

PROSPECTUS



bioAffinity Technologies, Inc.

1,632,000 Shares of Common Stock

This prospectus relates to the resale from time to time of up to 1,632,000 shares of common stock, par value \$0.001 per share (the “Common Stock”), of bioAffinity Technologies, Inc. by the Selling Stockholders identified in this prospectus (the “Selling Stockholders”), including their pledgees, assignees, donees, transferees or their respective successors-in-interest consisting of (i) 1,600,000 shares of Common Stock issuable upon the exercise of 1,600,000 Common Warrants to purchase shares of Common Stock (the “Common Warrants”) purchased by Selling Stockholders (the “Investor Selling Stockholders”) in a private placement transaction (the “Private Placement”) pursuant to the terms of a Securities Purchase Agreement dated as of March 6, 2024 (the “Purchase Agreement”) between us and the Investor Selling Stockholders and (ii) 32,000 shares of Common Stock issuable upon the exercise of 32,000 warrants (the “Placement Agent Warrants”) issued to designees of WallachBeth Capital LLC (“WallachBeth” or the “Placement Agent”) as partial compensation for WallachBeth acting as placement agent in connection with the Private Placement. The Private Placement closed on March 8, 2024. The shares of Common Stock issuable upon exercise of the Common Warrants are referred to as the “Common Warrant Shares,” and the shares of Common Stock issuable upon exercise of the Placement Agent Warrants are referred to as the “Placement Agent Warrant Shares.”

We are filing this registration statement on Form S-1, of which this prospectus forms a part, to fulfill our contractual obligations with the Selling Stockholders to provide for the resale by the Selling Stockholders of the shares of Common Stock offered hereby. See “Selling Stockholders” beginning on page 41 of this prospectus for more information about the Selling Stockholders. The registration of the shares of Common Stock to which this prospectus relates does not require the Selling Stockholders to sell any of their shares of our Common Stock.

We are not offering any shares of Common Stock under this prospectus and will not receive any proceeds from the sale or other disposition of the shares of our Common Stock covered hereby. However, we will receive the proceeds from any exercise of the Common Warrants and Placement Agent Warrants for cash. See “Use of Proceeds” beginning on page 37 of this prospectus.

The Selling Stockholders identified in this prospectus, or their pledgees, assignees, donees, transferees or their respective successors-in-interest, from time to time may offer and sell through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices the shares held by them directly or through underwriters, agents or broker-dealers on terms to be determined at the time of sale, as described in more detail in this prospectus. See “Plan of Distribution” beginning on page 78 of this prospectus for more information about how the Selling Stockholders may sell their respective shares of Common Stock. The Selling Stockholders may be deemed “underwriters” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

In connection with the Private Placement, we have agreed, pursuant to the terms of the Purchase Agreement, to bear all of the expenses in connection with the registration of the Common Warrant Shares and the Placement Agent Warrant Shares pursuant to this prospectus. The Selling Stockholders will pay or assume all commissions, discounts, fees of underwriters, agents, selling brokers or dealer managers and similar expenses, if any, attributable to their respective sales of the shares of Common Stock.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol “BIAF”. Our Tradeable warrants are listed on the Nasdaq Capital Market under the symbol “BIAFW”. On April 15, 2024, the last reported sale price of (i) our Common Stock on Nasdaq was \$2.76 per share, and (ii) our Tradeable Warrants on Nasdaq was \$0.69 per Tradeable Warrant. There is no established public trading market for the Common Warrants and Placement Agent Warrants and we do not expect a market to develop.

Investing in our securities involves risks. You should review carefully the risks and uncertainties described under the heading “Risk Factors” contained in this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus, as described beginning on page 8 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

The date of this prospectus is April 15, 2024

bioAffinity Technologies, Inc.

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The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the Common Stock offered under this prospectus. The registration statement, including the exhibits, can be read on our website and the website of the Securities and Exchange Commission. See “Where You Can Find More Information.”

Information contained in, and that can be accessed through our web site, www.bioaffinity.com, shall not be deemed to be part of this prospectus or incorporated herein by reference and should not be relied upon by any prospective investors for the purposes of determining whether to purchase the Common Stock offered hereunder.

Unless the context otherwise requires, the terms “we,” “us,” “our,” “the Company,” “bioAffinity” and “our business” refer to bioAffinity Technologies, Inc. and “this offering” refers to the offering contemplated in this prospectus.

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ABOUT THIS PROSPECTUS

Neither we nor the Selling Stockholders have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any post-effective amendment, or any applicable prospectus supplement prepared by or on behalf of us or to which we have referred you. We and the Selling Stockholders take no responsibility for and can provide no assurance as to the reliability of any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of the date on the front cover of the prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled “Where You Can Find Additional Information.”

Industry and Market Data

This prospectus includes estimates regarding market and industry data. Unless otherwise indicated, information concerning our industry and the markets in which we operate, including our general expectations, market position, market opportunity, and market size, are based on our management’s knowledge and experience in the markets in which we operate, together with currently available information obtained from various third-party sources, including publicly available information, industry reports and publications, surveys, our customers, trade and business organizations, and other contacts in the markets in which we operate. Although we believe these third-party sources are reliable as of their respective dates, neither we nor the underwriters have independently verified the accuracy or completeness of this information. Some data is also based on our good faith estimates. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications.

Trademarks and Trade Names

We own or have rights to various trademarks, service marks, and trade names that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks, and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names, or products in this prospectus is not intended to, and does not imply a relationship with or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks, and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, service marks, and trade names.

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PROSPECTUS SUMMARY

This summary provides an overview of information appearing elsewhere in this prospectus and highlights the key aspects of this Offering. This summary does not contain all of the information you should consider prior to investing in our Common Stock or Warrants. You should read this entire prospectus carefully, including the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes appearing at the end of this prospectus, before making any investment decision. Our fiscal year ends on December 31. Unless the context otherwise requires, references to “bioAffinity,” the “Company,” “we,” “us,” and “our” in this prospectus refer to bioAffinity Technologies, Inc. and our consolidated subsidiaries.

Overview

bioAffinity Technologies, Inc. (the “Company,” “bioAffinity,” “we,” or “our”) develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We are advancing research into our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future. We develop proprietary noninvasive diagnostic tests using flow cytometry and automated analysis developed by artificial intelligence (“AI”). Our diagnostic tests analyze cell populations, including cancer and cancer-related cells, that are indicative of a specific diseased state.

We were formed as a Delaware corporation on March 26, 2014. On June 15, 2016, we formed OncoSelect[®] Therapeutics, LLC (“OncoSelect[®]”), a Delaware limited liability company and our wholly owned subsidiary which is a preclinical-stage biopharmaceutical discovery company with a focus on therapeutics that deliver cytotoxic (cell-killing) effects on a broad selection of human cancers from diverse tissues while having little or no effect on normal cells. On August 14, 2023, we formed Precision Pathology Laboratory Services, LLC (“PPLS”), a Texas limited liability company and our wholly owned subsidiary. Research and optimization of our platform technologies for in vitro diagnostics and technologies are conducted in laboratories at The University of Texas at San Antonio and PPLS in San Antonio, Texas.

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

CyPath[®] Lung uses flow cytometry technology to detect and analyze cell populations in a person’s sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories. Flow cytometry collects data pertaining to properties of single cells labeled with antibodies and dyes specific to cell types and characteristics. Sputum is an excellent sample for analysis because

it is in direct contact with any malignancy in the lungs and can provide information about its area of field cancerization and the lung microenvironment. CyPath[®] Lung uses automated data analysis developed by AI that allows an entire sample of sputum averaging 16 million cells to be examined in approximately 30 minutes, allowing for cost-effective, large-scale commercialization.

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

Through OncoSelect[®], our research has led to discoveries of novel potential cancer therapeutics that specifically and selectively target cancer cells that have been grown in petri dishes.

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

Recent Developments

Registered Direct Offering

On March 6, 2024, we raised \$2.5 million in gross proceeds from the sale to four institutional investors of (1) 1,600,000 shares of our Common Stock (the "Shares"), par value \$0.007 per share ("Common Stock") in a registered direct offering, and (2) warrants to purchase an aggregate of 1,600,000 shares of Common Stock (the "Common Warrants") with an exercise price of \$1.64 in a concurrent private placement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed discussion of this transaction.

CPT Code Specific to CyPath[®] Lung for Proprietary Laboratory Analyses

On November 30, 2023, we announced that the Centers for Medicare and Medicaid Services ("CMS") had made a final determination for payment for CyPath[®] Lung, our noninvasive test for early-stage lung cancer, for the 2024 calendar year. Effective January 1, 2024, CyPath[®] Lung is on CMS' 2024 clinical laboratory fee schedule. The CPT Proprietary Laboratory Analyses ("PLA") code assigned to CyPath[®] Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer."

CyPath[®] Lung Branding

In 2023, we developed a series of marketing tools based on branding for CyPath[®] Lung that emphasize our test's ability to assist physicians with next steps in patient care. In January 2024, we began using the new marketing materials with both physicians and patients. The branding concepts were developed by the marketing and advertising firms of Havas Health & You, Trinity Life Sciences, and K2MD to build the CyPath[®] Lung brand and position it for success in the cancer diagnostics sector.

PPLS Passes CAP Inspection

On January 11, 2024, PPLS successfully passed its bi-annual CAP inspection necessary for continuing operations. CAP accreditation ensures that laboratories meet the highest standards of quality and patient care under the Clinical Laboratory Improvement Amendments (CLIA), including personnel qualifications, equipment, facilities, safety protocols, and overall management and quality of testing.

Jamie Platt, PhD, Joins Board of Directors

In December 2023, Jamie Platt, PhD, Managing Director and Chief Executive Officer of Pictor Limited, where she is leading a turnaround by restructuring and accelerating product development, joined the bioAffinity Technologies Board of Directors. Dr. Platt has more than two decades of experience bringing novel diagnostic technologies to global markets. She was instrumental in merger and acquisition exits for two diagnostic companies with a combined value of approximately \$1 billion. She previously was Chief Operating Officer of Personal Genome Diagnostics which was acquired by LabCorp for \$575 million. We believe Dr. Platt's scientific acumen, business leadership, and board experience will contribute to the Company's growth and successful commercialization of CyPath[®] Lung.

Sandeep Bansal, MD, Joins Medical and Science Advisory Board

In February 2024, Sandeep Bansal, MD, Medical Director of Pennsylvania's Lung Innovations Network, joined our Medical and Scientific Advisory Board. Dr. Bansal is Board certified in pulmonary disease, critical care medicine and interventional pulmonology and has also served as principal investigator of multiple clinical research trials and peer reviewer for several medical journals. Lung Innovations Network, a patient-centered practice that offers comprehensive lung care to over 10,000 patients in central and western Pennsylvania, incorporated CyPath[®] Lung into its practice to aid in the detection of early-stage lung cancer in March 2024. We believe Dr. Bansal's experience as both clinician and researcher is an important asset for bioAffinity Technologies.

Continuation of Department of Defense Research

In the fourth quarter of 2023, we began selling CyPath[®] Lung tests to the Department of Defense (DOD) to conduct an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath[®] Lung Assay," and for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. An additional research study was opened by Brooke Army Medical Center in March 2023 to collect bronchoalveolar lavage samples to advance the research and development of a lung cancer test to be used in conjunction with bronchoscopy to improve diagnostic accuracy with combined testing.

Acquisition of Laboratory

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

morphological stains, histological services, DNA extractions, STI testing, and women's and men's health testing.

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

Pursuant to the Asset Purchase Agreement, PPLS assumed all liabilities and obligations and obtained any and all rights, title and interest of Village Oaks in and to (1) all leases for equipment and personal property related to the laboratory assets, pursuant to an Assumption Agreement by and between Village Oaks and PPLS; (2) certain other contracts related to the laboratory assets, including the license to develop, manufacture, use, market, and sell CyPath[®] Lung pursuant to the Assumption Agreement; (3) all accounts payable of Village Oaks as of September 18, 2023, that were incurred in the ordinary course of business consistent with past custom and practice; and (4) the lease of the premises used in connection with operation of the CLIA-certified and CAP-accredited clinical pathology laboratory, pursuant to an Assignment and Assumption of Lease by and between and PPLS.

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

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

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

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

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 22211 West Interstate 10, Suite 1206, San Antonio, Texas 78257, 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 prospectus. Investors should not consider any such information to be part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” (an “*EGC*”) as defined in the Jumpstart Our Business Startups Act of 2012 (the “*JOBS Act*”). As an EGC, for up to five years, we may elect to take advantage of certain specified exemptions from reporting and other regulatory requirements that are otherwise generally applicable to public companies. For example, these exemptions would allow us to:

- present two, rather than three, years of audited financial statements with correspondingly reduced disclosure in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section (the “*MD&A*”) of this prospectus;
- defer the auditor attestation requirement on the effectiveness of our system of internal control over financial reporting;
- make reduced disclosures about our executive compensation arrangements; and
- forego the adoption of new or revised financial accounting standards until they would be applicable to private companies.

Certain of these reduced reporting requirements and exemptions were already available to us due to the fact that we also qualify as a “smaller reporting company” under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding internal control over financial reporting, to provide a compensation discussion and analysis, or to provide a pay-for-performance graph or CEO pay ratio disclosure, and they may present two, rather than three, years of audited financial statements and related MD&A disclosure.

We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our initial public offering or until we are no longer an EGC, which would be the case if (i) our total annual gross revenues are \$1.235 billion or more; (ii) we issue more than \$1 billion in non-convertible debt during a consecutive three-year period; or (iii) we become a “large accelerated filer,” as defined in the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”). We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting obligations in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. For more information, see “Risk Factors—General Risk Factors—*We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.*”

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Summary of Risk Factors

Like any emerging growth company, we face significant risk factors that may impede our plans for successful commercialization of our diagnostic and therapeutic products. These risks are discussed in detail under the “Risk Factors” discussion beginning on page 8 of this prospectus.

The following summarizes the principal factors that make an investment in our Company speculative or risky, all of which are more fully described in the section below titled “Risk Factors.” This summary should be read in conjunction with the section below titled “Risk Factors” and should not be relied upon as an exhaustive summary of the material risks facing our business. The following factors could result in harm to our business, reputation, revenue, financial results, and prospects, among other impacts:

Risks Related to this Offering

- Resales of our Common Stock in the public market as a result of this offering may cause the market price of our Common Stock to fall.
- Investors who buy shares at different times will likely pay different prices.
- This offering may cause the trading price of our Common Stock to decrease.
- Our management will have broad discretion over the use of the net proceeds.

Risks Related to Our Financial Position

- Our business plan relies upon our ability to obtain additional sources of capital and financing.
- We must raise additional capital to fund our operations in order to continue as a going concern.
- Our limited operating history makes it difficult to evaluate our current business and future prospects.
- We will require additional financing to implement our business plan.

Risks Related to the Acquisition of Precision Pathology Laboratory Services (“PPLS”)

- The combined company may not experience the anticipated strategic benefits of the acquisition.
- We may not be able to enforce claims under the Asset Purchase Agreement.
- We are unable to estimate when we will begin to generate significant profit from revenue.
- Operating a clinical laboratory is a new business for us, and we have limited experience doing so.

Risks Related to our Diagnostic Product

- The FDA could promulgate regulations that impose greater regulatory burdens on laboratory developed tests such as CyPath[®] Lung.
- Clinical trials are expensive, time-consuming, and may not be successful.
- Delays or difficulties in the enrollment of patients could delay or prevent the regulatory approvals.

