our diagnostic patent portfolio, we have one issued U.S. patent and nine counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom. Diagnostic lung health patents have issued in Australia, China and Japan. Our diagnostic lung health 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 lung health family of pending patent applications includes three pending non-provisional U.S. patent applications and 21 counterpart patent applications in Australia, Canada, China, European Patent Office, Hong Kong, Japan, Mexico, and Singapore filed in 2019 and 2024, and one non-provisional U.S. patent application directed to compensation beads for flow cytometry.

With regard to our therapeutic product candidates, we have two issued U.S. patents, three issued patents in China, Hong Kong, and Mexico, one pending U.S. application, and 7 counterpart applications pending in Canada, China, European Patent Office, and Hong Kong. The therapeutic intellectual property patent portfolio is made up of two families, 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

Clinical Laboratories

In the U.S., clinical laboratories are subject to regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which is administered by the Center for Medicare and Medicaid Services (CMS) in partnership with the states. A clinical laboratory is defined as a facility that performs testing on materials derived from the human body for the purpose of diagnosing, preventing, or treating disease, or for assessing health. 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, which requires inspection by either CMS or a

deemed accreditation organization. The College of American Pathologists (CAP), a member-based physician organization comprising approximately 18,000 board-certified pathologists. has been granted deeming authority from the federal government, meaning that laboratories accredited by CAP's Laboratory Accreditation Program qualify for a CLIA Certificate of Accreditation and undergo periodic CAP inspection to maintain their accreditation.

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."

A state can be exempted from CLIA requirements if it has laws in effect that provide for requirements equal to or more stringent than CLIA requirements. New York State has been exempted from CLIA; to operate a laboratory in or testing specimens from New York State a laboratory must hold a permit issued by the New York State Clinical Laboratory Evaluation Program. Certain states that administer the CLIA program also require laboratories to hold a state license in order to operate in or test specimens from the state.

Laboratory Developed Tests

Laboratories can perform tests using in vitro diagnostic (IVD) products manufactured by third parties or using their own proprietary methods. Tests developed, manufactured, and used within a single CLIA-certified laboratory are known as laboratory developed tests or LDTs.

Third party manufactured IVDs are regulated as medical devices by FDA. FDA historically asserted that LDTs were also subject to regulation as IVD medical devices, but historically exercised enforcement discretion with respect to (i.e., did not regulate) most LDTs. On May 6, 2024, FDA published a final rule amending the definition of an in vitro diagnostic ("IVD") device to include tests manufactured by a clinical laboratory. The final rule also announced FDA's intention to apply its medical device requirements, including in some cases the requirement to obtain premarket authorization, to LDTs. On March 31, 2025, a federal district court vacated the FDA final rule, thereby cancelling the rulemaking's associated requirements. The court held that laboratory developed tests do not meet the definition of a medical device under the Federal Food, Drug, and Cosmetic ("FD&C") Act and the FDA therefore lacks jurisdiction to regulate them. The court directed FDA to rescind the final rule, which occurred on September 19, 2025.

Medical Devices

Medical devices are subject to regulation by the FDA, under the federal Food, Drug and Cosmetic Act ("FDCA") and its implementing 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.

FDA classifies medical devices into one of three categories—Class I, Class II, and Class III— based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I (low risk) devices are subject only to general regulatory controls. Class II (moderate risk) devices are subject to general controls and may also be subject to special controls. Class III (high risk) require premarket approval and are subject to postmarket conditions of approval in addition to general regulatory controls.

Most Class I devices can be marketed without prior FDA review and authorization. Some Class I and most Class II devices require FDA review and authorization before they can be marketed through 510(k) notification or de novo classification pathways. To obtain clearance of a 510(k) notification, a device must be shown to be substantially equivalent to a legally marketed predicate device. Novel low and moderate risk devices, for which substantial equivalence to a legally marketed predicate cannot be demonstrated, can be marketed pursuant to FDA grant of a request for de novo classification. Class III medical devices can be legally sold within the U.S. only if the FDA has approved an application for premarket approval (PMA). PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of user fees.

After a device is placed on the market, numerous general regulatory controls apply. Manufacturers must register their establishment with FDA and list the devices they manufacture. Other postmarket requirements may include those relating to labeling, corrections, removals, and recalls, medical device reporting, and establishing a quality system.

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.

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.

Software

Software that is intended for use in diagnosis, cure, treatment, mitigation or prevention of disease meets the definition of a medical device and is subject to FDA regulation. Software that is included in a hardware device (Software in a Medical Device or SiMD) is regulated as part of the hardware device. Freestanding software (Software as a Medical Device or SaMD) may be subject to regulation by FDA but may be exempt if it meets certain criteria. In 2016, the 21st Century Cures Act, (the "Cures Act"), among other things, amended the medical device definition in the FDC Act to exclude certain software from FDA regulation. Exempt categories include ertain types of clinical decision support (CDS) software. CDS software is exempt from the medical device definition if it: (a) displays, analyzes or prints medical information about a patient or other medical information; (b) is intended for the purpose of supporting or providing recommendations about a patient's care to a health care professional, ("HCP"), user; and (c) provides sufficient information about the basis for the recommendations to the HCP user, so that the HCP user does not rely primarily on any of the recommendations to make a clinical decision about an individual patient; unless (d) the software function acquires, processes, or analyzes a medical image, a signal from an in vitro diagnostic device, or a pattern or signal from a signal acquisition system. In January 2026 FDA issued an updated final guidance document interpreting the Cures Act as it pertains to CDS software and provides examples of CDS that that meet the exemption criteria and those that do not.

Clinical Trials

Clinical trials conducted with investigational devices or to support FDA marketing authorization or with a device that requires but does not have marketing authorization are subject to regulations to protect human subjects and ensure data integrity. 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 are exempt from IDE requirements altogether. Clinical studies with investigational drugs must be subject to an approved investigational new drug (IND) exemption.

Separate from FDA oversight, clinical trials that are conducted or supported by the Department of Health and Human Services and many other federal agencies are subject to the requirements of the Common Rule. Many institutions that conduct both

federally funded and privately funded research hold a federal-wide assurance from the government stating that all research conducted by the institution will comply with the Common Rule.

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.

Clinical trials that are not conducted in accordance with applicable federal requirements or present an unacceptable risk to participants may be subject to temporary or permanent discontinuation as well as other sanctions. 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. Investigational drugs must be manufactured in accordance with good manufacturing practice (GMP) requirements.

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.

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.

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, two 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 Medical Officer, Gordon Downie, MD, Ph.D, brings more than three decades of experience in pulmonary medicine, clinical research, medical innovation, and interventional pulmonology to the role. He has authored more than 30 peer-reviewed publications, many centered on innovation in bronchoscopy, early lung cancer diagnosis and medical device development, and worked extensively in both academic medicine and private practice, led FDA-approved research programs, and served in national leadership roles with the American College of Chest Physicians in the areas of interventional pulmonology, lung cancer, and medical ethics. 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. Clinical operations are 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. Dallas Coleman, Vice President of Sales, brings more than 15 years of experience in medical sales and marketing, including 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 (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 or (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 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, 2025, and December 31, 2024, we generated revenue of approximately $6.2 million and $9.4 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;
- 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 therapeutic product(s) to FDA standards, 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, 2025, we had an accumulated deficit of $68.6 million and $6.4 million cash on hand. For the year 2025, cash used in operations was $9.3 million and net loss was $14.9 million. 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 June 2026. 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, 2025, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2025, 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 anatomical laboratory services offered by PPLS and the marketing of CyPath® Lung in Texas and the recent expansion into the Mid-Atlantic region and Veterans Administration. 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, 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 substantive 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, $9.4 million in 2024, and $6.2 million in 2025 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 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 that we will be able to successfully address these risks.

Risks Related to our Diagnostic Product

Until we complete our prospective, longitudinal clinical trial, we may encounter physicians who will not order an LDT.

Physicians may require a prospective longitudinal clinical trial to confirm the performance of our CyPath® Lung test. We launched our longitudinal trial in March 2026; however, there can be no assurance that the trial will have favorable results. Without results of a larger clinical trial of CyPath® Lung, 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 some physicians or 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 military observational study titled "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay."

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 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 J. Michael Edwards, our Chief Financial Officer.

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 to support certain commercialization and clinical development activities, including marketing support for our diagnostic tests, the design of clinical trials, the arrangement and oversight of clinical trials, and the collection and analysis of 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 Technologies 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 CMS, the FDA or foreign health authorities; (2) provide true, complete, and accurate information to CMS, 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, and 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. The impact of these tariffs is uncertain given recent court decisions; however, uncertainty can lead to greater instability. 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 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 Russian invasion of Ukraine, conflict 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 our pathologists and vice versa. 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 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 and services. 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 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 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 USPTO 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 initiates 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

PPLS currently offers CyPath® Lung as an LDT by PPLS. While a federal district court decision concluded FDA does not have jurisdiction to regulate LDTs, FDA could in the future determine that CyPath® Lung is not an LDT, or Congress could enact legislation granting FDA authority to regulate LDTs, which could adversely affect our commercialization strategy and negatively affect our results of operations and financial condition.

The FDA historically asserted its authority to regulate LDTs as medical devices under the FDCA, but for many years generally exercised enforcement discretion with regard to most LDTs. FDA's approach changed on May 6, 2024, when FDA promulgated a final rule phasing out its enforcement discretion over LDTs, and stating that compliance with premarket review and quality system requirements would be expected for many LDTs marketed after that date.

On March 31, 2025, a federal district court vacated the FDA final rule, thereby cancelling the rulemaking's associated requirements. The court held that laboratory developed tests do not meet the definition of a medical device under the Federal Food, Drug, and Cosmetic ("FD&C") Act and the FDA therefore lacks jurisdiction to regulate them. The court directed FDA to rescind the final rule, which occurred on September 19, 2025. FDA has not indicated how it will interpret the court ruling or whether it will seek a different regulatory approach with respect to LDTs or components thereof.

We believe that CyPath® Lung is an LDT within the scope of the district court decision and that it is not subject to regulation by FDA. Should FDA take the position that CyPath® Lung, or a component thereof, is not an LDT, or should the Company change the way CyPath® Lung is offered in the future such that it is no longer an LDT, or should Congress in the future enact legislation granting FDA authority to regulate LDTs, CyPath® Lung could become subject to regulation by FDA and face new regulatory burdens including but not limited to premarket authorization 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 medical device requirements, including in some cases 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. Authorization 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 approval of any of our therapeutic product candidates and obtain CMS validation for our diagnostic tests, 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 are 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

We are currently listed on The Nasdaq Capital Market ("Nasdaq"). If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our Common Stock is currently listed on Nasdaq and we are in compliance with the exchange's minimum listing requirement, we may not be able to continue to meet Nasdaq's minimum listing requirements or those of any other national exchange. The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our Common Stock;
- the market price of our Common Stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our Common Stock;
- the number of market makers in our Common Stock;
- the availability of information concerning the trading prices and volume of our Common Stock; and
- the number of broker-dealers willing to execute trades in shares 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.

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.

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.

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
- 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.

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 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 our 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, we maintain 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 our IT assets, data, and services from threats and vulnerabilities. We partner 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 our 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.

Our 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 our 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 our 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.

We face risks from cybersecurity threats that could have a material adverse effect on its business, financial condition, results of operations, cash flows, or reputation. We acknowledge 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 our business. However, prior cybersecurity incidents have not had a material adverse effect on our business, financial condition, results of operations, or cash flows. We proactively seek 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 us to additional liability and reputational harm. In response to such risks, we have 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. UTSA provided notice in January 2026 that our lease would not be renewed, and as a result we will relocate our research operations from UTSA to privately owned laboratory space.

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 1, 2026, there were approximately 88 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, 2025, 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, 2025, 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	2,179	$ 36.46	41,800
2014 Equity Incentive Plan	11,247	$ 179.99	—
Equity compensation plans not approved by security holders	—	—	—
Total	13,413	$ 156.67	41,800

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, 2025, to the year ended December 31, 2024.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Estimates* – Accounting estimates 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.

CyPath® Lung, our first commercial diagnostic test, addresses the need for noninvasive detection of early-stage lung cancer by detecting lung cancer as early as curative Stage 1A. 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 development of our diagnostic tests in the pipeline and advancement of our therapeutic discoveries have been conducted at leased laboratory space at The University of Texas at San Antonio. We plan to move our research and development efforts to privately owned laboratory space in the second quarter 2026.

Current Year Financial Highlights

Key financial results for the year ended December 31, 2025, include:

- Primarily as a result of the Company's targeted strategic actions to discontinue unprofitable pathology services, reduce costs through operational efficiency, and drive sales growth for CyPath® Lung, consolidated revenue decreased approximately 34% to $6.2 million as compared to $9.4 million for the year ended December 31, 2024. While these actions contributed to lower consolidated revenue in the short term, they improved operating focus and cost structure and are intended to position our noninvasive lung cancer diagnostic for scalable growth and improved long-term margin potential.
- CyPath® Lung testing revenue increased approximately 87% to $963,000 as compared to $516,000 for the year ended December 31, 2024, due to a 99% increase in total test results delivered of more than 600 for the current year.
- Raised approximately $16.9 million in gross proceeds from equity transactions to fund operating activities.

Recent Financial Developments

Public and Private Offerings

All share and per-share amounts in the accompanying footnotes have been retroactively adjusted to reflect our 1-for-30 reverse stock split, which occurred on September 18, 2025.

In October 2025, we entered into definitive agreements for the purchase and sale of 720,000 shares of Common Stock, at a purchase price of $2.50 per share in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds from the offering were approximately $1.8 million before deducting placement agent fees and other offering expenses payable by us.

On September 29, 2025, we consummated a best efforts public offering of an aggregate of (i) 1,047,694 shares of Common Stock and (ii) pre-funded warrants to purchase up to 874,067 shares of Common Stock in lieu of shares of Common Stock. Each share was sold at a public offering price of $2.50. Each pre-funded warrant was sold at a public offering price of $2.493. The total gross proceeds for the transaction were approximately $4.8 million.

On August 13, 2025, we entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which we agreed to issue and sell in a private placement (i) 990 shares of our newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share, for gross proceeds to us of $990,000, which were initially convertible into 143,476 shares of our Common Stock at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of our Common Stock at an exercise price of $10.56 per share of Common Stock.

On May 7, 2025, the Company completed a public offering of securities for gross proceeds to the Company of $3.25 million, before deducting agent fees and other estimated expenses payable by the company. The offering consisted of 338,541 shares of our Common Stock, of which 79,044 were pre-funded warrants, together with warrants to purchase up to 507,812 shares of Common Stock, at a combined offering price for each share of common stock (or pre-funded warrant) and accompanying warrant of $9.60 per share. The warrants have an exercise price of $10.56 per share and have certain provisions that allow for additional shares to be issued in the event of a reverse split of the Company's common stock. Additionally, the warrants include an anti-dilution adjustment which is subject to stockholder approval.

On February 26, 2025, pursuant to the terms of a warrant inducement agreement (the "February Inducement Agreement"), we entered into with certain holders of existing warrants dated February 25, 2025, such holders exercised for cash (i) warrants to purchase an aggregate of up to 43,402 shares of Common Stock issued on August 5, 2024 (the "August Warrants"), at the reduced exercise price of $17.40 per share, and (ii) warrants to purchase an aggregate of up to 37,878 shares of Common Stock issued on October 21, 2024 (the "October Warrants"), at the reduced exercise price of $17.40 per share. We 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, we issued unregistered common warrants to purchase an aggregate of up to 97,538 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.