Risks Related to Our Diagnostic Tests

- If our tests do not perform as expected, our operating results, reputation, and business will suffer.
- We may experience delays in development, introduction, or marketing of enhanced or new tests.
- If clinical testing does not yield successful results, we will be unable to commercialize that test or product candidate.
- Even if our tests or products receive marketing approval, they may fail to achieve market acceptance.
- We may not be successful in commercializing our diagnostic tests or therapeutic products.
- We are currently dependent upon PPLS to offer and perform CyPath[®] Lung.
- Market acceptance may depend upon our ability to convince physicians of benefits of our tests or products.
- We face substantial competition.
- Our success depends upon our ability to retain and attract key executives and qualified personnel.
- Our lack of operating experience may make it difficult to manage our growth.
- Failure to comply with obligations imposed by intellectual property licenses could result in loss of rights.
- We may need to obtain additional licenses of technology that may not be available to us.
- We will depend on third parties to manufacture and market our diagnostic tests and to design trial protocols.
- We are exposed to product liability and pre-clinical and clinical liability risks.
- Our failure to comply with privacy and security regulations could result in significant liability.
- Our ability to obtain adequate reimbursement from third-party payors may impact our revenues.
- Our employees, consultants, partners, and vendors may engage in misconduct or other improper activities.
- Failure to comply with healthcare fraud and abuse laws and regulations could result in 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.
- Our competitive position depends on protection of our intellectual property.
- Diagnostic tests and therapeutic products we develop could be subject to infringement claims.
- We may become involved in lawsuits to protect or enforce our intellectual property.
- If we are unable to protect our trade secrets, our business and competitive position could be harmed.
- Disruption of our internal information technology systems will adversely affect our business.
- Declining general economic or business conditions may have a negative impact on our business.
- Global climate change and related regulations could negatively affect our business.

Risks Related to the Operation of a CAP/CLIA Laboratory

- The operations of PPLS depend in part upon Roby Joyce, MD, and his relationship with existing customers.
- PPLS may be unable to effectively maintain equipment.
- We will be adversely impacted if our sole laboratory facility becomes inoperable.
- PPLS relies on commercial courier delivery services to transport sputum samples for CyPath[®] Lung.
- Security breaches, loss of data, and other disruptions could compromise sensitive information.
- If PPLS uses hazardous chemicals in a manner that causes injury, PPLS could be liable for damages.
- If PPLS is unable to scale its operations to support demand for CyPath[®] Lung, its business could suffer.
- Delays of third-party billing and collection providers could have an adverse effect on PPLS.

Risks Related to Intellectual Property Rights

- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- Changes in patent law could impair our ability to protect our tests and product candidates.
- Our patent protection could be impacted by non-compliance with requirements of patent agencies.
- Patent terms may be inadequate to protect our diagnostic tests or therapeutic product candidates.
- Issued patents covering our product candidates could be found invalid or unenforceable if challenged.
- If we do not obtain patent term extension, our business may be harmed.
- We enjoy only limited geographical protection with respect to certain patents.
- If our trademarks and trade names are not adequately protected, we may not be able to build name recognition.

Risks Related to Government Regulations

- Should the FDA disagree that CyPath[®] Lung is an LDT our commercialization strategy may be adversely affected.
- FDA failure to grant our request for de novo classification would adversely affect our business.
- Noncompliance with laws pertaining to LDTs or in vitro devices (“IVDs”) could adversely affect our business.
- The third-party licensors of our future therapeutic products, may be unable to obtain regulatory approval.
- We may fail to obtain regulatory approval in foreign jurisdictions.
- We may never obtain approval or commercialize such products outside of the U.S.
- The impact of healthcare spending and recent healthcare reform legislation is currently unknown.

Risks Related to Ownership of Our Common Stock and Warrants

- We do not expect to pay dividends in the foreseeable future.
- The Warrants may never have a market price that exceeds the exercise price and holders have no rights as stockholders until the warrants are exercised.
- The provisions of the Warrants could limit a holder’s ability to choose a judicial forum for disputes.
- Our failure to file a registration statement to register the Common Stock issuable upon exercise of the Warrants that we issued in March 2024 or to timely hold a stockholders’ meeting to obtain stockholder approval will result in a breach of the Securities Purchase Agreement.
- We may be unable to meet the continued listing requirements of The Nasdaq Capital Market.
- Our stock price has been volatile and thinly traded and may be volatile in the future.
- 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.
- Certain provisions in our Charter and Amended and Restated (“A&R”) Bylaws could make a merger, tender offer, acquisition or proxy contest difficult and have anti-takeover effects.
- Our Charter designates a state or federal court located within Delaware as the exclusive forum for disputes.
- Certain provisions in our Charter and A&R Bylaws may discourage stockholder lawsuit.
- Our management collectively owns a substantial percentage of our Common Stock.
- Any inability to file our financial results accurately and timely could harm our reputation and stock price.

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THE OFFERING

This prospectus relates to the resale or other disposition from time to time by the Selling Stockholders identified in this prospectus of up to 1,632,000 shares of our Common Stock. None of the shares registered hereby are being offered for sale by us.

Shares of Common Stock offered by the Selling Stockholders	1,632,000 shares (consisting of: (i) 1,600,000 shares of our Common Stock issuable upon the exercise of the Common Warrants, and (ii) 32,000 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants).
Common stock to be outstanding after this offering⁽¹⁾	13,146,354 shares of Common Stock, assuming the exercise of all of the Common Warrants and the Placement Agent Warrants
Registration Rights	Under the terms of the Purchase Agreement, we agreed to file this registration statement with respect to the registration of the resale by the Investor Selling Stockholders of the Common Warrant Shares by the 30 th calendar day following the date of the Purchase Agreement, and to use commercially reasonable efforts to have the registration statement declared effective as promptly as practical. In addition, we agreed that, upon the registration statement being declared effective under the Securities Act, we will use commercially reasonable efforts to maintain the effectiveness of the registration statement until the date that (i) the Investor Selling Stockholders has sold all of the Common Warrants and the Common Warrant Shares and (ii) the Placement Agent has sold all of the Placement Agent Warrants and the Placement Agent Warrant Shares.
Use of Proceeds	The Selling Stockholders will receive all of the proceeds of the sale of shares of Common Stock offered from time to time pursuant to this prospectus. Accordingly, we will not receive any proceeds from the sale of shares of Common Stock that may be sold from time to time pursuant to this prospectus; however, we will receive proceeds from the any cash exercise of the Common Warrants and the Placement Agent Warrants. See “Use of Proceeds.” We intend to use the proceeds from the any cash exercise of the Common Warrants and the Placement Agent Warrants for working capital purposes.
Plan of Distribution	The Selling Stockholders named in this prospectus, or their pledgees, donees, transferees, distributees, beneficiaries or other successors-in-interest, may offer or sell the shares of Common Stock offered hereby from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The Selling Stockholders may also resell the shares of Common Stock to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions.
Risk Factors	See “Risk Factors” beginning on page 8 of this prospectus and in the documents incorporated by reference in this prospectus and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.
Nasdaq Capital Market trading symbol	Our Common Stock is listed on the Nasdaq Capital Market under the symbol “BIAF.” Our tradeable warrants are listed on the Nasdaq Capital Market under the symbol “BIAFW.”

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus may contain “forward-looking statements” within the meaning of the federal securities laws. Our forward-looking statements include, but are not limited to, statements about us and our industry, as well as statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. Additionally, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. We intend the forward-looking statements to be covered by the safe harbor provisions of the federal securities laws. Words such as “may,” “should,” “could,” “would,” “predicts,” “potential,” “continue,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” and similar expressions, as well as statements in future tense, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management’s good faith belief as of that time with respect to

future events, and are subject to significant risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

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

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

Website and Social Media Disclosure

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

RISK FACTORS

Investing in our Company involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Prospectus before deciding to invest in our Company. The occurrence of any of the following risks could have a material and adverse effect on our business, reputation, financial condition, results of operations, and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the market value of our Common Stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and market value.

Risks Related to this Offering

Resales of our Common Stock in the public market by our stockholders as a result of this offering may cause the market price of our Common Stock to fall.

We are registering Common Stock issuable upon the exercise of the Common Warrants and Placement Agent Warrants. Sales of substantial amounts of our Common Stock in the public market, or the perception that such sales might occur, could adversely affect the market price of our Common Stock. The issuance of new shares of Common stock could result in resales of our Common Stock by our current stockholders concerned about the potential ownership dilution of their holdings. Furthermore, in the future, we may issue additional shares of Common Stock or other equity or debt securities exercisable or convertible into Common Stock. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Investors who buy shares at different times will likely pay different prices.

Investors who purchase shares in this offering at different times will likely pay different prices, and so may experience different levels of dilution and different outcomes in their investment results.

This offering may cause the trading price of our Common Stock to decrease.

The price per share of our Common Stock, together with the number of shares of Common Stock we propose to issue upon exercise of the Common Warrants and Placement Agent Warrants and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our Common Stock. This decrease may continue after the completion of this offering. Sales of substantial amounts of our Common Stock in the public market, or the perception that such sales might occur, could adversely affect the market price of our Common Stock.

Our management will have broad discretion over the use of the net proceeds from this offering, you may not agree with how we use the proceeds, and the proceeds may not be invested successfully.

We have not designated any portion of the net proceeds from the exercise of Common Warrants and Placement Agent Warrants to be used for any particular purpose. Accordingly, our management will have broad discretion as to the use of the net proceeds and you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest the net proceeds in a way that does not yield a favorable, or any, return for our company. Our management's judgment may not result in positive returns on your investment and you will not have the opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

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, 2023, and December 31, 2022, we generated revenue of approximately \$2.5 million and \$5,000, respectively. During the year ended December 31, 2023, we generated \$2.2 million from laboratory patient services (of which approximately \$37,000 related to our first diagnostic test, CyPath[®] Lung), and approximately \$273,000 from histology laboratory test, approximately \$19,000 from medical director fees, and in connection with CyPath[®] Lung tests purchased by the DOD in the approximate amount of \$19,000 for an observational study.

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);

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

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

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

As of December 31, 2023, we had an accumulated deficit of \$44.6 million and \$2.8 million cash on hand. For the year 2023, cash used in operations was \$6.0 million and net loss was \$7.9 million. Despite raising an additional \$2.5 million in gross proceeds in March 2024 through the offering of our securities, 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 September 2024. 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, 2023, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2023, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

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

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

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

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

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

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

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

Risks Related to the Acquisition

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

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

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

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

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

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

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

We have never operated a clinical laboratory. To date, only our Chief Operating Officer, Xavier Reveles, has operated a CAP-accredited, CLIA-certified clinical laboratory and

therefore it may be difficult for investors to analyze our ability to successfully operate a clinical laboratory. Our management team may not successfully or efficiently manage our transition to operating a CAP-accredited and CLIA-certified laboratory subject to significant regulatory oversight and reporting obligations. However, to ease the transition, Roby Joyce, MD, the Medical Director and Laboratory Director of Village Oaks prior to the acquisition, continues to serve as the Medical Director and Laboratory Director of PLS. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition, and operating results.

Risks Related to our Diagnostic Product

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

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

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

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

Patient enrollment is affected by many other factors, including:

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

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

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

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

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

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

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate; or
- regulators may revise the requirements for approving our diagnostic or therapeutic technologies, or such requirements may not be as we anticipate.

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

- be delayed in obtaining marketing approval;

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

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

Risks Related to Our Diagnostic Tests

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

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

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

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

We cannot be certain that:

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

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

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

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

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

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

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

- their efficacy, safety, and other potential advantages compared to alternative tests or products;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative diagnostics or treatments;

- the willingness of the target patient population to try new diagnostic tests and of physicians to order these tests;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of governmental agencies and third-party medical insurance and adequate reimbursement for our diagnostic tests or therapeutic products;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other diagnostic methods or therapeutic treatments;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other medications;
- inability of certain types of patients to produce adequate samples for analysis in the use of our diagnostic tests;
- inability of certain types of patients to use our diagnostic tests or take our therapeutic products; and
- the prevalence and severity of side effects from our therapeutic products.

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

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

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of our diagnostic tests and therapeutic products. To achieve commercial success for any diagnostic test or therapeutic product for which we obtain marketing approval, we will need to successfully establish and maintain relationships directly and with third parties to perform sales and marketing functions.

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

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

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

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

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

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

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

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

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

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic tests or therapeutic products that are more accurate, more

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

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

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

We are highly dependent on the principal members of our management, scientific, and clinical teams, including Maria Zannes, JD, our President and Chief Executive Officer, Vivienne Rebel, MD, PhD, our Chief Science and Medical Officer and Executive Vice President, Xavier Reveles, MS, CG(ASCP)^{cm}, our Chief Operating Officer, and Michael Dougherty, CPA, MBA, our Chief Financial Officer, as well as Roby Joyce, MD, the Medical Director and Laboratory Director of PPLS and the principal of Village Oaks.

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.

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. We had previously been granted a license from Village Oaks to use its intellectual property, pursuant to a joint development and project agreement, to develop CyPath[®] Lung for commercialization. In connection with the acquisition of PPLS, Village Oaks assigned its rights pursuant to such joint development and project agreement to PPLS, as well as the intellectual property that is the subject of our license under such agreement. 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 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 our 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 these patent rights 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 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, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the U.S. and similar foreign fraudulent misconduct laws; or (5) report financial information or data accurately or to disclose unauthorized activities to us.

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

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

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

We face intense competition in the biotechnology and pharmaceutical industries.

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

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

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

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

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

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

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

Our competitive position depends on protection of our intellectual property.

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

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

The patent applications we file, including applications that will follow the filing of provisional patents, may not issue as patents or the claims of any issued patents may not

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

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

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

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

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

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

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

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

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

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

Declining general economic or business conditions may have a negative impact on our business.

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

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

Actual events involving reduced or limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain, and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants, such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

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

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

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

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

Risks Related to the Operation of a CAP/CLIA Laboratory

The operations of PPLS will depend in part upon Roby Joyce, MD, and his relationship with existing customers and our ability to establish relationships with these customers.

PPLS' future success will depend in significant part upon the continued relationships with existing customers, many of whom have developed professional relationships with Roby Joyce, MD. While Dr. Joyce is the Medical Director and Laboratory Director of PPLS and a member of our Board of Directors, we cannot assure you that we will be able to retain his services. Although we have entered into a three-year employment agreement with him, there can be no assurance that the agreement will not be terminated prior to its expiration. We do not have an insurance policy on the life of Dr. Joyce, and we do not have "key person" life insurance policies for any of our other officers or advisors. The loss of the technical knowledge and management and industry expertise of Dr. Joyce or any of our key personnel could result in delays in services, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results.

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

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

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

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

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

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

is inoperable would significantly impact our ability to generate revenue.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Several factors make the billing process complex, including:

- the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing Medicare;

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

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

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

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

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

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

Risks Related to Intellectual Property Rights

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

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

- others may be able to make diagnostic tests and therapeutic product candidates that are the same as or similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the U.S. Patent and Trademark Office ("USPTO") and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment, and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests and products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that are directed to our diagnostic tests and product candidates or uses thereof in the U.S. or foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing diagnostic tests and product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; and
- if enforced, a court may not hold that our patents are valid, enforceable, and infringed.

Changes in patent law in the United States 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 includes 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 medications, including generic medications. Given the amount of time required for the development, testing, and regulatory review and approval of new diagnostic test or therapeutic product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests and therapeutic products similar or identical to ours.

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

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

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

In the U.S., a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration, and conditions of FDA marketing authorization of our diagnostic tests or therapeutic product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), which permits a patent term extension of up to five years for a patent covering an approved diagnostic test or therapeutic product as

compensation for effective patent term lost during diagnostic test or therapeutic product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of diagnostic test or therapeutic product approval, and only claims covering such approved diagnostic test or drug product, a method for using it, or a method for manufacturing it may be extended. In Europe, our diagnostic test or therapeutic product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Even if we are granted such an extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened, and our competitors may obtain approval to market competing diagnostic tests or products sooner. The resulting reduction of years of revenue from applicable diagnostic tests or products could be substantial.