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, 2025, we had working capital surplus of $4.7 million and an accumulated deficit of approximately $68.6 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, 2025 Compared to the Year Ended December 31, 2024

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, 2025 was approximately $14.9 million, compared to a net loss of approximately $9.0 million for the year ended December 31, 2024, resulting from the operational activities described below.

Revenue

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

	Year Ended December 31,	
	2025	2024
Patient service fees[1]	$ 4,917,342	$ 8,175,670
Histology service fees	1,116,912	1,103,751
Medical director fees	68,268	66,576
Department of Defense observational studies	577	8,654
Other revenues	4,860	7,371
Total net revenue	$ 6,161,959	$ 9,362,022

[1]Patient services fees includes direct billing for CyPath® Lung diagnostic test of approximately $963,000 and $516,000 for the years ended December 31, 2025 and 2024, respectively.

Operating Expenses

	Year Ended December 31,		Change in 2025 Versus 2024	
	2025	2024	$	%
Operating expenses:				
Direct costs and expenses	$ 4,226,799	$ 5,983,475	$ (1,756,676)	(29)%
Research and development	1,383,359	1,461,227	(77,868)	(5)%
Clinical development	705,744	321,655	384,089	119%
Selling, general and administrative	9,913,729	9,943,473	(29,744)	0%
Depreciation and amortization	504,836	605,637	(101,801)	(17)%
Total operating expenses	$ 16,734,467	$ 18,315,467	$ (1,581,800)	(9)%

Operating expenses totaled $16.7 million and $18.3 million for the years ended December 31, 2025 and 2024, respectively. The decrease in operating expenses is the result of the following factors.

Direct Costs and Expenses

Our direct costs and expenses are primarily direct labor for pathology services, laboratory supplies and reagents, laboratory equipment, and allocated shared facilities. Direct costs and expenses totaled $4.2 million and $6.0 million during the years ended December 31, 2025 and 2024, respectively. The decrease of approximately $1.8 million for 2025 compared to 2024 was primarily attributable to the targeted strategic actions which occurred in March 2025, aimed at streamlining operations and reducing costs related to our lab operations.

Research and Development

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 $1.4 million and $1.5 million for the years ended December 31, 2025 and 2024, respectively.

Clinical Development

Clinical development expenses totaled approximately $706,000 and $322,000 for the years ended December 31, 2025 and 2024, respectively. The increase of approximately $384,000, or 119%, for the year ended December 31, 2025, compared to the same period in 2024 was primarily attributable to an increase in professional fees in 2025 related to managing our clinical strategy for our pivotal clinical trial.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately $9.9 million and $9.9 million for each year ended December 31, 2025 and 2024, respectively. Our selling, general and administrative costs stayed level despite an increase of approximately $1.0 million in costs related to the addition of personnel and services to support sales of our diagnostic test, CyPath® Lung, offset by decreases in expenses from targeted strategic actions aimed at streamlining operations and reducing costs in our lab operations.

Depreciation and Amortization

Depreciation and amortization expenses totaled approximately $505,000 and $606,000 for the years ended December 31, 2025 and 2024, respectively. The decrease of approximately $101,000, or 17%, for the year ended December 31, 2025, compared to the same period in 2024 was primarily attributable to the termination of a financing lease in April 2025 due to the Company's targeted strategic actions announced in March 2025.

Other Income (Expense)

	Year Ended December 31,		Change in 2025 Versus 2024	
	2025	2024	$	%
Interest (expense) income, net	$ (20,987)	$ (74,865)	$ 53,878	72%
Other (expense) income, net	(461,939)	129	(462,068)	(358,192)%
Gain (loss) on remeasurement of warrant liabilities	(3,810,278)	—	(3,810,278)	(100)%
Total other (expense) income	$ (4,293,204)	$ (74,736)	$ (4,218,468)	5,644%

Other Income (Expense)

Total other income (expense), net totaled ($4.3 million) and approximately $(75,000) for the years ended December 31, 2025 and 2024, respectively. The increase in total other expenses of approximately $4.2 million is mostly attributable to the remeasurement of warrant liability and offering costs related to the May public offering, which was further reclassified as equity after the completion of certain events which prevented equity classification.

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 $58.2 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

In October 2025, we entered into definitive agreements for the purchase and sale of 720,000 shares of Common Stock, at a purchase price of $2.50 per share in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds to us from the offering were approximately $1.8 million before deducting placement agent fees and other offering expenses payable by us.

On September 29, 2025, we consummated a best efforts public offering of an aggregate of (i) 1,047,694 shares of Common Stock and (ii) pre-funded warrants to purchase up to 874,067 shares of Common Stock in lieu of shares of Common Stock. Each share was sold at a public offering price of $2.50. Each pre-funded warrant was sold at a public offering price of $2.493. The total gross proceeds for the transaction were approximately $4.8 million.

On August 13, 2025, we entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which we agreed to issue and sell in a private placement (i) 990 shares of our newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share, for gross proceeds to us of $990,000, which were initially convertible into 143,476 shares of our Common Stock at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of our Common Stock at an exercise price of $10.56 per share of Common Stock.

On May 7, 2025, the Company completed a public offering of securities for gross proceeds to the Company of $3.25 million, before deducting agent fees and other estimated expenses payable by the company. The offering consisted of 338,541 shares of our Common Stock, of which 79,044 were pre-funded warrants, together with warrants to purchase up to 507,812 shares of Common Stock, at a combined offering price for each share of common stock (or pre-funded warrant) and accompanying warrant of $9.60 per share. The warrants have an exercise price of $10.56 per share and have certain provisions that allow for additional shares to be issued in the event of a reverse split of the Company's common stock. Additionally, the warrants include an anti-dilution adjustment which is subject to stockholder approval.

On February 26, 2025, pursuant to the terms of a warrant inducement agreement (the "February Inducement Agreement"), we entered into with certain holders of existing warrants dated February 25, 2025, such holders exercised for cash (i) warrants to purchase an aggregate of up to 43,402 shares of Common Stock issued on August 5, 2024 (the "August Warrants"), at the reduced exercise price of $17.40 per share, and (ii) warrants to purchase an aggregate of up to 37,878 shares of Common Stock issued on October 21, 2024 (the "October Warrants"), at the reduced exercise price of $17.40 per share. We 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, we issued unregistered common warrants to purchase an aggregate of up to 97,538 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 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 2025 and 2024, we had net losses of $14.9 million and $9.0 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately $68.6 million as of December 31, 2025. Based on our current expected level of operating expenditures and the cash on hand of approximately $4.0 million 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 June 2026.

Cash and cash equivalents were approximately $6.4 million as of December 31, 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,	
	2025	2024
Cash and cash equivalents at beginning of year	$ 1,105,291	$ 2,821,570
Net cash used in operating activities	(9,328,842)	(7,264,795)
Net cash used in investing activities	(60,568)	(79,083)
Net cash provided by financing activities	14,733,901	5,627,599)
Cash and cash equivalents at end of year	$ 6,449,782	$ 1,105,291

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $9.3 million and $7.3 million for the years ended December 31, 2025 and 2024, respectively. The increase of approximately $2.0 million in cash used by operations during the years ended December 31, 2025, compared to the same period in 2024 was primarily attributable to an increase of $5.9 million in our loss from operations, a decrease in accounts payable and accrued expenses by $0.5 million offset by a decrease in accounts receivable by $0.9 million compared to the prior year, decrease in stock compensation by $0.3 million, decrease in depreciation and amortization by $0.1 million, and a fair value adjustment to the warrant liability by $3.8 million related to the May 2025 warrant agreement.

Net Cash Used in Investing Activities

We used approximately $61,000 for the year ended December 31, 2025, in investing activities related primarily to purchase of computer and lab equipment, compared to approximately $79,000 used in investing activities for the year ended December 31, 2024.

Net Cash Provided by Financing Activities

Cash provided in financing activities was approximately $14.7 million compared to cash provided by financing activities of approximately $5.6 million for the years ended December 31, 2025 and 2024, respectively. The change in proceeds from prior year was primarily related to net proceeds from the equity transactions of $15.1 million offset by payments for loans and finance leases of $0.4 million, compared to the prior year of equity transactions of $5.8 million offset by payments for loans and finance leases of approximately $0.2 million.

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, 2025. 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

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" as of December 31, 2025, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were 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 processes, 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, 2025.

As of December 31, 2025, we are a non-accelerated filer, and our independent registered public 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, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 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 is incorporated herein by reference to the Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated herein by reference to the Proxy Statement.

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)
3.10	Certificate of Amendment to the Certificate of Incorporation (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 August 14, 2025)
3.11	Certificate of Designations of Series B Convertible Preferred Stock (Incorporated by reference as Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 14, 2025)
3.12	Certificate of Amendment to Certificate of Incorporation of bioAffinity Technologies, Inc. (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 September 17, 2025)

Exhibit Number	Description
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 (Incorporated by reference as Exhibit 4.13 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 31, 2025)
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)

Exhibit Number	Description
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)
4.20	Form of April 2025 Warrant (Incorporated by reference as Exhibit 4.19 to the Registrant's Form S-1 filed May 2, 2025)
4.21	Form of Pre-Funded Arrant (Incorporated by reference as Exhibit 4.20 to the Registrant's Form S-1 filed May 2, 2025)
4.22	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.21 to the Registrant's Form S-1 filed May 2, 2025)
4.23	Form of Warrant Agent Agreement for the April 2025 Warrants (Incorporated by reference as Exhibit 4.22 to the Registrant's Form S-1 filed May 2, 2025)
4.24	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 8, 2025)
4.25	Form of May 2025 Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 8, 2025)
4.26	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 8, 2025)
4.27	Form of 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 14, 2025)
4.28	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 14, 2025)
4.29	Form of New Warrant (Incorporated by reference as Exhibit 4.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 14, 2025)
4.30	Form of Warrant Amendment (Incorporated by reference as Exhibit 4.4 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 14, 2025)
4.31	Form of May 2025 Warrant Amendment (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 2, 2025)
4.32	Form of August 2025 Warrant Amendment (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 2, 2025)
4.33	Form of Pre-Funded 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 September 30, 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)

Exhibit Number	Description
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 10.7 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)

Exhibit Number	Description
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)

Exhibit Number	Description
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)
10.42	Form of Securities Purchase Agreement (Incorporated by reference as Exhibit 10.42 to the Registrant's Form S-1 filed May 2, 2025)

Exhibit Number	Description
10.43	Placement Agency Agreement, dated as of May 5, 2025, by and between bioAffinity Technologies, Inc. and WallachBeth Capital LLC (Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 8, 2025)
10.44	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 8, 2025)
10.45	At-The-Market Issuance Sales Agreement by and between bioAffinity Technologies, Inc. and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on May 27, 2025)
10.46	Placement Agency Agreement dated August 13, 2025 (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 14, 2025)
10.47	Form of Securities Purchase 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 August 14, 2025)
10.48	Form of Registration Rights 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 14, 2025)
10.49	Form of Warrant Inducement Agreement (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 14, 2025)
10.50	Financial Advisory Agreement dated August 13, 2025 (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 August 14, 2025)
10.51	Placement Agency Agreement dated as of September 25, 2025, by and between bioAffinity Technologies, Inc. and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 30, 2025)
10.52	Form of Securities Purchase 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 September 30, 2025)
10.53	Placement Agency Agreement, dated October 8, 2025, by and between bioAffinity Technologies Inc. and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 9, 2025)
10.54	Form of Securities Purchase Agreement, dated as of October 8, 2025, 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 9, 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 (Incorporated by reference as Exhibit 19.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 31, 2025)
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

Exhibit Number	Description
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.
** Furnished 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 13th day of March, 2026.

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 13, 2026
/s/ J. Michael Edwards J. Michael Edwards	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2026
/s/ Steven Girgenti Steven Girgenti	Executive Chairman and Director	March 13, 2026
/s/ Robert Anderson Robert Anderson	Director	March 13, 2026
/s/ John Oppenheimer John Oppenheimer	Director	March 13, 2026
/s/ Peter S. Knight Peter S. Knight	Director	March 13, 2026
/s/ Roberto Rios Roberto Rios	Director	March 13, 2026
/s/ Jamie Platt Jamie Platt	Director	March 13, 2026

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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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 13, 2026
PCAOB ID Number 100

bioAffinity Technologies, Inc.
Consolidated Balance Sheets
As of December 31, 2025 and 2024

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,449,782	$ 1,105,291
Accounts and other receivables, net	541,962	1,139,204
Inventory	53,548	27,608
Prepaid expenses and other current assets	519,916	422,995
Total current assets	7,565,208	2,695,098
Non-current assets:		
Property and equipment, net	265,593	375,385
Operating lease right-of-use asset, net	334,289	463,011
Finance lease right-of-use asset, net	661,575	780,872
Goodwill	1,404,486	1,404,486
Intangible assets, net	716,806	775,139
Other assets	12,815	19,676
Total assets	$ 10,960,772	$ 6,513,667
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 761,901	$ 987,311
Accrued expenses	1,717,989	1,398,722
Unearned revenue	42,405	24,404
Operating lease liability, current portion	139,220	127,498
Finance lease liability, current portion	139,490	395,301
Notes payable, current portion	105,161	171,669
Total current liabilities	2,906,166	3,104,905
Non-current liabilities		
Operating lease liability, net of current portion	202,878	342,098
Finance lease liability, net of current portion	532,759	444,448
Notes payable, net of current portion	41,313	20,180
Total liabilities	3,683,116	3,911,631
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 per share; 20,000,000 shares authorized; 700 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively	1	—
Common Stock, par value $0.007 per share; 350,000,000 shares authorized; 4,498,675 and 519,158 issued and outstanding at December 31, 2025 and 2024, respectively(1)	31,461	3,553
Additional paid-in capital(1)	75,800,258	56,242,793
Accumulated deficit	(68,554,064)	(53,644,310)
Total stockholders' equity	7,277,656	2,602,036
Total liabilities and stockholders' equity	$ 10,960,772	$ 6,513,667

(1) The values of Common Stock and paid-in capital, as well as the number of shares issued and outstanding, have been retroactively adjusted in order to give effect to the Company's 1-for-30 reverse stock split.

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, 2025 and 2024

	2025	2024
Net Revenue	$ 6,161,959	$ 9,362,022
Operating expenses:		
Direct costs and expenses	4,226,799	5,983,475
Research and development	1,383,359	1,461,227
Clinical development	705,744	321,655
Selling, general and administrative	9,913,729	9,943,473
Depreciation and amortization	504,836	605,637
Total operating expenses	16,734,467	18,315,467
Loss from operations	(10,572,508)	(8,953,445)
Other income (expense):		
Interest income	23,385	17,610
Interest expense	(44,372)	(92,475)
Other income	40,490	10,323
Other expense	(502,429)	(10,194)
Change in fair value of warrants issued	(3,810,278)	—
Loss before income tax expense	(14,865,712)	(9,028,181)
Income tax expense	(44,042)	(11,650)
Net loss	$ (14,909,754)	$ (9,039,831)
Net loss per common share, basic and diluted(2)	$ (8.66)	$ (22.50)
Weighted average common shares outstanding(2)	1,721,082	404,167

(2) The values of Common Stock and paid-in capital, as well as the number of shares issued and outstanding, have been retroactively adjusted in order to give effect to the Company's 1-for-30 reverse stock split.