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

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

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

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

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

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

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

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

Risks Related to Government Regulations

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

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

In September 2023, the FDA announced a proposed rule to ensure the safety and effectiveness of LDTs by amending regulations to explicitly say that IVDs offered as LDTs fall under the FDCA and phase out its general enforcement discretion approach for most LDTs. The proposed policy makes it clear that the FDA intends to provide greater

oversight of LDTs. The FDA plans to finalize its ruling in April 2024 and initiate a phased implementation process in which it will require laboratories to register their LDTs and begin the premarket review process over the next four years. Any future rulemaking, guidance, or other oversight of LDTs and clinical laboratories that develop and perform them, if and when finalized, may affect the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws.

There have been numerous legislative proposals to clarify the FDA's regulatory authority over medical devices. In 2021, two bills were reintroduced in the U.S. Congress: the Verifying Accurate, Leading-edge IVCT Development Act of 2020 (the "VALID Act"), which would have expressly granted the FDA authority to regulate LDTs under a risk-based framework; and the Verified Innovative Testing in American Laboratories Act of 2020 (the "VITAL Act"), which would have assigned LDTs to regulation solely under CLIA and would have directed CMS to update its CLIA regulations. Neither of these bills were enacted. The VALID Act was reintroduced in March 2023. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business.

Enactment of legislation directing FDA to regulate LDTs or promulgation of new regulations for LDT oversight by FDA could materially and adversely affect our business, financial condition, and results of operations. If FDA premarket review, classification, or approval is required for CyPath[®] Lung before we obtain *de novo* classification, our phased strategy for market entry would be adversely affected. Our laboratory licensee, PPLS, could be forced to stop offering CyPath[®] Lung as an LDT while we work to obtain *de novo* classification. Our business, results of operations, and financial condition would be negatively affected unless and until such review were completed and our request for *de novo* classification were granted.

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

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

The FDCA requires that medical devices introduced to the U.S. market, unless exempted by regulation, be authorized by the FDA pursuant to either the premarket notification pathway, known as 510(k) clearance, the *de novo* classification pathway, or the premarket approval ("PMA") pathway. We plan to seek *de novo* classification for the CyPath[®] Lung test in the second quarter of 2026. The FDA may not agree that CyPath[®] Lung meets the criteria for *de novo* classification, in which case we would be required to submit a PMA to obtain marketing authorization, which would require manufacturing information and a pre-approval inspection of the manufacturing facilities and could require review by an FDA advisory panel comprised of experts outside the FDA. Any delay by or failure of the FDA to grant our *de novo* request or PMA could adversely affect our consolidated revenues, results of operations and financial condition.

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

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

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

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

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

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

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

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

- the inability of our licensors to satisfactorily demonstrate that the product candidates have acceptable safety and efficacy profiles for the requested indication;
- the FDA's disagreement with the trial designs of our licensors or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- the licensors' inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;

- the FDA’s determination that additional preclinical or clinical trials are required;
- the FDA’s non-approval of the formulation, labeling, or specifications of our product candidates;
- the FDA’s failure to accept the manufacturing processes, drug product characteristics, or facilities of third-party manufacturers with which we or the third-party licensors contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering clinical data related to any therapeutic product candidate insufficient for approval.

Even if clinical testing approval of any regulatory filing for our product candidates eventually is completed, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than the third party originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If the FDA requires the licensors to narrow the indications to smaller patient subsets, the market opportunities for our product candidates, if approved, and the ability to generate revenues and royalties may be materially limited. To the extent the licensors seek 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. Approval 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 diagnostic tests or therapeutic product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

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

The impact of recent healthcare reform legislation, other changes in the healthcare industry, and in healthcare spending is currently unknown and may adversely affect our business model.

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

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

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

- the level of taxes that we are required to pay; and
- the availability of capital.

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

Risks Related to Ownership of Our Common Stock and Warrants

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

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

Our Warrants may never have a market price that exceeds the exercise price.

Each Tradeable Warrant and Non-Tradeable Warrant that we issued in our initial public offering has an exercise price of \$3.0625. Each Common Warrant that we issued in March 2024 has an exercise price equal to \$1.64. In the event our Common Stock price does not exceed the exercise price of the Warrants during the period when they are exercisable, the Warrants may not have any value.

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

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

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

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

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

Our failure to file a registration statement to register the shares of Common Stock issuable upon exercise of the Warrants that we issued in March 2024, or to timely hold a stockholders’ meeting to obtain stockholder approval of the issuance of shares of Common Stock upon the exercise of the Warrants that we issued in March 2024, will result in a breach of the terms of the Securities Purchase Agreement.

Pursuant to the terms of the Securities Purchase Agreement that we entered into with certain purchasers in March 2024, we are obligated to file a registration statement to register the shares of Common Stock issuable upon exercise of the Warrants within 30 days of the date of such agreement and to use commercially reasonable efforts to keep the registration statement effective at all times while the purchasers own any Warrants or shares of Common Stock issuable upon exercise of the Warrants. We are also obligated to hold a stockholders’ meeting 90 days after the closing date and, if approval is not obtained at the shareholders meeting, every three months thereafter seeking approval of the exercise of the Warrants issued to the Purchasers. The failure to take any of these actions will constitute a default under the Securities Purchase Agreement.

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

The projections that we provide herein or our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, regulatory, 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 failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.

The shares of our Common Stock are listed for trading on The Nasdaq Capital Market under the symbol “BIAF” and our Tradeable Warrants are listed under the symbol “BIAFW.” If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, the stockholder’s equity

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

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

Our 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;

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- 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.

The formation of our Company, as well as 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; 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our Common Stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Certain provisions in our Charter and A&R Bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our Common Stock.

Our Charter and A&R Bylaws contain provisions that could depress the trading price of our Common Stock by acting to discourage, delay, or prevent a change of control of our Company or changes in our management that the stockholders of our Company may deem advantageous. These provisions include the following:

- permit the Board to establish the number of directors and fill any vacancies and newly created directorships;
- authorize the issuance of “blank check” preferred stock that our Board could use to implement a stockholder rights plan;
- prohibit stockholders from calling special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the Board is expressly authorized to adopt, amend, alter, or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

Based on the provisions for determining beneficial ownership in accordance with Rule 13d-3 and Item 403 of Regulation S-K under the Exchange Act, immediately after this Offering, our officers and directors will own or exercise control of approximately 36% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

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

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

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

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

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

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

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DESCRIPTION OF THE PRIVATE PLACEMENT

On March 6, 2024, we entered into a Purchase Agreement with the Investor Selling Stockholders, pursuant to which we issued to the Investor Selling Stockholders, (i) in a registered direct offering, 1,600,000 shares of Common Stock and (ii) in a concurrent private placement, warrants to purchase an aggregate of 1,600,000 shares of Common Stock with an exercise price of \$1.64. Such registered direct offering and concurrent private placement are referred to herein as the “Transactions.”

The Company received aggregate gross proceeds from the Transactions of approximately \$2.5 million, before deducting fees to the Placement Agent and other estimated offering expenses payable by the Company. The securities were offered by the Company pursuant to a shelf registration statement on Form S-3 (File No. 333-275608), which was declared effective on November 27, 2023 (as amended from time to time, the “Registration Statement”). The Common Warrants and the Common Warrant Shares were issued in a concurrent private placement and had not been registered under the Securities Act, and were instead offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. The registration statement of which this prospectus forms a part registers the resale of Common Warrant Shares. The Common Warrants will be exercisable commencing on the Stockholder Approval Date and will expire on the fifth anniversary of the Stockholder Approval Date.

WallachBeth acted as the placement agent on a “reasonable best efforts” basis, in connection with the Transactions pursuant to the Placement Agency Agreement, by and between the Company and the Placement Agent. Pursuant to the Placement Agency Agreement, the Placement Agent will be entitled to a cash fee of 9.0% of the aggregate gross proceeds paid to the Company for the securities sold in the Transactions and reimbursement of certain out-of-pocket expenses. As additional compensation to the Placement Agent, in connection with the Transactions, the Company issued to the Placement Agent or its designees the Placement Agent Warrants to purchase an aggregate of 32,000 shares of Common Stock, such number of shares equal to two percent (2.0%) of the number of shares of Common Stock issued in the registered direct offering, at an exercise price per share equal to \$1.64, which is equal to the exercise price of the Common Warrants. The registration statement of which this prospectus forms a part registers the resale of Placement Agent Warrant Shares.

We agreed to file a registration statement to register the resale of the Common Warrant Shares and the shares of Common Stock issuable upon exercise of the Placement Agent Warrant (the “Placement Agent Warrant Shares”) within 30 days of the date of the Purchase Agreement and to use commercially reasonable efforts to keep such registration statement effective at all times until no Purchaser owns any Warrants or Warrant Shares and until the Placement Agent does not own the Placement Agent Warrant or any Placement Agent Warrant Shares.

Pursuant to the terms of the Purchase Agreement, until 60 days following the closing of the Transactions, we agreed not to issue (or enter into any agreement to issue) any shares of Common Stock or Common Stock equivalents, subject to certain exceptions. We further agreed not to enter into an agreement involving a variable rate transaction until 12 months following the closing of the Transaction, provided however that the prohibition on “at-the-market offerings” and the issuance of Common Stock pursuant to an equity line of credit shall expire on the six-month anniversary of the closing date of this offering. In addition, our Chief Executive Officer and each of the Company’s directors have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 60 days from the closing of the Transactions, offer, sell, transfer or otherwise dispose of the Company’s securities, subject to certain exceptions. In addition, from the date of the Purchase Agreement until the date that is nine (9) months after the date of the Purchase Agreement, upon any issuance by the Company or any of its subsidiaries of Common Stock, Common Stock equivalents for cash consideration, Indebtedness (as defined in the Purchase Agreement) or a combination of units thereof for capital raising purposes other than an at-the-market offering (a “Subsequent Financing”), the Investor Selling Stockholders shall have the right to participate in the Subsequent Financing in an amount up to the percentage of such Purchaser’s participation in the Transactions on the same terms, conditions and price provided for in the Subsequent Financing.

Support Agreements

Certain of our stockholders holding in excess of 21% of our outstanding shares of Common Stock have entered into a Support Agreement, pursuant to which such stockholders have agreed, at every meeting of the holders of our Common Stock that our stockholders are requested to vote upon a proposal to approve the exercise in full of the Common Warrants and the issuance of the Common Warrant Shares upon exercise of the Common Warrants (the “Warrant Exercise Proposal”), to vote all of the shares of Common Stock that they own in favor of the Warrant Exercise Proposal as well as any proposal to approve an adjournment of any such meeting of the Company’s stockholders for purposes of obtaining further votes in favor of the Warrant Exercise Proposal that are at any time or from time to time presented for consideration to the Company’s stockholders.

Terms of the Warrants

The Common Warrants are exercisable commencing on the effective date of the Stockholder Approval Date and will expire on the fifth anniversary of the Stockholder Approval Date. If at any time after 90 days from the closing of the offering a registration statement registering the issuance of the shares of Common Stock underlying the Common Warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the Common Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in such warrant.

The exercise price of the Common Warrants, and the number of Common Warrant Shares, is subject to adjustment in the event of any stock dividend or split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Common Warrants.

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A holder does not have the right to exercise any portion of the Common Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of such warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

In the event of a Fundamental Transaction (as such term is defined in the Common Warrant), then the successor entity will succeed to, and be substituted for the Company, and

may exercise every right and power that the Company may exercise and will assume all of its obligations under the Common Warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of Common Stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Common Warrants following such Fundamental Transaction. In addition, the successor entity, at the request of holders of Common Warrants, will be obligated to purchase any unexercised portion of the Common Warrants in accordance with the terms thereof. Notwithstanding the foregoing, in the event of a Fundamental Transaction, the holders of the Common Warrants have the right to require the Company or a successor entity to redeem the Common Warrants for cash in the amount of the Black Scholes Value (as defined in the Common Warrant) of the unexercised portion of the Common Warrants concurrently with or within 30 days following the consummation of a Fundamental Transaction. However, in the event of a fundamental transaction which is not in our control, including a Fundamental Transaction not approved by the Company's board of directors, the holders of the Common Warrants will only be entitled to receive from the Company or its successor entity, as of the date of consummation of such Fundamental Transaction, the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the Common Warrant that is being offered and paid to the holders of Common Stock in connection with the Fundamental Transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our Common Stock are given the choice to receive alternative forms of consideration in connection with the Fundamental Transaction.

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

The Placement Agent Warrant terms are similar to those of the Common Warrants.

USE OF PROCEEDS

The Selling Stockholders will receive all of the proceeds of the sale of shares of Common Stock offered from time to time pursuant to this prospectus. Accordingly, we will not receive any proceeds from the sale of shares of Common Stock that may be sold from time to time pursuant to this prospectus; however, we will receive proceeds from the cash exercise of the Common Warrants and Placement Agent Warrants. We currently intend to use these net proceeds for general corporate purposes, which may include operating expenses, research and development, including clinical and pre-clinical testing of our product candidates, working capital, future acquisitions and general capital expenditures. We have not determined the amount of net proceeds to be used specifically for any of such purposes.

The expected use of net proceeds from the cash exercise of the Common Warrants and Placement Agent Warrants represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve and change. The amounts and timing of our actual expenditures, specifically with respect to working capital, may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We have no current agreements, commitments or understandings for any material acquisitions or licenses of any products, businesses or technologies that are definitive or probable to close.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our Common Stock to be sold by the Selling Stockholders pursuant to this prospectus. Other than registration expenses, the Selling Stockholders will bear any underwriting discounts, commissions, placement agent fees or other similar expenses payable with respect to sales of shares of our Common Stock.

DILUTION

If you purchase Common Stock in this offering, your interest will be diluted immediately to the extent of the difference between the exercise price of the Common Warrants and Placement Agent Warrants and the pro forma as adjusted net tangible book value per share of our Common Stock immediately following this offering. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the number of outstanding shares of our common stock. As of December 31, 2023, we had a net tangible book value of approximately \$2.6 million or \$0.28 per share of common stock.

Our pro forma net tangible book value as of December 31, 2023 was approximately \$4.6 million or \$0.40 per share of common stock. Pro forma net tangible book value represents net tangible book value adjusted to take into account the issuance, subsequent to December 31, 2023, of: (i) an aggregate of 344,251 shares of Common Stock to directors, officers, employees and consultants subsequent to December 31, 2023; (ii) 64,848 shares of Common Stock to a director on February 26, 2024 pursuant to the exercise of stock options and our receipt of \$74,899 in cash proceeds; and (iii) 1,600,000 shares of Common Stock to investors in a registered direct offering and our receipt of \$1,955,000 in net proceeds.

After giving effect to our issuance of 1,632,000 shares of Common Stock upon the assumed exercise of the Common Warrants and Placement Agent Warrants at an exercise price of \$1.64 per share, our pro forma as adjusted net tangible book value as of December 31, 2023 would have been \$7.2 million, or \$0.63 per share. This represents an immediate increase in net tangible book value of \$0.23 per share to existing stockholders and an immediate dilution in net tangible book value of \$1.01 per share to investors purchasing from the Selling Stockholders.

The following table illustrates the per share dilution to investors purchasing shares in the offering and is based on 9,505,255 shares outstanding as of December 31, 2023, including 110,644 shares of unvested restricted Common Stock, 11,514,354 shares of Common Stock outstanding as of March 29, 2024, including 297,862 shares of unvested restricted Common Stock, and, for the pro forma as adjusted, the issuance of 1,632,000 shares of Common Stock upon the assumed exercise of the Common Warrants and Placement Agent Warrants:

Exercise price of Common Warrants and Placement Agent Warrants	\$	1.64
Net tangible book value per share as of December 31, 2023	\$	0.28
	\$	0.40
Pro forma net tangible book value per share		
Increase in net tangible book value per share attributable to this offering	\$	0.23
Pro forma as adjusted net tangible book value per share after this offering	\$	0.63
Dilution in net tangible book value per share to investors purchasing from Selling Stockholders	\$	1.01

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of shares of the Company's Common Stock as of April 4, 2024, by (1) each person known to the Company to beneficially own more than 5% of any class of the Company's outstanding voting securities, (2) each director and nominee for director, (3) each of our named executive officers, and (4) all of the Company's directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days. In computing the number of shares beneficially owned by a person or entity and the percentage ownership of that person or entity in the table below, all shares subject to options and warrants were deemed outstanding if such securities are currently exercisable or will vest within 60 days of the filing of this Proxy Statement. These shares were not deemed outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

The percentage of beneficial ownership of the Company's Common Stock is based on 11,514,354 shares of Common Stock outstanding as of April 4, 2024.