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, 2025 and 2024

	Convertible Preferred Stock		Common Stock[3]		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital[3]	Deficit	Equity
Balance at December 31, 2023	—	—	313,153	$ 2,192	$ 49,457,542	$ (44,604,479)	$ 4,855,255
Stock-based compensation	—	—	18,308	128	989,553	—	989,681
Exercise of stock options			6,931	49	74,850		74,899
Exercise of stock warrants	—	—	35,558	249	1,370,898	—	1,371,147
Sale of Common Stock	—	—	133,570	935	5,611,848	—	5,612,783
Offering Costs			—	—	(1,261,898)	—	(1,261,898)
Net loss	—	—	—	—	—	(9,039,381)	(9,039,831)
Balance at December 31, 2024	—	—	507,520	$ 3,553	$ 56,242,793	$ (53,644,310)	$ 2,602,036
Stock-based compensation	—	—	14,816	104	671,370	—	671,474
Sale of common stock	—	—	2,788,933	19,523	8,110,609	—	8,130,132
Exercise of stock warrants	—	—	1,140,947	7,987	4,806,040	—	4,814,027
Issuance of preferred stock	990	1	—	—	989,999	—	990,000
Conversion of preferred stock	(290)		42,028	294	(294)	—	—
Offering costs	—	—			(1,771,939)	—	(1,771,939)
Reclass of warrant liability to equity					6,751,680		6,751,680
Net loss	—	—	—	—	—	(14,909,754)	(14,909,754)
Balance at December 31, 2025	700	1	4,494,304	$ 31,461	$ 75,800,258	$ (68,554,064)	$ 7,277,656

(3) The values of Common Stock and paid-in capital, as well as the number of shares issued and outstanding, have been retroactively adjusted in order to give effect to the Company's 1-for-30 reverse stock split.

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, 2025 and 2024

	2025	2024
Cash flows from operating activities		
Net loss	$ (14,909,754)	$ (9,039,831)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	504,836	605,637
Stock-based compensation expense	671,474	989,681
Fair value adjustment on warrants	3,810,278	—
Changes in operating assets and liabilities:		
Accounts and other receivables	597,242	(327,530)
Inventory	(25,940)	(9,124)
Prepaid expenses and other assets	(90,060)	(105,594)
Accounts payable	(225,410)	382,521
Accrued expenses	319,267	248,911
Unearned revenue	18,001	(8,654)
Operating lease right-of-use asset	1,224	(812)
Net cash used in operating activities	(9,328,842)	(7,264,795)
Cash flows from investing activities		
Purchase of property and equipment	(60,568)	(79,083)
Net cash used in investing activities	(60,568)	(79,083)
Cash flows from financing activities		
Proceeds from issuance of Common Stock from direct offering	11,071,534	5,612,783
Proceeds from exercised stock options	—	74,899
Proceeds from exercise of warrants	4,814,027	1,371,147
Proceeds from issuance of Convertible Preferred Stock	990,000	—
Payment of offering costs for financing activities	(1,771,939)	(1,261,898)
(Payments) proceeds from loans payable	(45,375)	191,849
Principal repayments on finance leases	(324,346)	(361,181)
Net cash provided by financing activities	14,733,901	5,627,599
Net change in cash and cash equivalents	5,344,491	(1,716,279)
Cash and cash equivalents at beginning of year	1,105,291	2,821,570
Cash and cash equivalents at end of year	$ 6,449,782	$ 1,105,291
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	$ 44,042	$ 11,650
Interest paid	23,385	17,610
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 ("AI"), to preferentially target cancer cell populations and other cell populations indicative of a diseased state. The Company's first diagnostic test, CyPath® Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. CyPath® Lung is offered for sale to physicians by the Company's subsidiary, Precision Pathology Laboratory Services, LLC ("PPLS"). The Company is developing its flow cytometry platform to address the need to identify patients who can benefit from new and emerging therapies for asthma and chronic obstructive pulmonary disease ("COPD") with noninvasive precision diagnostic tests. Research also is advancing the Company's therapeutic discoveries that could in the future result in broad-spectrum cancer treatments, beginning with treatment delivered topically for squamous cell skin cancer. Commercial operations and product development are conducted in laboratories at PPLS and laboratory space leased at The University of Texas at San Antonio.

Organization

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

Basis of Presentation

The 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").

All share and per-share amounts in the accompanying footnotes have been retroactively adjusted to reflect the Company's 1-for-30 reverse stock split.

Going Concern

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 $68.6 million at December 31, 2025. The Company's cash and cash equivalents at December 31, 2025, were approximately $6.4 million. Based on the Company's current expected level of operating expenditures and the cash and cash equivalents on hand at December 31, 2025, management concludes that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Without funding from the proceeds from the issuance of equity or debt securities, exercise of outstanding warrants, funding from a potential strategic relationship or grants, management anticipates that the Company's cash resources are sufficient to continue operations through June 2026. The Company will need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations, if revenue from operations does not significantly increase. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan may be curtailed. 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.

Cash and Cash Equivalents

For the purpose of the consolidated statements 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 $340,000 and $267,000 for the years ended December 31, 2025 and 2024, respectively.

Loss Per Share

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of the Company's Common Stock, 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 preferred stock, warrants, and unvested restricted stock 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, 2025 and 2024, as they would be anti-dilutive:

	As of December 31,	
	2025	2024
Shares underlying options outstanding	9,055	9,649
Shares underlying convertible preferred stock	101,448	—
Shares underlying warrants outstanding	1,348,494	409,847
Shares underlying unvested restricted stock	4,371	11,638
	1,463,368	431,134

Revenue Recognition

To determine revenue recognition for the arrangements that the Company determines are within the scope of Accounting Standards Codification ("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 since 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.

	Year Ended December 31,	
	2025	2024
Patient service fees[1]	$ 4,971,342	$ 8,175,670
Histology service fees	1,116,912	1,103,751
Medical director fees	68,268	66,576
Department of Defense observational studies	577	8,654
Other revenues	4,860	7,371
Total net revenue	$ 6,161,959	$ 9,362,022

[1] Patient services fees include direct billing for CyPath® Lung diagnostic test of approximately $963,000 and $516,000 for the years ended December 31, 2025 and 2024.

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 loss or stockholders' equity.

Accounts and other receivables, net

Substantially all accounts receivable are due from insurance companies, U.S. and state governmental agencies, and patients. The Company believes credit risks are mitigated as a result of the large number customers. The portion of the Company's accounts receivable due from patients comprises the largest portion of credit risk, assumptions and judgments are used to assess collectability from patients.

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, 2025 or 2024.

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

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

Intangible Assets

The Company's acquisition of PPLS on September 18, 2023, identified Goodwill and intangible assets. Goodwill represents the purchase price in excess of fair values assigned to the underlying identifiable net assets of the acquired business. The 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, 2025 and 2024:

	December 31,	
	2025	**2024**
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		
Trade names and trademarks	(19,028)	(10,694)
Customer relationships	(114,166)	(64,167)
	(133,194)	(74,861)
Intangible assets, net	$ 2,121,292	$ 2,179,625

For the years ended December 31, 2025 and 2024, amortization of intangible assets totaled $58,334.

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, 2025. 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.

The estimated amortization expense related to amortizable intangible assets for each of the five succeeding fiscal years and thereafter as of December 31, 2025 is as follows:

Year Ending December 31,	
2026	$ 58,333
2027	58,333
2028	58,333
2029	58,333
2030	58,333
Thereafter	425,141
Total	$ 716,806

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 ASU No. ASU 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures.* The standard requires enhanced annual disclosures, including: (i) disaggregated information in the rate reconciliation, (ii) disaggregation of income (loss) from continuing operations before income tax expense (benefit) between domestic and foreign, (iii) disaggregation of income tax expense (benefit) from continuing operations by federal, state, and foreign, and (iv) disaggregated disclosure of income taxes paid by jurisdiction. The Company adopted ASU 2023-09 on January 1, 2025 prospectively. The adoption of ASU 2023-09 resulted in expanded income tax disclosures in Note 15. Income Taxes.

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, 2025 and 2024, and the Company had no accruals for interest and penalties at December 31, 2025 or 2024.

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,	
	2025	2024
Net revenues:		
Diagnostic R&D	$ 577	$ 8,654
Laboratory services	6,161,382	9,353,368
Total net revenues	6,161,959	9,362,022
Operating expenses:		
Diagnostic R&D	(2,089,103)	(1,782,882)
Laboratory services	(6,952,050)	(9,946,452)
General corporate activities	(7,693,314)	(6,586,133)
Total operating loss	(10,572,508)	(8,953,445)
Non-operating expense, net	(4,293,204)	(74,736)
Net loss before income taxes	(14,865,712)	(9,028,181)
Income tax expense	(44,042)	(11,650)
Net loss	$ (14,909,754)	$ (9,039,831)

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, 2025 and 2024, are summarized below:

	December 31,	
	2025	2024
Patient service fees	$ 356,432	$ 915,488
Histology service fees	142,889	190,648
Medical director fees	16,346	5,194
Other receivables	26,295	27,874
Total accounts and other receivables, net	$ 541,962	$ 1,139,204

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2025 and 2024, are summarized below:

	December 31,	
	2025	2024
Prepaid insurance	$ 227,950	$ 248,364
Legal and professional	21,530	27,448
Other	270,436	147,183
Total prepaid expenses and other current assets	$ 519,916	$ 422,995

Note 5. PROPERTY AND EQUIPMENT, NET

Property and equipment at December 31, 2025 and 2024, are summarized below:

	December 31, 2025	December 31, 2024
Lab equipment	$ 679,995	$ 662,747
Computers and software	81,433	81,433
Leasehold improvements	32,781	19,353
Vehicles	175,630	148,103
	969,839	911,636
Less: accumulated depreciation and amortization	(704,246)	(536,251)
Total property and equipment, net	$ 265,593	$ 375,385

Total property and equipment depreciation and amortization expense was $170,359 and $162,332 for the years ended December 31, 2025 and 2024, respectively.

Note 6. ACCRUED EXPENSES

Accrued expenses at December 31, 2025 and 2024, are summarized below:

	December 31, 2025	December 31, 2024
Compensation	$ 1,309,738	$ 1,079,839
Legal and professional	337,936	98,477
Clinical	46,177	160,371
Other	24,138	60,035
Total accrued expenses	$ 1,717,989	$ 1,398,722

Note 7. UNEARNED REVENUE

The Company engaged in an observational study of CyPath® Lung with the Department of War. 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 41 units as of December 31, 2025. The performance obligation is deemed complete after samples have been collected and processed and results analyzed. The unearned revenue balance amounted to $23,827 and $24,404 as of December 31, 2025 and 2024, respectively.

During August 2025, the Company engaged with Veterans Administration ("VA") medical centers to purchase CyPath® Lung tests. A total of 30 tests were ordered and shipped. However, in compliance with FASB ASC 606, the performance obligation was complete for only eight tests as of December 31, 2025. The performance obligation is deemed complete after samples have been collected, processed, and analyzed and results communicated to patients. The unearned revenue balance amounted to $18,578 as of December 31, 2025.

Note 8. FAIR VALUE MEASUREMENTS

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

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

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

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

Warrants

The Company issued liability classified warrants in connection with the issuance of the May 2025 warrants. The warrants were liability classified as a result of certain terms in the May 2025 warrant agreement, and the terms were amended during September 2025 to trigger an equity classification on the date of the reverse stock split. The Company uses a Black-Scholes model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized in "Change in fair value of warrants issued" for each reporting period in the consolidated statements of operations.

There were no warrant liabilities as of December 31, 2025 and 2024. The Company initially recorded a warrant liability of $2.9 million as a result of the May 2025 public offering. The Company revalued and recognized an aggregate of $3.8 million for the change in fair value of warrants issued before adjusting the warrant liability to equity classified warrants.

Note 9. LEASES

The Company has one operating lease for its real estate and office space for the CAP/CLIA laboratory, as well as multiple finance leases for lab equipment in Texas that were acquired through the September 18, 2023, acquisition. On April 1, 2025, the Company terminated one of the finance leases and entered into a new finance lease agreement for equipment on October 20, 2025. Additionally, the Company entered into another operating lease on September 1, 2024, with regard to office space. The Company has operating leases consisting of office space with remaining lease terms ranging from 1.6 to 4.7 years as of December 31, 2025. The Company has finance leases consisting of lab equipment with remaining lease terms ranging from approximately 0.3 to 6.8 years as of December 31, 2025, for which the Company has determined that it will use the equipment for a major part of its remaining economic life.

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

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

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

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

Components of lease expense:	**2025**	**2024**
Amortization of right-of-use assets - finance lease	$ 275,533	$ 384,971
Interest on lease liabilities - finance lease	34,935	83,041
Operating lease cost	159,057	93,029
Total lease cost	$ 469,525	$ 561,041
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 324,346	$ 361,181
Operating cash flows from operating leases	157,368	133,605

Operating leases:	2025	2024
Operating lease right-of-use assets	$ 334,289	$ 463,011
Operating lease liability, current	$ 139,220	$ 127,498
Operating lease liability, non-current	202,878	342,098
Total operating lease liabilities	$ 342,098	$ 469,596

Financing leases:	2025	2024
Financing lease right-of-use assets, gross	$ 1,184,598	$ 1,294,168
Accumulated amortization	(523,023)	(513,296)
Finance lease right-of-use assets, net	$ 661,575	$ 780,872
Financing lease liability, current	$ 139,490	$ 395,301
Financing lease liability, non-current	532,759	444,448
Total finance lease liabilities	$ 672,249	$ 839,749

Weighted-average remaining lease term:	2025	2024
Operating leases (in years)	3.04	4.21
Finance leases (in years)	6.18	2.39

Weighted-average discount rate:	2025	2024
Operating leases	7.28%	7.41%
Finance leases	6.86%	8.03%

	Operating Leases	Finance Leases
2026	$ 159,282	$ 179,133
2027	110,065	111,708
2028	40,616	111,708
2029	42,252	111,708
2030	28,919	111,708
2031 and thereafter	—	201,495
Total undiscounted cash flows	381,134	827,460
Less discounting	(39,036)	(155,211)
Present value of lease liabilities	$ 342,098	$ 672,249

Note 10. NOTES PAYABLE

Vehicles Notes Payable

On January 10, 2025, the Company entered into a finance agreement to purchase a 2024 Toyota Corolla for $33,517 with a maturity date of January 18, 2031. The loan bears fixed interest at a rate of 11.65% per annum, with monthly payments of $651, which is comprised of principal and interest. This loan is collateralized by the underlying vehicle. The balance of this loan as of December 31, 2025, was $29,774. The current portion of the balance of this loan as of December 31, 2025 was $4,588.

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, 2025 and 2024, was $20,618 and $24,849, respectively. The current portion of the balance of this loan as of December 31, 2025 and 2024, was $4,491 and $5,603, respectively.

Directors and Officers Insurance Policy – 2025

In September 2025, the Company obtained short-term financing of approximately $127,500 with 10 monthly payments of approximately $13,000 and interest at a 6.70% fixed annual rate for director and officer insurance policies. The current portion of the balance of the Company's Directors and Insurance short-term financing as of December 31, 2025, was $90,002 and $167,000 as of December 31, 2024, for the 2024 Directors and Officers Insurance Policy. In 2024, the Company financed the director and officer insurance policy.