Unless otherwise indicated, the Company believes that each person named in the table below has sole voting and investment power with respect to all shares of Common Stock beneficially owned by such person.

Name and Address ⁽¹⁾	Number of Shares of Common Stock	Percent of Class
Directors and Executive Officers:		
Maria Zannes ⁽²⁾	285,928	2.46%
Michael Dougherty ⁽³⁾	84,203	*
Steven Girgenti ⁽⁴⁾	1,104,742	*%
Robert Anderson ⁽⁵⁾	181,135	9.51%
Stuart Diamond ⁽⁶⁾	84,148	1.57%
Jamie Platt	12,668	*
Peter Knight ⁽⁷⁾	143,942	1.24%
Gary Rubin ⁽⁸⁾	1,720,800	14.90%
Roby Joyce ⁽⁹⁾	607,665	5.28%
All Directors and Current Executive Officers as a Group (12 Individuals):		
	4,381,875	36.44%
Five Percent Holders:		
The Harvey Sandler Revocable Trust ⁽¹⁰⁾	1,584,144	13.76%
The Joyce Living Trust ⁽¹¹⁾	583,130	5.06%

* Ownership of less than 1%.

- (1) Unless otherwise indicated, the address for each person is c/o bioAffinity Technologies, Inc., 22211 West Interstate 10, Suite 1206, San Antonio, Texas, 78257.
- (2) Includes (i) 39,998 shares of Common Stock owned by Ms. Zannes of record or beneficially; (ii) 124,660 shares of Common Stock issued to Ms. Zannes as restricted stock; and (iii) 121,270 shares of Common Stock issuable upon exercise of options that are immediately exercisable. Does not include the following outstanding warrants that were amended by the Warrant Amendment and therefore are not exercisable: (i) 23,571 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$6.125 per share; and (ii) 79,997 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625 per share.
- (3) Includes 84,203 shares issued to Mr. Dougherty as restricted stock.
- (4) Includes (i) 831,130 shares of Common Stock owned by Mr. Girgenti of record or beneficially; (ii) 160,528 shares of Common Stock issued to Mr. Girgenti as restricted stock; (iii) 8,955 shares of Common Stock owned directly by the Cranye Girgenti Testamentary Trust, for which Mr. Girgenti serves as trustee; and (iv) 104,129 shares of Common Stock issuable upon exercise of options that are immediately exercisable. Does not include the following outstanding warrants that were amended by the Warrant Amendment and therefore are not exercisable: (i) 345,252 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$6.125 per share; (ii) 123,811 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share; (iii) 200,486 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625 per share; (iv) 5,952 shares of Common Stock underlying warrants having an exercise price of \$6.125 per share held by the Cranye Girgenti Testamentary Trust; and (v) 2,380 shares of Common Stock underlying warrants having an exercise price of \$5.25 per share held by the Cranye Girgenti Testamentary Trust.
- (5) Includes (i) 4,081 shares of Common Stock owned by Mr. Anderson of record or beneficially; (ii) 117,775 shares of Common Stock issued to Mr. Anderson as restricted stock; (iii) 39,281 shares of Common Stock issuable upon exercise of options that are immediately exercisable; and (iv) 19,998 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625.
- (6) Includes (i) 4,081 shares of Common Stock owned by Mr. Diamond of record or beneficially; (ii) 52,927 shares of Common Stock issued to Mr. Diamond as restricted stock; (iii) 7,142 shares of Common Stock issuable upon exercise of options that are immediately exercisable; and (iv) 19,998 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625.
- (7) Includes (i) 22,448 shares of Common Stock owned directly by Mr. Knight of record; (ii) 452,927 shares of Common Stock issued to Mr. Knight as restricted stock; (iii) 28,568 shares of Common Stock issuable upon exercise of options that are immediately exercisable; and (iv) 39,999 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625 per share.
- (8) Includes (i) 51,590 shares of Common Stock owned directly by Mr. Rubin of record; (ii) 52,927 shares of Common Stock issued to Mr. Rubin as restricted stock; (iii) 32,139 shares of Common Stock issuable upon exercise of options that are immediately exercisable and (iv) 1,584,144 shares of Common Stock owned by the Harvey Sandler Revocable Trust, for which Mr. Rubin serves as co-trustee. Does not include the following outstanding warrants that were amended by the Warrant Amendment and therefore are not exercisable: (i) 12,241 shares of Common Stock underlying warrants with a term of five years having an exercise price \$6.125 per share; (ii) 4,896 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share; (v) 408,125 shares of Common Stock underlying warrants with a term of five years having an exercise price \$6.125 per share held by the Harvey Sandler Revocable Trust; (vi) 163,248 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share held by the Harvey Sandler Revocable Trust; (vii) 79,997 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625 per share held by the Harvey Sandler Revocable Trust.

- (9) Includes (i) 583,130 shares of Common Stock owned by the Joyce Living Trust. Dr. Joyce is co-trustee of the Joyce Living Trust, together with his wife, Joyce M. Joyce, each of whom may act unilaterally with regard to voting and disposition power over the shares held by the Joyce Living Trust. The Joyce Living Trust has an address at 1092 Madeline Street, New Braunfels, Texas 78132, and (ii) 24,535 shares of Common Stock issued to Dr. Joyce as restricted stock. Does not include 19,999 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share that were amended by the Warrant Amendment and therefore are not exercisable.
- (10) Includes 1,584,144 shares of Common Stock owned by the Trust either of record or beneficially. Does not include the following outstanding warrants that were amended by the Warrant Amendment and therefore are not exercisable: (i) 408,125 shares of Common Stock underlying warrants with a term of five years having an exercise price \$6.125 per share; (ii) 163,248 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share; (iii) 79,997 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$3.0625.
- (11) Includes 583,130 shares of Common Stock owned by the Joyce Living Trust. Dr. Joyce is co-trustee of the Joyce Living Trust, together with his wife, Joyce M. Joyce, each of whom may act unilaterally with regard to voting and disposition power over the shares held by the Joyce Living Trust. The Joyce Living Trust has an address at 1092 Madeline Street, New Braunfels, Texas 78132. Does not include 19,999 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share that were amended by the Warrant Amendment and therefore are not exercisable.

SELLING STOCKHOLDERS

The shares Common Stock being offered by the Selling Stockholders are those issuable to the Investor Selling Stockholders upon exercise of the Common Warrants and those issuable to designees of the Placement Agent upon exercise of the Placement Agent Warrants. For additional information regarding the issuances of the Common Warrants and the Placement Agent Warrants, see “Description of the Private Placement” above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares of Common Stock for resale from time to time. Except for the ownership of the Common Warrants and the shares of Common Stock issued in the registered direct offering and shares of Common Stock and warrants purchased in our initial public offering, the Investor Selling Stockholders have not had any material relationship with us within the past three years. WallachBeth Capital LLC served as the underwriter for our initial public offering that closed on September 6, 2022 and received cash compensation and warrants were issued to its designees to purchase up to 25,652 shares of Common Stock. In addition, WallachBeth Capital LLC served as our placement agent in connection with our sale of convertible bridge notes in 2021 and 2022 and received compensation that included a warrant to purchase 29,464 shares of Common Stock. Except as described above, WallachBeth Capital LLC and its designees have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by the Selling Stockholders, based on its ownership of the shares of Common Stock, the Common Warrants and the Placement Agent Warrants, as of April 4, 2024, assuming exercise of the Common Warrants and Placement Agent Warrants held by the Selling Stockholders on that date, without regard to any limitations on exercises.

The third column lists the maximum number of shares of Common Stock being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of the Purchase Agreement with the Investor Selling Stockholders and an agreement with WallachBeth, this prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon exercise of the Common Warrants and the Placement Agent Warrants, determined as if the outstanding Common Warrants and Placement Agent Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration right agreement, without regard to any limitations on the exercise of the Common Warrants and the Placement Agent Warrants. The fourth and fifth columns assume the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

Under the terms of the Common Warrants and the Placement Agent Warrants, the Selling Stockholders may not exercise the Common Warrants or the Placement Agent Warrants to the extent such exercise would cause such Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock that would exceed 4.99%, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such warrants which have not been exercised. The number of shares in the second and fourth columns do not reflect this limitation. The Selling Stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Stockholders	Number of Shares of Common Stock Beneficially Owned Prior to Offering⁽¹⁾	Maximum Number of Shares of Common Stock to be Sold in this Offering	Number of Shares of Common Stock Beneficially Owned After Offering	Percentage of Shares Beneficially Owned after Offering⁽¹⁾
Ionic Ventures, LLC ⁽¹⁾⁽²⁾	533,333	533,333	0	—
District 2 Capital Fund LP ⁽¹⁾⁽³⁾	533,333	266,667	382,738	2.89%
Bigger Capital Fund, LP ⁽¹⁾⁽⁴⁾	533,333	266,667	382,738	2.89%
L1 Capital Global Opportunities Master Fund ⁽¹⁾⁽⁵⁾	533,333	533,333	0	—
Douglas Bantum ⁽⁶⁾⁽⁷⁾	30,467	12,320	18,147	*
Michael Wallach ⁽⁶⁾⁽⁸⁾	20,162	7,200	12,962	*
Kenneth Bantum ⁽⁶⁾⁽⁹⁾	6,529	2,640	3,889	*
Gene McNeil ⁽⁶⁾⁽¹⁰⁾	6,529	2,640	3,889	*
David Beth ⁽⁶⁾⁽¹¹⁾	20,162	7,200	12,962	*

* Ownership of less than 1%.

- (1) The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which in each case restricts the Investor Selling Stockholders from exercising that portion of the warrants that would result in the Investor Selling Stockholders and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation. The number of shares set forth in the above table does not reflect the application of this limitation.
- (2) Consists of Common Warrants to purchase 533,333 shares of Common Stock. Brendan O’Neil and Keith Coulston are the managers of Ionic Ventures, LLC and in such capacity have joint voting and dispositive power over shares held by Ionic Ventures, LLC. Mr. O’Neil and Mr. Coulston each disclaim beneficial ownership of the reported securities except to the extent of their pecuniary interest therein. Ionic Ventures, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer. The business address of Ionic Ventures, LLC is 3053 Fillmore Street, Ste. 256, San Francisco, CA 94123.

- (3) Consists of (i) 266,667 shares of Common Stock; (ii) Common Warrants to purchase 266,667 shares of Common Stock; and (iii) warrants to purchase 116,071 shares of Common Stock. Michael Bigger is the managing member of District 2 Holdings LLC, which is the managing member of District 2 GP LLC, the general partner of District 2 Capital Fund LP and has voting control and investment discretion over securities helpfully owned directly by District 2 Capital Fund LP. Michael Bigger is the managing member of Bigger Capital Fund GP, LLC, the general partner of Bigger Capital Fund, LP and has voting control and investment discretion over securities beneficially owned directly by Bigger Capital Fund, LP. In such roles, Mr. Bigger may be deemed to beneficially own the securities owned by District 2 Capital Fund LP and Bigger Capital Fund, LP. We have been advised that none of Mr. Bigger or District 2 Capital Fund LP is a member of the Financial Industry Regulatory Authority, or FINRA, or an independent broker-dealer, or an affiliate or associated person of a FINRA member or independent broker-dealer. The foregoing should not be construed in and of itself as an admission by Mr. Bigger as to beneficial ownership of the securities beneficially owned directly by District 2 Capital Fund LP. The business address of District 2 Capital Fund LP is 14 Wall Street, 2nd Floor, Huntington, NY 11743.
- (4) Consist of (i) 266,667 shares of Common Stock; (ii) Common Warrants to purchase 266,667 shares of Common Stock; and (iii) warrants to purchase 116,071 shares of Common Stock. Michael Bigger is the managing member of Bigger Capital Fund GP, LLC, the general partner of Bigger Capital Fund, LP and has voting control and investment discretion over securities beneficially owned directly by Bigger Capital Fund, LP. Michael Bigger is the managing member of District 2 Holdings LLC, which is the managing member of District 2 GP LLC, the general partner of District 2 Capital Fund LP and has voting control and investment discretion over securities beneficially owned directly by District 2 Capital Fund LP. In such roles, Mr. Bigger may be deemed to beneficially own the securities owned by District 2 Capital Fund LP and Bigger Capital Fund, LP. We have been advised that none of Mr. Bigger or Bigger Capital Fund, LP is a member of the Financial Industry Regulatory Authority, or FINRA, or an independent broker-dealer, or an affiliate or associated person of a FINRA member or independent broker-dealer. The foregoing should not be construed in and of itself as an admission by Mr. Bigger as to beneficial ownership of the securities beneficially owned directly by Bigger Capital Fund, LP. The business address of Bigger Capital Fund, LP is 11700 W Charleston Blvd. 170-659, Las Vegas, NV 89135.
- (5) Consists of Common Warrants to purchase 533,333 shares of Common Stock. David Feldman and Joel Arber are the directors of L1 Capital Global Opportunities Master Fund and have voting control and investment discretion over the securities held by L1 Capital Global Opportunities Master Fund. As such they may be deemed to be beneficial owners of such shares of Common Stock. To the extent Mr. Feldman and Mr. Arber are deemed to beneficially own these securities, Mr. Feldman and Mr. Arber disclaim beneficial ownership over the securities except to the extent of any pecuniary interest therein. L1 Capital Global Opportunities Master Fund's principal business address is 161A Shedden Road, 1 Artillery Court, PO Box 10085, Grand Cayman KY1-1001, Cayman Islands.
- (6) Each of these Selling Stockholders is affiliated with WallachBeth Capital LLC. WallachBeth Capital, LLC is a registered broker dealer and has a registered address of c/o WallachBeth Capital, LLC, 1001 Yamato Road, Suite 404, Boca Raton, Florida 33431. WallachBeth Capital, LLC has sole voting and dispositive power over the securities held. The number of shares beneficially owned prior to this offering consist of shares of Common Stock issuable upon exercise of Placement Agent Warrants, which were received as compensation for the Private Placement. WallachBeth Capital, LLC acquired the placement agent warrants in the ordinary course of business and, at the time the placement agent warrants were acquired, WallachBeth Capital, LLC had no agreement or understanding, directly or indirectly, with any person to distribute such securities.
- (7) Includes 12,320 shares of Common Stock issuable upon exercise of Placement Agent Warrants; 10,312 shares of Common Stock issuable upon exercise of warrants issued to Mr. Bantum as a designee of WallachBeth Capital LLC in connection with our sale of convertible bridge notes in 2021 and 2022; and 7,835 shares of Common Stock issuable upon exercise of warrants issued to Mr. Bantum as a designee of WallachBeth Capital LLC in connection with our initial public offering.
- (8) Includes 7,200 shares of Common Stock issuable upon exercise of Placement Agent Warrants; 7,366 shares of Common Stock issuable upon exercise of warrants issued to Mr. Wallach as a designee of WallachBeth Capital LLC in connection with our sale of convertible bridge notes in 2021 and 2022; and 5,596 shares of Common Stock issuable upon exercise of warrants issued to Mr. Wallach as a designee of WallachBeth Capital LLC in connection with our initial public offering.
- (9) Includes 2,640 shares of Common Stock issuable upon exercise of Placement Agent Warrants; 2,210 shares of Common Stock issuable upon exercise of warrants issued to Mr. Bantum as a designee of WallachBeth Capital LLC in connection with our sale of convertible bridge notes in 2021 and 2022; and 1,679 shares of Common Stock issuable upon exercise of warrants issued to Mr. Bantum as a designee of WallachBeth Capital LLC in connection with our initial public offering.
- (10) Includes 2,640 shares of Common Stock issuable upon exercise of Placement Agent Warrants; 2,210 shares of Common Stock issuable upon exercise of warrants issued to Mr. McNeil as a designee of WallachBeth Capital LLC in connection with our sale of convertible bridge notes in 2021 and 2022; and 1,679 shares of Common Stock issuable upon exercise of warrants issued to Mr. McNeil as a designee of WallachBeth Capital LLC in connection with our initial public offering.
- (11) Includes 7,200 shares of Common Stock issuable upon exercise of Placement Agent Warrants; 7,366 shares of Common Stock issuable upon exercise of warrants issued to Mr. Beth as a designee of WallachBeth Capital LLC in connection with our sale of convertible bridge notes in 2021 and 2022; and 5,596 shares of Common Stock issuable upon exercise of warrants issued to Mr. Beth as a designee of WallachBeth Capital LLC in connection with our initial public offering.

MARKET INFORMATION FOR SECURITIES AND DIVIDEND POLICY

Our Common Stock is currently listed on the Nasdaq Capital Market under the symbol "BIAF." Our Tradeable Warrants are currently listed on the Nasdaq Capital Market under the symbol "BIAWF." The last reported sale price of our Common Stock and Tradeable Warrants on Nasdaq on April 15, 2024 was \$2.76 per share of Common Stock and \$0.69 per Tradeable Warrant.

Holders of Record

As of April 4, 2024, we had approximately 79 holders of record of our Common Stock.

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 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 may deem relevant.

Issuer Purchases of Equity Securities

None.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis is set forth at the end of this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements" and "Market, Industry and Other Data."

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 prospectus. 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 prospectus and in the "Risk Factors" in this prospectus.

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, 2023, to the year ended December 31, 2022.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows and discussion of our financial condition and potential sources of liquidity.
- *Critical Accounting Estimates* – Accounting estimates are those estimates made in accordance with 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

bioAffinity Technologies, Inc. (the "Company," "bioAffinity," "we," or "our") develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We are advancing research into our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future. We develop proprietary noninvasive diagnostic tests using flow cytometry and automated analysis developed by 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. Research and optimization of our platform technologies are conducted in laboratories at our wholly owned subsidiary, Precision Pathology Laboratory Services, LLC ("PPLS") and The University of Texas at San Antonio. Commercial laboratory services are performed at PPLS.

Our diagnostic test, CyPath[®] Lung, addresses the need for noninvasive detection of early-stage lung cancer. Lung cancer is the leading cause of cancer-related deaths worldwide. Physicians order CyPath[®] Lung to assist in their assessment of patients who are at high risk for lung cancer. The CyPat[®] 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.

Through our wholly owned subsidiary, OncoSelect[®] Therapeutics, LLC, our research has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells.

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

Recent Developments

On March 6, 2024, we received aggregate gross proceeds of \$2.5 million from the sale to four institutional investors (the "Purchasers") of (1) 1,600,000 shares of our Common Stock in a registered direct offering, and (2) Common Warrants to purchase an aggregate of 1,600,000 shares of Common Stock (the "Common Warrants") with an exercise price of \$1.64 in a concurrent private placement (the "Transactions").

The Common Stock was offered pursuant to a shelf registration statement on Form S-3 (File No. 333-275608), which was declared effective on November 27, 2023, (as amended from time to time, the "Registration Statement"). The Common Warrants and the shares of Common Stock issuable upon exercise of the Common Warrants (the "Common Warrant Shares") were issued in a concurrent private placement and have not been registered. The Common Warrants will be exercisable commencing on the effective date of stockholder approval for the issuance of the shares of Common Stock issuable upon exercise of the Common Warrants (the "Stockholder Approval Date") and will expire on the fifth anniversary of the Stockholder Approval Date.

Pursuant to the terms of the Purchase Agreement, until 60 days following the closing of the Transactions, we have agreed not to issue (or enter into any agreement to issue) any shares of Common Stock or Common Stock equivalents, subject to certain exceptions. We have further agreed not to enter into an agreement involving a variable rate transaction until 12 months following the closing of the Transactions, provided however that the prohibition on "at-the-market offerings" and the issuance of Common Stock pursuant to an equity line of credit shall expire on the six-month anniversary of the closing date of this offering. In addition, our Chief Executive Officer and each of our directors have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 60 days from the closing of the Transactions, offer, sell, transfer or otherwise dispose of our securities, subject to certain exceptions. In addition, from the date of the Purchase Agreement until the date that is nine (9) months after the date of the Purchase Agreement, upon any issuance by the Company or any of its subsidiaries of Common Stock, Common Stock equivalents for cash consideration, Indebtedness (as defined in the Purchase Agreement) or a combination of units thereof for capital raising purposes other than an at-the-market offering (a "Subsequent Financing"), the Purchasers shall have the right to participate in the Subsequent Financing in an amount up to the percentage of such Purchaser's participation in the Transactions on the same terms, conditions and price provided for in the Subsequent Financing.

WallachBeth Capital LLC acted as the placement agent for the offering and received a cash fee of 9.0% of the aggregate gross proceeds paid to us for the securities sold in the transactions and reimbursement of certain out-of-pocket expenses. As additional compensation we issued to WallachBeth Capital LLC a warrant (the "Placement Agent Warrant") to purchase an aggregate of 32,000 shares of Common Stock, such number of shares equal to two percent (2.0%) of the number of shares of Common Stock issued in the registered direct offering, at an exercise price per share equal to \$1.64, which is equal to the exercise price of the Common Warrants. The Placement Agent Warrant is exercisable via "cashless exercise" in certain circumstances.

We also agreed to file a registration statement to register the resale of the Common Warrant Shares and the shares of Common Stock issuable upon exercise of the Placement Agent Warrant (the "Placement Agent Warrant Shares") within 30 days of the date of the Purchase Agreement and to use commercially reasonable efforts to keep such registration statement effective at all times until no Purchaser owns any Warrants or Warrant Shares and until the Placement Agent does not own the Placement Agent Warrant or any Placement Agent Warrant Shares. We are also obligated to hold a stockholders' meeting 90 days after the closing date and every three months thereafter seeking approval of the exercise of the Common Warrants.

Financial

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

Prior to the acquisition, Precision Pathology Services had licensed and developed CyPath[®] Lung as an LDT for sale to physicians. The license agreement provided that revenues from the sale would be split evenly between the Company and Village Oaks. In the second quarter of 2022, prior to the acquisition, we started to recognize revenue as part of a limited beta market testing program of the CyPath[®] Lung test. We have never been profitable, and as of December 31, 2023, we had total working capital of \$1.7 million and an accumulated deficit of approximately \$44.6 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 the acquisition. We intend to license our therapeutic products for clinical development should animal and pre-clinical studies prove successful.

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

Results of Operations

Year Ended December 31, 2023, Compared to the Year Ended December 31, 2022

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, 2023, was approximately \$7.9 million, compared to a net loss of approximately \$8.2 million for the year ended December 31, 2022, resulting from the operational activities described below.

Revenue

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

	For year ended December 31,	
	2023	2022
Patient service fees ¹	\$ 2,199,558	\$ —
Histology service fees	272,660	—
Medical director fees	19,324	—
Department of Defense observational studies	19,442	—
Other revenues ²	21,515	4,803
Total net revenue	<u>\$ 2,532,499</u>	<u>\$ 4,803</u>

1 Patient services fees includes direct billing for CyPath[®] Lung diagnostic test.

2 Other revenues include pre-acquisition CyPath[®] Lung royalty income and laboratory services.

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Operating Expenses

	Year Ended December 31,		Change in 2023 Versus 2022	
	2023	2022	\$	%
Operating expenses:				
Direct costs and expenses	\$ 1,740,884	\$ 467	\$ 1,740,417	372,680%
Research and development	1,467,936	1,378,624	89,312	6%
Clinical development	256,661	145,546	111,115	76%
Selling, general and administrative	6,790,654	2,481,042	4,314,612	174%
Depreciation and amortization	249,592	10,185	239,410	2,351%
Total operating expenses	<u>\$ 10,505,727</u>	<u>\$ 4,015,861</u>	<u>\$ 6,494,866</u>	<u>162%</u>

Operating expenses totaled \$10.5 million and \$4.0 million during 2023 and 2022, respectively. The increase in operating expenses is the result of the following factors.

Direct costs and expenses

Our direct costs and expenses are primarily direct labor for pathology services, laboratory supplies and reagents, laboratory equipment and allocated shared facilities. Direct costs and expenses totaled \$1.7 million and \$467 during 2023 and 2022, respectively. The increase of approximately \$1.7 million for 2023 compared to 2022 was primarily attributable to the laboratory operations of the newly acquired PPLS.

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 totaled \$1.5 million and \$1.4 million during 2023 and 2022, respectively. The increase of approximately \$89,000, or 6%, for 2023 compared to 2022 was primarily attributable to an increase in compensation costs and benefits as we added research personnel.

Clinical Development

Clinical development expenses totaled approximately \$257,000 and \$146,000 during 2023 and 2022, respectively. The increase of approximately \$111,000, or 76%, for 2023 compared to 2022 was primarily attributable to an increase in compensation costs and benefits as we added clinic development personnel.

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Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately \$6.8 million and \$2.5 million during 2023 and 2022, respectively. The increase of approximately \$4.3 million, or 174%, for 2023 compared to 2022, was primarily attributable to general and administration costs acquired from PPLS (\$820,000), accounting, legal, and professional fee costs associated with the acquisition of PPLS (\$811,000), the accounting, legal, and professional fee costs associated with the SEC filing of a registration statement on Form S-1 (\$197,000), increase in stock-based compensation (\$486,000), increase in employee compensation (\$838,000) as we added sales and administrative personnel, increase in branding and marketing collateral (\$391,000), increase in directors and officers (“D&O”) insurance (\$290,000), increase in public company-related expenses (\$294,000) as well as an increase related to board compensation (\$147,000), and other operational expenses. Additionally, compensation increased due to additional personnel and support services to support the launch of sales of our diagnostic test, CyPath[®] Lung.

Other Income (Expense)

	Year Ended December 31,		Change in 2023 Versus 2022	
	2023	2022	\$	%
Interest income (expense), net	\$ 85,006	\$ (2,485,932)	\$ 2,570,938	62%
Other income (expense), net	(27,796)	—	(27,796)	0%
Gain on extinguishment of debt	—	212,258	(212,258)	-100%
Loss on change in fair value of convertible notes	—	(1,866,992)	1,866,922	100%
Total other income (expense)	\$ 57,210	\$ (4,140,596)	\$ 4,197,806	7,237%

Other income (expense) totaled approximately \$57,210 and (\$4.1) million for 2023 and 2022, respectively.

Interest income (expense)

We had net interest income (expense) of approximately \$85,000 and (\$2.5) million for the years ended December 31, 2023 and 2022, respectively. The current year amount related to approximately \$120,000 interest earned from money market account partially offset by interest paid in financing lease for laboratory equipment. The favorable improvement is based on convertible notes being converted to Common Stock in the prior year.

(Loss) gain on change in fair value of convertible notes

The loss on the change in fair value of convertible notes was \$0 during 2023 compared to a loss of \$1.9 million during 2022, respectively. The prior year recognized the change in the fair value of convertible notes converted to stock, the reduction in the expected term, and other assumptions during the reported periods.

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 \$36.8 million. The Company has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern for at least one year after the date the consolidated financial statements are issued.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic test or therapeutic products to generate revenue. During 2023 and 2022, we had net losses of \$7.9 million and \$8.2 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately \$44.6 million as of December 31, 2023. Based on the Company’s current expected level of operating expenditures and the cash on hand of approximately \$2.7 million at the time of this filing, 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. Cash and cash equivalents were approximately \$2.8 million as of December 31, 2023 which does not take into account the gross proceeds of \$2.5 million that we received in March 2024. At the time of this filing, cash is expected to be sufficient through September 2024. 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,	
	2023	2022
Cash and cash equivalents at beginning of year	\$ 11,413,749	\$ 1,360,638
Net cash used in operating activities	(6,037,806)	(4,070,845)
Net cash used in investing activities	(2,209,399)	(219,987)
Net cash provided (used) by financing activities	(344,984)	14,343,953
Cash and cash equivalents at end of year	\$ 2,821,570	\$ 11,413,759

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$6.0 million and \$4.1 million for the years ended December 31, 2023, and 2022, respectively. The increase of approximately \$1.9 million in cash used by operations during the year ended December 31, 2023, compared to 2022, was primarily attributable to prior year recognizing approximately \$1.9 million in fair value adjustments on convertible notes payable.

Net Cash Used in Investing Activities

The Company used approximately \$2.2 million in investing activities in 2023, compared to \$0.2 million used for the year ended December 31, 2022. The increase in cash used in investing activities in 2023, compared to 2022, is attributable to the acquisition of PPLS.

Net Cash Provided by Financing Activities

During the year ended December 31, 2023, net cash used by financing activities was \$345,000 as compared to net cash proceeds of \$14.3 million during 2022. During the year ended December 31, 2022, net cash provided by financing activities was \$14.3 million primarily due to net proceeds of approximately \$6.0 million from issuance of Common Stock in our IPO, as well as proceeds of approximately \$7.8 million from the exercise of warrants and options.

Critical Accounting Estimates

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

Patient Fee Revenues

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

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 CROs, hospitals, and independent laboratories. The Company enters into contracts with its customers for these enters. 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 ASC 842, *Leases*. In February 2016, the FASB issued Topic 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 increment 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.

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.

BUSINESS

bioAffinity Technologies, Inc. (the “Company,” “bioAffinity,” “we,” or “our”) develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We are advancing research into our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future. We develop proprietary noninvasive diagnostic tests using flow cytometry and automated analysis developed by artificial intelligence (“AI”). Our diagnostic tests analyze cell populations, including cancer and cancer-related cells, that are indicative of a specific diseased state.

We were formed as a Delaware corporation on March 26, 2014. On June 15, 2016, we formed OncoSelect[®] Therapeutics, LLC (“OncoSelect[®]”), a Delaware limited liability company and our wholly owned subsidiary which is a preclinical-stage biopharmaceutical discovery company with a focus on therapeutics that deliver cytotoxic (cell-killing) effects on a broad selection of human cancers from diverse tissues while having little or no effect on normal cells. On August 14, 2023, we formed Precision Pathology Laboratory Services, LLC (“PPLS”), a Texas limited liability company and our wholly owned subsidiary. Research and optimization of our platform technologies for in vitro diagnostics and technologies are conducted in laboratories at The University of Texas at San Antonio and PPLS in San Antonio, Texas.

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

CyPath® Lung uses flow cytometry technology to detect and analyze cell populations in a person's sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories. Flow cytometry collects data pertaining to properties of single cells labeled with antibodies and dyes specific to cell types and characteristics. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can provide information about its area of field cancerization and the lung microenvironment. CyPath® Lung uses automated data analysis developed by AI that allows an entire sample of sputum averaging 16 million cells to be examined in approximately 30 minutes, allowing for cost-effective, large-scale commercialization.

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

Through OncoSelect®, our research has led to discoveries of novel potential cancer therapeutics that specifically and selectively target cancer cells that have been grown in petri dishes.

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

Recent Developments

Registered Direct Offering

On March 6, 2024, we raised \$2.5 million in gross proceeds from the sale to four institutional investors of (1) 1,600,000 shares of our Common Stock (the "Shares"), par value \$0.007 per share ("Common Stock") in a registered direct offering, and (2) warrants to purchase an aggregate of 1,600,000 shares of Common Stock (the "Common Warrants") with an exercise price of \$1.64 in a concurrent private placement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed discussion of this transaction.

CPT Code Specific to CyPath® Lung for Proprietary Laboratory Analyses

On November 30, 2023, we announced that the Centers for Medicare and Medicaid Services ("CMS") had made a final determination for payment for CyPath® Lung, our noninvasive test for early-stage lung cancer, for the 2024 calendar year. Effective January 1, 2024, CyPath® Lung is on CMS' 2024 clinical laboratory fee schedule. The CPT Proprietary Laboratory Analyses ("PLA") code assigned to CyPath® Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer."