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. CONVERTIBLE PREFERRED AND COMMON STOCK

Convertible Preferred Stock

The Company has authorized a total of 20,000,000 shares of $0.001 per share par value preferred stock. The Company has issued 700 shares of preferred stock, designated as Series B. In August 2025, the Company entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell, in a private placement, (i) 990 shares of the Company's newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share initially convertible into 143,476 shares of the Company's Common Stock, par value $0.007 per share at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of the Company's Common Stock at an exercise price of $10.56 per share of Common Stock. The investors have converted 290 of the 990 Series B Convertible Preferred Stock in exchange for 42,028 shares of Common Stock as of December 31, 2025. The holders of the Series B preferred stock have various rights as follows:

Voting Rights. Except as otherwise required by law, holders of Series B Preferred Stock shall not be entitled to any voting rights.

Dividends. The holders of Series B Preferred Stock shall be entitled to receive dividends on shares of Series B Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock.

Conversion. The Series B Preferred Stock will be convertible into shares of Common Stock at an initial conversion price of $0.23 per share (the "Conversion Price"). Each share of Series B Preferred Stock shall be convertible into such number of shares of Common Stock that results from dividing the Stated Value by the Conversion Price. Holders of Series B Preferred Stock are prohibited from converting shares of Series B Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own in excess of 4.99% of the total number of shares of Common Stock issued and outstanding immediately after giving effect to such conversion. If and whenever on or after the date on which the Company obtains the Preferred Stockholder Approval, the Company is deemed to have issued or sold any shares of Common Stock for a consideration per share less than the Conversion Price, the Conversion Price will be reduced to such new issuance price subject to a floor price of $0.10 per share.

Common Stock

The Company has authorized a total of 350,000,000 shares of Common Stock, $0.007 par value per share. On July 22, 2025, the Company received stockholder approval to increase the number of authorized shares of Common Stock from 100,000,000 shares to 350,000,000 shares, and on August 13, 2025, 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 4,498,675 shares of Common Stock, of which 4,371 are unvested restricted stock awards as of December 31, 2025, and 519,158 shares of Common Stock, of which 11,638 are unvested restricted stock awards as of December 31, 2024, adjusted for the 30-1 reverse stock split.

On September 29, 2025, the Company consummated a best efforts public offering of an aggregate of (i) 1,047,694 shares of Common Stock and (ii) pre-funded warrants to purchase up to 874,067 shares of Common Stock in lieu of shares of Common Stock. Each share was sold at a public offering price of $2.50. Each pre-funded warrant was sold at a public offering price of $2.493. The total gross proceeds for the transaction were approximately $4.8 million.

In October 2025, we entered into definitive agreements for the purchase and sale of 720,000 shares of Common Stock, at a purchase price of $2.50 per share in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds from the offering were approximately $1.8 million before deducting placement agent fees and other offering expenses payable by us.

On May 22, 2025, the Company entered into an at-the-market issuance sales agreement (the "ATM Agreement") with WallachBeth Capital LLC ("WallachBeth"), as sales agent providing for the sale of common stock from time to time in an "at the market offering" program. The aggregate market value of the shares of Common Stock eligible for sale is currently $5,801,000. The ATM Agreement provides that WallachBeth will receive 3.0% of the gross sales price sold under the ATM Agreement. From May 22, 2025, through December 31, 2025, the Company sold 114,672 shares of Common Stock through the ATM Agreement which accumulated approximately $1.2 million in gross proceeds.

Note 13. STOCK-BASED COMPENSATION

Under the Company's 2014 Equity Incentive Plan (the "2014 Plan"), the Company is authorized to grant options or restricted stock for up to 66,666 shares of Common Stock. On June 6, 2023, the Company received stockholder approval to increase the number of authorized shares from 38,095 to 66,666, adjusted for the 30-1 reverse split. 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 at the end of its 10-year term 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 consolidated statements of operations:

	Year Ended December 31,	
	2025	2024
Research and development	$ 51,953	$ 99,174
Clinical	10,282	10,000
Selling, general and administrative	609,239	880,507
Total stock-based compensation expense	$ 671,474	$ 989,681

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, 2024	9,649	$ 207.84	4.45	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(594)	147.28	—	—
Outstanding at December 31, 2025	9,055	$ 211.56	3.67	—
Vested and exercisable at December 31, 2025	9,055	$ 211.56	3.67	—

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

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, 2025	
				Vested number of RSA	Unvested number of RSA
Balance at December 31, 2024	44,261	$ 56.88	$ 2,517,630	40,244	3,859
Granted	8,598	22.37	214,003	7,195	512
Forfeited	(1,049)	21.30	(21,651)	—	—
Balance at December 31, 2025	51,810	$ 51.87	$ 2,709,982	47,439	4,371

During the year ended December 31, 2025, the Company issued restricted stock awards ("RSAs") for 8,598 shares of Common Stock to employees, non-employees, and the board of directors. The shares vest in equal monthly installments over terms of immediately and up to three years, subject to the employees and non-employees providing continuous service through the vesting date. During the year ended December 31, 2025, 7,195 shares vested from RSAs granted in 2025, and 7,621 shares vested from RSA's granted prior to 2025.

Note 14. WARRANTS

The Company's outstanding Common Stock warrants are equity classified. As of December 31, 2025 and 2024, the Company had 1,348,494 and 409,937 warrants outstanding to purchase one share of the Company's Common Stock for each warrant at a weighted average price of $28.44. These warrants expire at various dates through August 2030. During the year ended December 31, 2025, a total number of 1,204,854 warrants were exercised into 1,140,947 shares of Common Stock as compared to 35,558 being exercised during the year ended December 31, 2024. During the year ended December 31, 2025, a total of 63,907 warrants were forfeited as a result of cashless exercises. The proceeds from the exercise of warrants for the year ended December 31, 2025, was approximately $4.8 million, compared to proceeds of $1.3 million for the year ended December 31, 2024.

On February 25, 2025, the Company entered into a warrant inducement agreement (the "February Inducement Agreement") with certain holders (the "Holders") of the Company's warrants to purchase shares of the Company's Common Stock, issued in a private placement offering that closed on October 21, 2024 (the "October Warrants"), and a private placement offering that closed on August 5, 2024 (the "August Warrants" and, together with the October Warrants, collectively, the "Existing Warrants"). In consideration of the Holders' immediate exercise of the Existing Warrants in accordance with the February Inducement Agreement, the Company issued unregistered Common Stock purchase warrants (the "New Warrants") to purchase an aggregate of up to 97,538 shares of Common Stock (the "New Warrant Shares") to the Holders of the Existing Warrants, with an exercise price of $25.50.

On May 7, 2025, the Company completed a public offering with warrants ("May 2025 Warrants") to purchase of 507,812 shares of Common Stock. The May 2025 were initially recorded as liability classified until certain requirements were met, at which time the May 2025 warrants were reclassified as equity. The May 2025 Warrants have an initial exercise price of $10.56 per share and are exercisable for a term of five years on a date that is five years after receiving shareholder approval. The number of shares of Common Stock issuable upon exercise of the May 2025 Warrant Shares is subject to the following adjustments: (i) a 30% increase in the number of shares of Common Stock that would be issuable upon exercise of the May 2025 Warrants if a reverse stock split is effected prior to the expiration of the May 2025 Warrants (the "Reverse Stock Split Adjustment"), and (ii) subject to Warrant Stockholder Approval (as defined below), a decrease of the exercise price of the May 2025 Warrants, if in a subsequent offering of the Company's securities the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering is less than the exercise price immediately prior to such subsequent offering, to an exercise price that is equal to the lowest of the price paid for Common Stock, the exercise price of any options or warrants, or the conversion price of any convertible securities issued in such subsequent offering (subject to a floor of $4.50 per share) and an increase in the number of shares of Common Stock underlying the May 2025 Warrants upon such exercise price reset so that the reset exercise price multiplied by the increased number of shares equals the aggregate proceeds that would have resulted from the full exercise of the May 2025 Warrants immediately prior to the reset (the "Anti-Dilution Adjustment"). After the adjustments, the Company issued a total of 962,862 additional warrants related to the May 2025 Warrants at an exercise price of $4.50.