CyPath® Lung Branding

In 2023, we developed a series of marketing tools based on new branding for CyPath® Lung that emphasize our test's ability to assist physicians with next steps in patient care. In January 2024, we began using the new marketing materials with both physicians and patients. The branding concepts were developed by the marketing and advertising firms of Havas Health & You, Trinity Life Sciences, and K2MD to build the CyPath® Lung brand and position it for success in the cancer diagnostics sector.

PPLS Passes CAP Inspection

On January 11, 2024, PPLS successfully passed its bi-annual CAP inspection necessary for continuing operations. CAP accreditation ensures that laboratories meet the highest standards of quality and patient care under the Clinical Laboratory Improvement Amendments (CLIA), including personnel qualifications, equipment, facilities, safety protocols, and overall management and quality of testing.

Jamie Platt, PhD, Joins Board of Directors

In December 2023, Jamie Platt, PhD, Managing Director and Chief Executive Officer of Pictor Limited, where she is leading a turnaround by restructuring and accelerating product development, joined the bioAffinity Technologies Board of Directors. Dr. Platt has more than two decades of experience bringing novel diagnostic technologies to global markets. She was instrumental in merger and acquisition exits for two diagnostic companies with a combined value of approximately \$1 billion. She previously was Chief Operating Officer of Personal Genome Diagnostics which was acquired by LabCorp for \$575 million. We believe Dr. Platt's scientific acumen, business leadership, and board experience will contribute to the Company's growth and successful commercialization of CyPath® Lung.

Sandeep Bansal, MD, Joins Medical and Science Advisory Board

In February 2024, Sandeep Bansal, MD, Medical Director of Pennsylvania's Lung Innovations Network, joined our Medical and Scientific Advisory Board. Dr. Bansal is Board certified in pulmonary disease, critical care medicine and interventional pulmonology and has also served as principal investigator of multiple clinical research trials and peer reviewer for several medical journals. Lung Innovations Network, a patient-centered practice that offers comprehensive lung care to over 10,000 patients in central and western Pennsylvania, incorporated CyPath® Lung into its practice to aid in the detection of early-stage lung cancer in March 2024. We believe Dr. Bansal's experience as both clinician and researcher is an important asset for bioAffinity Technologies.

Continuation of Department of Defense Research

In the fourth quarter of 2023, we began selling CyPath® Lung tests to the Department of Defense (DOD) to conduct an observational study, "Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay," and for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection. An additional research study was opened by Brooke Army Medical Center in March 2023 to collect bronchoalveolar lavage samples to advance the research and development of a lung cancer test to be used in conjunction with bronchoscopy to improve diagnostic accuracy with combined testing.

Acquisition of Laboratory

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

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

Pursuant to the Asset Purchase Agreement, PPLS assumed all liabilities and obligations and obtained any and all rights, title and interest of Village Oaks in and to (1) all leases for equipment and personal property related to the laboratory assets, pursuant to an Assumption Agreement by and between Village Oaks and PPLS; (2) certain other contracts related to the laboratory assets, including the license to develop, manufacture, use, market, and sell CyPath[®] Lung pursuant to the Assumption Agreement; (3) all accounts payable of Village Oaks as of September 18, 2023, that were incurred in the ordinary course of business consistent with past custom and practice; and (4) the lease of the premises used in connection with operation of the CLIA-certified and CAP-accredited clinical pathology laboratory, pursuant to an Assignment and Assumption of Lease by and between and PPLS.

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

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

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

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

Our First Diagnostic Test – CyPath[®] Lung

Lung cancer remains the most commonly diagnosed cancer and the leading cause of cancer-related deaths worldwide. Globally, there were an estimated 2.21 million lung cancer cases and 1.8 million lung cancer deaths in 2020, as reported by the World Health Organization in its 2020 Cancer Fact Sheet. According to the American Lung Association (“ALA”), screening for individuals at high risk for lung cancer has the potential to improve lung cancer survival rates by finding disease at an earlier stage when it is more likely to be curable. A study published in the *New England Journal of Medicine* titled “Survival of patients with stage I lung cancer detected on CT screening” dated October 26, 2006, reported that the survival rate of individuals with Stage I lung cancer who underwent surgical resection within one month after diagnosis had a ten-year survival rate of 92%, as compared to the overall five-year survival rate in the U.S. of 26.5% as reported by the ALA. 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 20% as compared to screening by X-ray if LDCT screening is used by patients at high risk for lung cancer on an annual basis. Therefore, LDCT scans are recommended for screening of an estimated 14 million Americans who are at high risk for lung cancer. If half of these high-risk individuals were screened, more than 12,000 lung cancer deaths could be prevented, according to the ALA. However, the *New England Journal of Medicine* article also reported that LDCT was shown to have a low positive predictive value of less than 4%. This means that for every 100 people who receive a positive result from LDCT screening and are suspected of having lung cancer, only four actually have the disease. A reliable, noninvasive, and cost-effective diagnostic test can increase diagnosis of early-stage lung cancer while lowering the number of unnecessary and invasive procedures for patients with a false positive result from LDCT screening. (A false positive test result indicates that the patient has lung cancer when he or she does not have the disease.)

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

CyPath[®] Lung uses flow cytometry technology to detect and analyze cell populations in a person’s sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories. Flow cytometry collects data pertaining to properties of single cells labeled with antibodies and dyes specific to cell types and characteristics. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can provide information about its area of field cancerization and the lung microenvironment. While studies have shown that expert cytological analysis of sputum can detect cancerous and pre-malignant cells, the level of scrutiny required for the analysis is not feasible in the laboratory routine, according to an October 22, 2009, article, “Premalignant and malignant cells in sputum from lung cancer patients,” published in *Cancer Cytopathology*. The process of looking at microscopy slides is an extremely laborious approach and demands years of expertise. CyPath[®] Lung uses flow cytometry and automated data analysis developed by AI that allows for an entire sample of sputum averaging 16 million cells to be examined in approximately 30 minutes, allowing for cost-effective, large-scale commercialization.

In particular, CyPath[®] Lung uses a synthetic porphyrin called meso-tetra (4-carboxyphenyl) porphyrin (“TCPP”). Porphyrins are biological pigments that, when exposed to ultraviolet light at certain wavelengths, can result in the cell fluorescing a red or purplish color that can be detected under a microscope or by flow cytometry, according to an

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

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

CyPath® Lung can be put into routine lab use without requiring expert evaluation of samples or being subject to operator bias. Our approach allows the entire sputum sample to be rapidly analyzed. The numerical analysis developed with machine learning captures complex interactions between lung cancer, the microenvironment, and areas of field cancerization that would be difficult if not 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 may be 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 are suspected to be lung cancer. A patient collects his or her sample using a hand-held, noninvasive assist device, ICU Medical’s Acapella® Choice Blue, that acts to break up mucus in the lungs and help a person cough up sputum from the lung into a collection cup. The Acapella® Choice Blue has been 510(k) cleared by the FDA as a positive expiratory pressure device to help mobilize lung secretions in people with certain lung conditions.

The sputum sample is shipped overnight by the patient to PPLS and processed into a single-cell suspension, then labeled with antibodies that distinguish different cell types and the synthetic porphyrin TCPP that identifies cancer cells and/or cancer-associated cells. Our test can analyze an average sputum sample containing about 16 million cells in approximately 30 minutes using integrated software for high-throughput, user-friendly standardized analysis of flow cytometric sample data. A physician’s report is generated within minutes after data acquisition. The report stratifies the patient into one of two risk groups. Those patients deemed “likely or very likely” to have cancer may benefit from aggressive intervention. Those “unlikely or very unlikely” to have a malignancy may continue imaging surveillance. The physician also receives a numerical score between 0.1 to 1.0, with 0.1-0.49 being a negative result and 0.5 to 1.0 considered positive for lung cancer. The proprietary automated analysis software was developed and is wholly owned and patent protected by bioAffinity Technologies.

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

As reported in an article titled “Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning,” published in *Respiratory Research* on January 21, 2023, we conducted a 150-patient test validation trial of people at high risk for lung cancer including patients with the disease (N=28) and those who were cancer-free (N=122) that resulted in CyPath® Lung’s overall 88% specificity, meaning the ability to correctly identify a person without cancer, and 82% sensitivity, meaning the ability to correctly identify cancer in a person with the disease. For the subset of patients in this trial who had lung nodules 20 mm or smaller or no nodules at all, this trial resulted in 92% sensitivity, 87% specificity, 99% negative predictive value, and 88% accuracy. In this subset of 132 individuals with small nodules, 119 patients were cancer-free and 13 had confirmed lung cancer. Eight out of 10 (80%) of Stage I tumors were correctly identified. Sensitivity is the percentage of persons with the disease – in this case, lung cancer – who are correctly identified by the test. Specificity is the percentage of persons without lung cancer who are correctly identified by the test. The cancer group included all lung cancer types, but mostly squamous cell carcinoma and adenocarcinoma lung cancer (in near equal numbers), showing that CyPath® Lung detects all types of lung cancer. The detection of small lung nodules in people who have early-stage cancer can increase lung cancer survival.

In this 19-month test validation trial participants provided a sputum sample and were released from the study after a physician either confirmed the individual was cancer-free by examination of CT imaging or confirmed the presence of lung cancer by biopsy. Flow cytometry and patient data used in the analysis produced results that included (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVSS10) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age.

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

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

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

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

The Cancer Diagnostics Market and CyPath® Lung

The global cancer diagnostic market is projected to grow from an estimated \$102.24 billion in 2022 to \$162.57 billion in 2030, with a compound annual growth rate (“CAGR”) of 6.1%, according to a market research report issued by *Research and Markets* in June 2023. A January 2023 report, also by *Research and Markets*, stated that the market worldwide for lung cancer diagnostic tests was estimated at \$2.6 billion in 2022 and is projected to reach \$4.7 billion by 2030, with a CAGR of 7.8% over 2022-2030. We have the potential to play a significant role in the cancer diagnostic market because our platform is noninvasive, cost-effective, and has the potential to lead to better patient outcomes.

Comparison of CyPath® Lung to Current Standards of Care

Diagnostic Test or Procedure	Intended Patient	Sensitivity	Specificity	Procedural Risk	Source
CyPath® Lung	High risk	82%	88%	None	“Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning,” published in <i>Respiratory Research</i> 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 <i>Respiratory Research</i> on January 21, 2023
Low-dose CT screening	High risk	93.80%	73.40%	Radiation exposure	“Results of initial low dose computed tomographic screening for lung cancer,” published in the <i>New England Journal of Medicine</i> 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 <i>JAMA</i> in September 2014
Bronchoscopy	Suspicious lung nodules – central lesions	88%	47%	Invasive; risk of collapsed/bleeding lung; infection	“A bronchial genomic classifier for the diagnostic evaluation of lung cancer,” published in the <i>New England Journal of Medicine</i> on July 16, 2015
Fine needle biopsy	Suspicious lung nodules	90.4%	75.4%	Invasive; risk of collapsed/bleeding lung; infection	“Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review,” published in <i>Current Oncology</i> in February 2012
Core needle biopsy ²¹	Suspicious lung nodules	89.1%	88.6%	Invasive; risk of collapsed/bleeding lung; infection	“Global patterns and trends in lung cancer incidence: a population-based study,” published in the <i>Journal of Thoracic Oncology</i> on February 16, 2021

Our business model is to immediately address the need for a quick-to-market, noninvasive, cost-effective lung cancer diagnostic that will save lives and reduce medical costs. The U.S. Preventive Services Task Force recommended new guidelines for screening in March 2021, nearly doubling the number of Americans at high risk for lung cancer who are recommended for annual screening to 14 million people, according to the ALA. In November 2023, the American Cancer Society updated its guidelines for lung cancer screening to include all former smokers over the age of 50 regardless of when they quit, increasing the number of American adults eligible for screening to 19 million. China has an estimated 300 million smokers, according to the World Health Organization. In Europe, it is estimated that there is one new case of lung cancer diagnosed every minute, with incidence rates for males the highest in Eastern European countries and a five-year survival rate of only 13%, as reported by a May 2021 article, “Lung cancer screening in Europe: where are we in 2021?” published in *Translational Lung Cancer Research*. We expect to pursue CE marking of CyPath® Lung for sale in the European Union.

We conducted market research in the U.S. with pulmonologists, oncologists, cardiothoracic surgeons, radiologists, and internists engaged in the diagnosis and treatment of lung cancer to help assess their reactions to our diagnostic tool. Research revealed a strong interest in CyPath® Lung, driven by the high level of unmet clinical need for noninvasive diagnostics. A survey conducted with 240 pulmonologists and internists, the primary audience for the test, showed that 96% would use CyPath® Lung if it were available today as an adjunct used for diagnosis after LDCT screening. Physicians responded favorably to a noninvasive diagnostic technology that gives them more confidence in their decision to proceed with more aggressive follow-up procedures if the test comes back positive. If test results are negative, physicians can rule out lung cancer, thus reducing the number of costly invasive procedures that result from the LDCT false-positive rate.

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 prospectus. However, the timing, strategies, and stages of our business plan may evolve in light of new circumstances that cannot be predicted with certainty at this time. Our business plan envisions four phases of expanding market entry into the U.S., the EU, and worldwide that are timed to maximize our resources and minimize market risk. Phase 1 of our business plan has already begun with a limited market launch of our LDT CyPath® Lung in Texas. This limited test market launch is designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market.

We believe that our strategy related to a limited market launch is proving successful. On March 5, 2024, we reported accelerating growth of 375% in CyPath® Lung tests ordered and processed over from December 1, 2023, through February 29, 2024, as compared to the prior three-month period. We attribute the growth in sales to three 2023 initiatives that came to fruition early in 2024: (1) CMS’ inclusion of reimbursement for CyPath® Lung on its 2024 clinical laboratory fee schedule; (2) the hiring of our new National Director of Sales, Dallas Coleman, who is experienced and well respected in the pulmonary field; and (3) marketing materials for the newly branded CyPath® Lung that emphasize our test’s ability to assist physicians with next steps in patient care.

The next step in our marketing plan is expansion into the Southwest market area in 2024 followed by a staged nationwide expansion of sales and marketing beginning later in

2024. In addition to introducing pulmonologists, family practitioners, and other providers to CyPath® Lung, we are selling CyPath® Lung tests to the Department of Defense, which represents a significant potential market for CyPath® Lung. Phase 2 of our business plan anticipates entering the EU market with CyPath® Lung as a CE-marked IVD test with sales in the Netherlands, followed by a staged EU expansion. Phase 3 of our business plan focuses on the marketing of an FDA-cleared CyPath® Lung test, beginning with a pivotal clinical trial in the U.S. Toward that end, we intend to voluntarily seek FDA clearance of the CyPath® Lung as a Class II IVD medical device for the detection of lung cancer. We have designed our pivotal trial with guidance from our Clinical Research Organization (“CRO”), Courante Oncology, and we are preparing a pre-submission that will be submitted to the FDA for review and feedback. We anticipate a three-year diagnostic trial including an 18-month patient enrollment of approximately 1,800 patients. Similar to the test validation trial, the planned pivotal trial will analyze flow cytometry and patient data including (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age. Patient enrollment is scheduled to begin in 2024 at up to 20 collection sites. Assuming the study is successful, we intend to submit a de novo classification request to the FDA within six months of study completion. Phase 4 of our business plan accelerates the market presence of CyPath® Lung in countries in Asia, Eastern Europe, and Australia after obtaining FDA marketing authorization.

At each phase of commercialization, we plan to develop messaging and marketing programs, including key convention attendance, digital marketing, social media presence, and advertising, to create an “inbound” lead generation mechanism that delivers our message to our target audience. In addition, we plan to collaborate with key opinion leaders (“KOLs”) to expand our pool of third-party experts and speakers. We will provide support and collateral materials, including posters, presentations, videos, and peer-reviewed papers, to our KOLs who will present data and their experience with CyPath® Lung at key meetings. This content can be shared across platforms, including websites and sales tools, and will be used as references to support our product claims as well as sales and marketing efforts to physicians, reference laboratories, and patients. We will also work with lung cancer advocacy groups throughout all phases to support the message that routine screening can save lives by diagnosing cancer at an early stage.

The Competition for CyPath® Lung

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

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

We believe that balanced tests, like CyPath® Lung, can be the most cost effective. Those that perform well are most useful to a physician and his or her patient because they provide the most information, allowing a quicker decision on what follow-up path to choose: whether to move forward with more aggressive follow-up procedures (i.e., in the case of CyPath® Lung, if the test reveals a “likely” or “highly likely” cancer result) or to follow a more conservative approach (i.e., when the CyPath® Lung test reveals an “unlikely” or “very unlikely” cancer result).

We completed a competitive analysis in 2022 of 67 companies that published research sufficient to provide a scientific basis for evaluation. We found only seven tests, including CyPath® Lung, that represent a balanced test for early lung cancer detection and have advanced to the point that there is sufficient data for evaluation. One test is sold by two companies: one from the U.S. and one from China. In the U.S., the test is called Lung LB (sold by LungLife AI) and is now on the market. LungLB is a FISH-based test that requires a significant amount of experience to conduct. Four companies, each selling unique tests for early lung cancer detection, conducted their studies on a population that does not match the high-risk population for which the test is intended. Their clinical data, therefore, is not necessarily representative of the results that would be achieved in the population of patients who actually will use the test. The remaining balanced test, ProLung, is from IONIQ Sciences. The test requires an expensive machine to measure transcutaneous bioconductance. The test is not on the market at this time.

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

We found two rule-out tests on the market. Both REVEAL, offered by MagArray, and Nodify-XL2, offered by Bodesix, are rule-out tests, meaning the tests aim to exclude patients without cancer. The REVEAL test is a blood test intended for patients with indeterminate nodules. In their 97-patient clinical validation trial, only patients with an intermediate risk of cancer, based either on a physician’s judgement or a clinical model, took part. This requirement led to 30% of high-risk patients being excluded at the onset of their analysis. In addition, the positive predictive value of the REVEAL test was 13.5% as compared to CyPath® Lung’s positive predictive value of 43.2%. Importantly, no patients were excluded from the CyPath® Lung test. The tests had negative predictive values of 98% and 97.8%, respectively. The second rule-out test, Nodify-XL2, is used only by people with a pre-test probability of cancer less than 50%. As with the REVEAL test, a large number of patients were excluded from analysis. In the case of Nodify-XL2, about 55% of patients with lung nodules that physicians considered indeterminate, namely lung nodules sized between 8-30 mm, were excluded from the study. In addition, Nodify XL-2 reported an AUC of 0.62 (unacceptable) and 0.76 (acceptable) for their two clinical trials, as compared to CyPath® Lung with an AUC of 0.89 and 0.90 in two independent study groups (excellent).

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

We believe there are many reasons why CyPath® Lung is a superior test when compared to its competitors. First, lung sputum is an excellent medium for early lung cancer detection because sputum is in close contact with the tumor and pre-cancerous areas that shed cancer and pre-cancerous cells directly into the sputum, can be obtained noninvasively, and can be transported easily. Moreover, sputum contains immune cell populations in reaction to the presence of a tumor. Second, our proprietary technology is straightforward. Our CyPath® Lung platform technology is not a molecular test and does not collect genetic material that requires immediate processing. CyPath® Lung uses well-established flow cytometry techniques to investigate cells contained in the sputum for characteristics that indicate the likelihood of lung cancer. Sample processing is straightforward, and laboratory technicians can be easily trained. Reagents used by the test are widely available. Data acquisition and analysis is fully automated, allowing for

non-biased, efficient test results. Third, CyPath[®] Lung has shown high specificity and sensitivity that is similar to far more invasive and more expensive procedures currently used to detect lung cancer. Fourth, CyPath[®] Lung is cost effective, with a Medicare reimbursement code billable to both government and private insurance carriers. Fifth and as important as any of our test's benefits, CyPath[®] Lung is patient friendly, providing at-home sample collection that is noninvasive and offers particular benefit during a public healthcare crisis like the coronavirus pandemic.

Research and Development Activities

We are continuing our research and development activities pertaining to diagnostics that include multiple studies we believe will support FDA final approval of CyPath[®] Lung, which we will seek after completing the pivotal trial. With support from the DOD, we are also conducting research advancing the development of CyPath[®] Lung for detection of COPD and a test for use with bronchoalveolar lavage fluid (BAL) as a companion test to bronchoscopy. With regard to therapeutic research, we continue our experiments focused on establishing proof-of-concept for our discovery that the silencing or knockdown of two genes that each encode a cell surface receptor result in cancer death without perceived harm to healthy cells.

Other Diagnostic Applications for the CyPath[®] Platform

We expect to expand our platform technology to detect and monitor other lung diseases. Our research is conducted, in part, in collaboration with Brooke Army Medical Center in San Antonio, Texas, and partially funded by the DOD.

Chronic Obstructive Pulmonary Disease and Other Diseases of the Lung.

The respiratory diagnostics market 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. The World Health Organization reports that COPD is the third leading cause of death in the world, causing nearly 3.23 million deaths in 2019. The disease is characterized as an abnormal inflammatory response and airflow obstruction that cannot be fully reversed. Early detection allows for the use of therapies when the disease is less severe, which slows the progression of the disease. We plan to build on our expertise in using sputum as a sample for flow cytometric analysis to develop a test to detect COPD at an early stage and monitor for signs of impending exacerbations before clinical signs occur. CyPath[®] Lung's flow cytometry platform provides for identification of cell populations and other parameters of disease in the lung. Our test illuminates the microenvironment of the lung. We believe that our flow cytometric test can be designed to identify other lung diseases, such as COPD and asthma, using antibodies that characterize cell populations in sputum specific to the disease.

Bronchoscopies.

The market research firm Markets and Markets reports that the bronchoscopy market is primarily driven by an increasing prevalence of various respiratory diseases such as COPD and lung cancer. Improving reimbursement code policies, growing hospital investment in bronchoscopy facilities, and technological advancements are factors driving growth of a market that was estimated at \$2.5 billion in 2022 and expected to reach an estimated \$3.7 billion in 2027. Despite advancements in bronchoscopy technologies, there remains a significant need for companion tests that can increase diagnostic performance. Bronchoscopy is considered minimally invasive but carries a risk of collapsed or bleeding lung and risk of infection. The sensitivity of bronchoscopy is 88% and specificity of 47%, according to the article "A bronchial genomic classifier for the diagnostic evaluation of lung cancer" published in the *New England Journal of Medicine* on July 16, 2015. In collaboration with Brooke Army Medical Center, the CyPath[®] process is being developed as a companion to bronchoscopy in which samples are collected as part of the bronchoscopy process and processed using flow cytometry and automated analysis developed using AI.

OncoSelect[®] Therapeutics Research

OncoSelect[®] Therapeutics, LLC, a Delaware limited liability company and our wholly owned subsidiary, is a preclinical-stage biopharmaceutical discovery company with a focus on therapeutics that deliver cytotoxic (cell-killing) effects on a broad selection of human cancers from diverse tissues while having little or no effect on normal cells.

Unlike many of our industry competitors, OncoSelect[®] does not pursue therapies that depend on specific mutations, biomarkers, or other genetic or epigenetic abnormalities for their effect. We pursue research based on 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 have established several specific areas of therapeutic research that offer the possibility of broad applications in cancer treatment. OncoSelect[®] will use a licensing business model for selective chemotherapeutic compounds to be developed by the Company.

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

siRNAs can be easily synthesized and are easily introduced into cells growing in a petri dish by a process called transfection. siRNAs have been broadly adopted by academic and industrial researchers for the fundamental study of the function of genes and their proteins. We designed siRNAs to effectively eliminate CD320 and LRP2 protein production to study their role in TCPP uptake into the cell. With these CD320 and LRP2 siRNAs, we achieved a reduction of CD320 and LRP2 protein levels of up to 90%. Simultaneous siRNA knock-down of CD320 and LRP2 in normal cells, including skin fibroblasts and breast epithelial cells, did not affect cell growth. However, knock-down of CD320 and LRP2 in cancer cell lines derived from diverse tissues (lung, breast, prostate, brain, and skin cancers) inhibited cell growth or killed the cells, in some cases up to 80%. Interestingly, in some cell lines, when either CD320 or LRP2 were silenced individually, a concurrent increase in protein expression of the other receptor was observed, suggesting that CD320 and LRP2 compensate for each other's function; hence, silencing *both* receptors is required for optimal cell killing. These discoveries can lead to novel and very promising therapeutic approaches for diverse cancers that do not appear to be dependent on any aberrant genetic or epigenetic profiles.

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 22211 West Interstate 10, Suite 1206, San Antonio, Texas 78257, 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 prospectus. Investors should not consider any such information to be part of this prospectus.

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 us 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 April 4, 2024, we and our OncoSelect[®] subsidiary have a patent estate that includes 16 issued U.S. and foreign counterpart patents including two U.S. patents and 14 foreign counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, India, Italy, Mexico, Spain, Sweden, and the United Kingdom. We and OncoSelect[®] own all patents and trademarks in our intellectual property portfolio. One U.S. patent and nine counterpart foreign patents directed at diagnostic applications expire in 2030. One U.S. patent and five counterpart foreign patents directed at therapeutic applications expire in 2037.

With regard to our diagnostic patent portfolio, we have one issued U.S. patent and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom. With regard to our diagnostic patent applications, there are two families of which one is directed at diagnosing lung health using flow cytometry and the other is directed at proprietary compensation beads used in analysis by flow cytometry. The diagnostic family of pending patent applications is directed at diagnosing lung health and includes one pending non-provisional U.S. patent application and eight foreign counterpart patent applications in Australia, Canada, China, European Patent Office, Japan, Hong Kong, Mexico, and Singapore filed in 2019, one International Patent Application filed in 2022 and one International Patent Application filed in 2023. Also, a patent application directed at the composition of compensation beads was filed as an International Patent application in 2022.

With regard to our therapeutic product candidates, we have one issued U.S. patent, five issued foreign patents in Australia, China, Hong Kong, India and Mexico, two pending U.S. applications, and 10 foreign applications pending in Canada, China, European Patent Office, Hong Kong, India, and Japan and one pending International Patent Application filed in 2022. The therapeutic intellectual property is made up of two families, including one family directed at our siRNA product candidates for the treatment of cancer, and another family directed at our porphyrin conjugates for treating cancer. One therapeutic patent application has been granted in China that expires in 2037.

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

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

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

Government Regulation

United States

Diagnostic Products (including Medical Devices and Tests)

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

Laboratory Developed Tests

CyPath[®] Lung has entered the U.S. market as an LDT. The FDA considers LDTs to be tests that are developed, validated, and performed within a single laboratory. While CMS oversees clinical laboratory operations through the CLIA program, the FDA has the authority to regulate LDTs as IVDs under the FDCA but has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose IVD regulatory requirements on LDTs, such as requirements to obtain premarket approval, authorization, or clearance, it has generally chosen not to enforce those requirements except in cases it deemed appropriate to address significant public

health concerns.

In September 2023, the FDA announced a proposed rule to ensure the safety and effectiveness of LDTs by amending regulations to explicitly say that IVDs offered as LDTs fall under the FDCA and phase out its general enforcement discretion approach for most LDTs. The proposed policy makes it clear that the FDA intends to provide greater oversight of LDTs. The FDA plans to finalize its ruling in April 2024 and initiate a phased implementation process in which it will require laboratories to register their LDTs and begin the premarket review process over the next four years.

In 2021, two bills were reintroduced in the U.S. Congress: the Verifying Accurate, Leading-edge IVCT Development Act of 2020 (the “VALID Act”), which would have expressly granted the FDA authority to regulate LDTs under a risk-based framework; and the Verified Innovative Testing in American Laboratories Act of 2020 (the “VITAL Act”), which would have assigned LDTs to regulation solely under CLIA and would have directed CMS to update its CLIA regulations. Neither of these bills were enacted. The VALID Act was reintroduced in March 2023. The likelihood that Congress will pass the VALID Act, VITAL Act, or similar legislation, and the extent to which such legislation may affect the FDA’s plans to regulate LDTs as medical devices is difficult to predict.

Clinical Laboratory Improvement Amendments of 1988

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

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

Medical Devices

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

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

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

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

Premarket Authorization and Notification

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

510(k) Premarket Notification

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

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

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

De Novo Classification

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

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

PMA Approval

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

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

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

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

Clinical Trials

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

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

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

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

Postmarket Requirements

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

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

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

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

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

Therapeutic Products

FDA Approval Process

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

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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 ten 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.

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The FDA may also refer applications for novel products, as well as products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee – typically a panel that includes clinicians, statisticians and other experts – for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug product is manufactured. The FDA will not

approve the product unless compliance with current good manufacturing practices (“cGMP”) is satisfactory. After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing or information in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (“REMS”) to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product’s safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product’s safety or efficacy.

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

Disclosure of Clinical Trial Information

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

Post-Approval Requirements

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

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

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

European Union

A medical device or diagnostic test must be CE marked to be sold in the EU. The In Vitro Diagnostic Device Regulation (“IVDR”) of the EU defines the necessary pre-conditions that must be fulfilled to CE mark an IVD test or in vitro medical device in the EU. The manufacture of the test and/or device must fulfill all applicable regulatory requirements in the IVDR. Objective evidence of fulfillment 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 (the “EEA”) are governed by the EU General Data Protection Regulations (the “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 75 employees at the time of this filing, 22 employed by bioAffinity and 53 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 nine employees engaged in research and development, all of whom are employed full-time, one holds an MD and six hold PhDs in biology or medicinal chemistry. Of the 53 employees at PPLS, nearly half have worked at our clinical laboratory for more than five years.

Our Executive Vice President and Chief Medical and Science Officer, Vivienne Rebel, holds an MD and PhD. Business development is led by our Chief Operating Officer, Xavier Reveles, who has 25 years of experience as a clinical geneticist skilled in the creation and management of CLIA clinical laboratories, coding, and CPT reimbursement valuations. Mr. Reveles is board certified by the American Society of Clinical Pathology as a clinical specialist in cytogenetics who has successfully launched multiple diagnostics and commercial laboratories. We have recently attracted experienced salespeople with a proven record in the pulmonary field. In November 2023, we hired Dallas Coleman as National Sales Director who has more than 15 years of experience in medical sales and marketing, most recently as Executive Account Manager for the respiratory portfolio of Olympus America’s therapeutic solutions division. In February 2024, Cole Koeppen joined us as Pulmonary Sales Executive for CyPath® Lung in North Texas. Previously, he was Territory Sales Associate for Pulmonx Corporation, a provider of treatments for patients with COPD. Our innovative and collaborative culture is in part responsible for our ability to attract and retain highly skilled professionals seeking professional advancement. Outside partnerships and collaborations that advance business and scientific research are encouraged, allowing us to multiply workforce efforts without expending significant capital.

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

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

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and selected financial data, and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended (“SOX”);
- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements, and proxy statements; and
- exemptions from the requirements to seek non-binding advisory votes on executive compensation or stockholder approval of any golden parachute arrangements.

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

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

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, (“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.

MANAGEMENT

The following is a list of our directors and executive officers as of April 4, 2024.