On August 13, 2025, the Company entered into a warrant inducement agreement with the holder of a warrant to purchase 15,000 shares of Common Stock originally issued on August 5, 2024, with a current exercise price of $37.50 per share (the "August 2024 Warrant") and a warrant to purchase 21,667 shares of Common Stock originally issued on October 21, 2024, with a current exercise price of $45.00 per share, pursuant to which the Holder agreed to exercise in cash the Existing Warrants at a reduced exercise price of $6.90 per share, for gross proceeds to the Company of $253,000. As an inducement to such exercise, the Company agreed to issue to the holder unregistered warrants to purchase up to 47,666 shares of the Company's Common Stock. The new warrants, which have an exercise price of $10.56 per share and will not become exercisable until the Company's stockholders approve the issuance of shares of Common Stock. Following stockholder approval, the warrants have a term of five years.

On August 13, 2025, the Company entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell, in a private placement, (i) 990 shares of the Company's newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share

initially convertible into 143,476 shares of the Company's Common Stock, par value $0.007 per share at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of the Company's Common Stock at an exercise price of $10.56 per share of Common Stock.

As of December 31, 2025, there were tradeable warrants to purchase up to an aggregate of 53,375 shares of Common Stock outstanding and non-tradeable warrants to purchase an aggregate of up to 90,149 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	96,616	$ 159.35	—	96,616
IPO tradeable	77,561	91.95	(24,186)	53,375
IPO non-tradeable	100,515	91.95	(10,366)	90,149
Direct offering March 8, 2024	53,530	37.50	(35,553)	17,977
Placement agent direct offering March 8, 2024	1,066	49.20	—	1,066
Inducement/direct offering August 5, 2024	58,402	—	(58,402)	—
Placement agent direct offering August 5, 2024	1,659	45.00	—	1,659
Direct offering October 21, 2024	88,757	23.92	(59,544)	29,213
Warrant inducement February 25, 2025	97,538	25.50	—	97,538
Public offering May 7, 2025	1,470,673	4.50	(781,262)	689,411
PIPE/Inducement offering August 13, 2025	271,490	10.56	—	271,490
Balance at December 31, 2025	2,317,607	$ 28.44	(969,313)	1,348,494

Note 15. INCOME TAXES

The Company's net loss before income taxes of $14.9 million and $9.0 million consisted entirely from U.S. operations for the years ended December 31, 2025 and 2024, respectively. The components of income tax expense and taxes paid by jurisdiction for the years ended December 31, 2025 and 2024 were as follows:

	December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State and local[(1)]	44,042	11,650
Foreign	—	—
Total	$ 44,042	$ 11,650

(1) For the year ended December 31, 2025, state and local taxes, net of federal benefit, were attributable to Texas and Delaware.

Deferred tax assets and valuation allowance

The tax effect of significant items comprising deferred tax assets are as follows:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryover	$ 9,916,597	$ 8,185,845
Stock compensation	247,574	247,574
Capitalized R&E costs	817,594	662,855
Bad debt expense	96,680	203,323
Other	165,788	107,538
Operating lease liabilities	196,805	274,962
Tax credits	510,729	480,724
Total deferred tax assets	11,951,767	10,162,821
Deferred tax liability:		
Right-of-use asset tax liability	$ (145,862)	$ (261,215)
Depreciation and amortization	(39,136)	(50,463)
Total deferred tax liability	(184,998)	(311,678)
Less: valuation allowance	(11,766,769)	(9,851,143)
	$ —	$ —

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets as of December 31, 2025 and 2024. The net change in total valuation allowance was an increase of approximately $1.9 million and $2.0 million for the years ended December 31, 2025 and 2024, respectively.

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2025 and 2024, was as follows:

	December 31,			
	2025		2024	
Tax at federal statutory rate	$ (3,131,048)	-21.00%	$ (1,898,365)	-21.00%
Permanent differences	953,106	6.4%	7,219	0.1%
Research and development credits	(103,949)	-0.7%	(73,945)	-0.8%
Deferred true-up	366,263	2.5%	—	0.0%
Change in valuation allowance	1,915,628	12.8%	1,965,091	21.7%
Effective income tax rate	$ —	0.00%	$ —	0.00%

Unrecognized tax benefits

As of December 31, 2025 and 2024, the Company has unrecognized tax benefits related to tax credits of $0.3 million and $0.3 million, respectively. None of the unrecognized tax benefits as of December 31, 2025, 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,	
	2025	2024
Beginning balance	$ 281,207	$ 249,516
Deductions based on tax positions related to the prior year	(31,691)	—
Additions based on tax positions related to the current year	44,549	31,691
Ending balance	$ 294,065	$ 281,207

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the years ended December 31, 2025 and 2024, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

Under the tax statute of limitations applicable to the Internal Revenue Code, the Company and its U.S. subsidiary, either standalone or as part of the consolidated group, is no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for tax years before tax year 2021. However, because the Company is carrying forward income tax attributes, such as net operating losses and tax credits from 2020 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future.

As of December 31, 2025 and 2024, the Company had net operating loss ("NOL") carryforwards of $47.2 million and $38.0 million for federal purposes, respectively. If not utilized, federal net operating losses of $6.0 million will begin to expire in 2034 and $41.2 million will be carried forward indefinitely.

As of December 31, 2025 and 2024, the Company had research and development tax credit carryforwards for federal purposes of $0.5 million and $0.7 million, respectively. The federal research and development tax credit carryforwards will expire at various dates between 2037 and 2045.

Sections 382 and 383 of the Internal Revenue Code provide for a limitation on the annual use of NOL and tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these carryforwards. The Company continues to disclose the NOL and tax credit carryforwards at their original amount in the table above as no potential limitation has been quantified. The Company has also established a full valuation allowance for all deferred tax assets, including the NOL and tax credit carryforwards, since the Company could not conclude that it was more likely than not able to generate future taxable income to realize these assets. Due to the existence of a full valuation allowance, limitations under Section 382 and 383 will not impact the Company's effective tax rate. Further analyses will be performed prior to recognizing the benefits of any losses or credits in the consolidated financial statements.

Beginning on January 1, 2022, the Tax Cuts and Jobs Act ("the Act"), enacted in December 2017, eliminated the option to deduct research and experimentation expenditures in the current period and requires taxpayers to capitalize and amortize U.S.-based and non-U.S. based research and experimentation expenditures over five and fifteen years, respectively. However, the enactment of the bipartisan OBBB Act, signed into law in July 2025, repeals the mandatory capitalization requirement for domestic R&D expenditures for tax years beginning after December 31, 2024. The Company has elected to continue to capitalize research and experimentation expenditures. This legislation does not impact the Company's current tax obligations.

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-1 (Nos. 333-290480 and 333-289944) and 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 13, 2026, 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, 2025 and 2024, which appear in this Form 10-K.

/s/ WithumSmith+Brown, PC

New York, New York
March 13, 2026

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 13, 2026

/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 13, 2026

/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, 2025 (the "Report") 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, 2025.

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer
Date: March 13, 2026

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, 2025 (the "Report") 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, 2025.

/s/ J. Michael Edwards
J. Michael Edwards
Chief Financial Officer
Date: March 13, 2026