Name	Age	Position(s)
Maria Zannes, JD	67	President, CEO, and Director
Vivienne Rebel, MD, PhD	58	Executive Vice President and Chief Science and Medical Officer
Michael Dougherty	45	Chief Financial Officer
Xavier Reveles	54	Chief Operating Officer
Timothy P. Zannes, JD	71	Executive Vice President, Secretary, and General Counsel
Steven Girgenti	77	Executive Chairman and Director
Robert Anderson	82	Director
Stuart Diamond	62	Director
Peter Knight	72	Director
Gary Rubin	67	Director
Roby P. Joyce, MD	78	Director
Jamie Platt, PhD	57	Director

Biographical Information

Maria Zannes, JD — President, Chief Executive Officer, and Director

Ms. Zannes has served as our President, Chief Executive Officer and director since 2014. She brings more than 30 years of executive-level management experience dedicated to defining and advancing company goals and overcoming obstacles impeding corporate success. Prior to her position at bioAffinity Technologies, Ms. Zannes founded The Zannes Firm focusing on strategic solutions for private industry in the medical, environmental and energy fields. In her current capacity as the Company’s CEO and President, she has built a team of award-winning scientists and executives who are advancing breakthrough oncology-focused diagnostics and therapeutics.

Ms. Zannes was President of the Energy Recovery Council, the national trade group for the \$10 billion waste-to-energy industry, and General Manager of ECOS Corporation, a subsidiary of Burlington Environmental. Ms. Zannes also served as a project manager at Wheelabrator Technologies, Inc. where she led project teams that developed, negotiated, and financed the company’s renewable energy generation facilities. Ms. Zannes began her career as a journalist, working for Voice of America and the Associated

Press. Before entering the business world, she served as a legislative aide specializing in energy policy and law for Congressman Charles Wilson (D-TX). She is licensed to practice law in New Mexico. She has been awarded Lifetime Achievement Awards by the American Society of Mechanical Engineers and the Earth Engineering Center Award from the WTE Council of Columbia University.

She is the co-founder of two engineering research centers at Columbia University. Ms. Zannes received her BA in Journalism from the University of New Mexico and her JD from the University of Puget Sound in Washington State. We believe Ms. Zannes should serve as a director of the Company because of her experience as a lawyer and business woman skilled in identifying, prioritizing and managing both the risks and rewards of business opportunities and her proven record of assembling and motivating award-winning teams of professionals focused on strategic corporate growth.

Vivienne I. Rebel, MD, PhD — Executive Vice President and Chief Science and Medical Officer

Dr. Rebel is a cancer (stem) cell biologist, with more than 20 years of experience in scientific research, focused on understanding the molecular events that lead to cancer development and has served as our Executive Vice President and Chief Science and Medical Officer since 2016. She received her MD and PhD from the Free University in Amsterdam, The Netherlands, and post-doctoral training at the Dana-Farber Cancer Institute, Harvard Medical School. From 2005 to 2016, she led her own research group at The University of Texas Health Science Center at San Antonio, where she first collaborated with bioAffinity. Dr. Rebel received the 2012 Cancer Therapy & Research Center Discovery of the Year Award. She is the (co)author of more than 50 publications in peer-reviewed journals.

Michael Dougherty — Chief Financial Officer

Michael Dougherty was appointed to serve as our new Vice President and Chief Financial Officer (principal financial officer and principal accounting officer) effective May 1, 2023.

Prior to joining the Company, Mr. Dougherty served from 2022 through April 2023 as the Chief Financial Officer of Alexa Business Domains, Amazon's Alexa AI and voice division, where he was responsible for financial strategy over Alexa's multi-billion-dollar investments in AI-generated customer experiences. From 2020 to 2022, Mr. Dougherty was Chief Financial Officer of TINT and Filestack, two software-as-a-service companies. From 2017 to 2020, Mr. Dougherty served as Chief Financial Officer for Amazon Pay, where he supported Amazon's digital payment wallet globally. Earlier in his career Mr. Dougherty held various finance positions at Russell Investments and Medisystems Corporation. He is a certified public accountant and a Chartered Global Management Accountant by the American Institute of Certified Public Accountants.

Xavier Reveles- Chief Operating Officer

Mr. Reveles was appointed as our Chief Operating Officer on September 18, 2023. Mr. Reveles has served as our Vice President of Operations since September 2022. He has 30 years of experience as a clinical cytogeneticist skilled in the design/concept and management of CAP/CLIA clinical laboratories, coding, CPT reimbursement valuations, and the development of LDTs. Mr. Reveles is board certified by the American Society of Clinical Pathology as a clinical specialist in cytogenetics. He joined bioAffinity as Director of Operations in 2017. Prior to joining bioAffinity, Mr. Reveles created the Oncopath Laboratory – START Cancer Center in San Antonio, Texas, and served as Laboratory Director. During his tenure at Oncopath, he commercialized eight LDTs, including bringing to market a proprietary cancer specific gene oligo array he designed for the deletions and amplifications of specific oncogenes for solid tumors. As the Director of the Cytogenetics Laboratory at UT Health San Antonio, Mr. Reveles' research included molecular evaluation of disease progression in prostate, breast and ovarian cancer, schizophrenia, diabetes and other constitutional genetic syndromes. He was a lecturer and instructor for the UT Health Graduate, Medical, and Allied Health Schools and the director of the NCI San Antonio Cancer Institute (SACI) Genetics and Cytogenetics Core facility. After leaving academia, Mr. Reveles was a genomic specialist for CombiMatrix Diagnostics, Irvine, CA, a diagnostic biotech company where he validated pre-natal, post-natal, and cancer gene arrays for commercialization as LDTs. Mr. Reveles is (co)author of 20 publications and six abstracts in peer-reviewed journals and is a member of the Association for Molecular Pathology.

Timothy P. Zannes, JD — Executive Vice President, General Counsel, and Secretary

Mr. Zannes has been corporate legal counsel to both public and private biomedical firms for more than 16 years, having begun his legal career as a sole practitioner accepting criminal, business, family, and tort litigation. Prior to receiving his JD, Mr. Zannes was a court bailiff and ran his own private investigation firm after serving as an investigator for the Albuquerque City Attorney. He received his JD from the University of New Mexico School of Law and attended the New England Conservatory with studies in violin and saxophone. Mr. Zannes began his undergraduate education at The University of North Carolina where he was a student athlete on scholarship. In addition to his duties as General Counsel and Secretary, Mr. Zannes is responsible for corporate compliance and directs Human Resources. Mr. Zannes and Maria Zannes are siblings.

Steven Girgenti — Executive Chairman of the Board

Mr. Girgenti has been Executive Chairman of bioAffinity Technologies, Inc. since November 2014. Mr. Girgenti was formerly CEO and co-founder of DermWorx Incorporated, a dermatology company that specialized in developing nanotechnology formulations to enhance the performance of topical drugs. He was also the founder and CEO of Healthworld Corporation, a leading global healthcare marketing services network with offices in 36 countries, until 2008. The network had more than 1,000 brand assignments from nearly 200 clients worldwide, providing strategic marketing and communications services to many of the world's leading healthcare companies. Mr. Girgenti founded Healthworld in 1986, and under his leadership the Company made numerous acquisitions to expand and diversify the business. Healthworld went public in 1997. In 1998 and again in 1999, Business Week named Healthworld one of the "Best Small Corporations in America." In 1999, Forbes listed Healthworld as one of the "200 Best Small Companies." Mr. Girgenti was recognized as "Entrepreneur of the Year" by Nasdaq in 1999 and was named Med Ad News' first "Medical Advertising Man of the Year" in 2000. In 2010, he was inducted into the Medical Advertising Hall of Fame. In addition, Mr. Girgenti is Vice Chairman of the Board of Governors for the Mt. Sinai Hospital Prostate Disease and Research Center in New York City and is on the Board of Directors for the Jack Martin Fund, a Mt. Sinai Hospital-affiliated charitable organization devoted to pediatric oncology research. He graduated from Columbia University. We believe Mr. Girgenti should serve as Executive Chairman because of his unparalleled experience in the healthcare field, particularly in marketing, and his skill in building emerging growth companies into multi-national corporations.

Robert Anderson — Director

Mr. Anderson has more than 50 years of broad experience in the healthcare industry in which he held executive positions at CIBA Pharmaceutical Co., Becton Dickinson and Company, Pfizer, Inc., Parke-Davis Division of Warner-Lambert Co, Schering-Plough Corp., and Centocor, Inc. Mr. Anderson was Vice President of Marketing for the Key Pharmaceuticals Division of Schering-Plough Corp. and later at Centocor, Inc. Subsequently, Mr. Anderson joined Physicians World Communications Group, the largest medical education company in the U.S. where he was Chief Operating Officer. Mr. Anderson currently is a marketing consultant to several healthcare companies. Mr. Anderson received a BA in political science from Rutgers University. We believe Mr. Anderson should serve as a director of the Company because of his experience and skill in marketing and product positioning of medical products to bioAffinity Technologies.

Stuart Diamond — Director

Mr. Diamond is the Global Chief Financial Officer for GroupM, the world's leading media investment company responsible for over \$50 billion in media investment through agencies Mindshare, MediaCom, Wavemaker, Essence and m/SIX, as well as the outcome-driven programmatic audience company, Xaxis, LLC. Before joining GroupM, Mr.

Diamond was a member of the WPP plc family as the CFO for Healthworld Corporation (now called Ogilvy Health), where he took the company public and negotiated its sale to Cordiant Communications Group in 2000. He also served as CFO for National Medical Health Card Systems, Inc., a comprehensive pharmacy benefit management company. From 2008 to 2014, Mr. Diamond was the CFO for GroupM North America, where he established financial strategies and supervised all corporate accounting and financial activities for GroupM and its agencies. Earlier in his career, he held the positions of Vice President and Controller for Calvin Klein, Inc. and as Senior Vice President and CFO for Medicis Pharmaceutical Corporation. Mr. Diamond holds a BS from the State University of New York, a Master of Science, Taxation degree from Pace University, and an MBA from Fordham University. We believe Mr. Diamond should serve as a director of the Company because of his substantial business and financial acumen to his position as Chairman of the Audit Committee and to the Board.

Peter S. Knight — Director

Mr. Knight is a Partner at Cyan Capital Partners, a fund dedicated to helping new fund managers and asset owners in the field of sustainable investing. Prior to that, he was a Founding Partner at Generation Investment Management, where he and his partners Al Gore and David Blood helped build a leading global sustainable investing firm with assets under management now exceeding \$40 billion. Prior to his retirement from the firm in 2018, Mr. Knight held leadership positions within Generation IM, notably developing and overseeing the firm's U.S. business. Prior to Generation, Mr. Knight was a Managing Director of Met West Financial, a Los Angeles-based asset management company. Mr. Knight started his career at the Antitrust Division of the U.S. Department of Justice. From 1977 to 1989, he served as the Chief of Staff to Representative and later Senator Al Gore. He served as the General Counsel of Medicis Pharmaceutical and then started his law practice where he represented the International Olympic Committee, the U.S. Olympic Committee, and numerous Fortune 500 Companies. Mr. Knight has also served in senior positions on four Presidential campaigns including serving as the Campaign Manager for President Clinton's 1996 re-election campaign. Mr. Knight has extensive board experience in both the for-profit and nonprofit sectors. He served on a number of public company boards including Medicis Pharmaceutical, Par Pharmaceutical, EntreMed (Casi Pharmaceuticals Inc.), Healthworld Corporation, Whitman Education, Comsat, and the Schroder Mutual Fund Board complex. Mr. Knight currently serves on the boards of Generation Investment Management and Gratitude Railroad. His philanthropic efforts include serving as Chair of the Climate Museum and the board of Emergent, a nonprofit intermediary to help stop deforestation in tropical forest nations. He received a BA from Cornell University and a JD from the Georgetown Law School. We believe Mr. Knight should serve as a director of the Company because of his considerable experience in finance and business to his position of Chairman of the Compensation Committee, as well as his expertise and skill in building new ventures into leading global firms.

Gary Rubin — Director

Mr. Rubin, a Certified Public Accountant, serves as a Managing Member of Masters Research Partners, LLC, an investment fund of hedge funds that he co-founded in October 2000. Mr. Rubin began his career with Deloitte & Touche and later served as Managing Partner at Schissel, Rubin & Lehman, a New York-based certified public accounting firm. He has been involved in the investment business, including hedge funds, private equity, and investment banking, for more than 20 years. Mr. Rubin is active in numerous charities as well as his family's foundation and presently serves on the board of Boca Raton Regional Hospital Foundation. He also sits on the finance committee of the Levitz Jewish Community Center. He graduated with a BS cum laude from the State University of New York at Buffalo. We believe Mr. Rubin should serve as a director of the Company because of his financial expertise and organizational skills to his position as Chairman of the Nominating and Governance Committee and to the Board.

Roby Joyce, MD — Director

Roby P. Joyce was appointed to serve on our Board of Directors on September 14, 2023. He is board-certified in anatomic and clinical pathology by the College of American Pathologists and is a Diplomat in the American Board of Pathology. He is also board-certified in neurology by the American Academy of Neurology and is a Diplomat in the American Board of Psychiatry and Neurology. Dr. Joyce founded Village Oaks in 2008. He is Medical Director and Laboratory Director of Precision Pathology Laboratory Services ("**PPLS**") and owner of Village Oaks, the medical professional association whose pathologists provide pathology interpretation services to PPLS. In addition to his role at Village Oaks, he has served in various capacities at Northeast Methodist Hospital in San Antonio, including Chairman of the Board of Trustees and Chief of Staff of the Methodist Healthcare System. Throughout a career in pathology that spans more than 40 years, he has been a highly regarded speaker at medical and scientific conferences, has served in leadership roles on dozens of professional organizations and committees, and has served as lead or co-author of numerous scientific articles. Dr. Joyce received his medical degree from Louisiana State University, where he also received a BS in zoology. He performed his internship at Fitzsimons Army Medical Center in Denver, his residency in neurology at the Letterman Army Medical Center at the University of California Moffett Hospital in San Francisco, and his residency in pathology at Brooke Army Medical Center in San Antonio. We believe Dr. Joyce should serve as a director of the Company because of his extensive experience as a clinical pathologist, his substantial professional relationships with physician practices and hospital systems and his business acumen in the creation and operation of a successful pathology laboratory that developed CyPath[®] Lung as an LDT.

Jamie Platt, PhD — Director

Jamie Platt has 20 years of progressive leadership in genomics and molecular diagnostics, guiding teams in developing, validating, and commercializing more than 40 innovative, high-complexity molecular tests for U.S. and global firms, both LDTs and in-vitro diagnostic tests ("**IVDs**"). Since April 2023, she has served as Managing Director and Chief Executive Officer at Pictor Ltd., an in-vitro diagnostics company using a proprietary enzyme-linked immunosorbent assay platform to test complex and infectious diseases, and since January 2021, has served as a member of its board of directors. From August 2021 until April 2023, Dr. Platt served as Chief Operations Officer at Personal Genome Diagnostics, a company dedicated to advancing precision oncology acquired by Laboratory Corporation of America Holdings. Since May 2015, Dr. Platt has served as President and Chief Executive Officer of BRIDGenomics, a private consulting and contract commercialization firm she founded in 2015 to provide molecular and genomic-based strategies to clients. Dr. Platt has served since March 2021 as a member of the board of directors of DxTerty Diagnostics Inc., a company pioneering the use of RNA-based immune system profiling to better understand the root causes of immune mediated conditions. From February 2017 until January 2021, Dr. Platt served as Chief Operations Officer of Inivata Limited, a company applying pioneering liquid biopsy technology acquired by NeoGenomics Laboratories, Inc. Dr. Platt earned her PhD in molecular and cellular biology from Oregon State University and completed post-doctoral studies at the University of California, Berkeley. Dr. Platt is an industry-recognized peer educator and speaker, holds multiple U.S. and international patents and has authored numerous peer-reviewed publications. We believe Dr. Platt should serve as a director of the Company because of her scientific background, her start-up company experience, her prior leadership and laboratory experience, her involvement in transforming research organizations into successful commercial entities and her experience expanding product market share in the diagnostics market.

Director Independence

Under the corporate governance standards of Nasdaq, a majority of our directors must meet the independence requirements specified in those rules. The Nasdaq listing standards also subject members of the Company's Audit Committee and Compensation Committee to additional independence requirements. The Board has affirmatively determined that each of the Company's non-employee directors, which include Robert Anderson, Stuart Diamond, Peter Knight, Gary Rubin, and Jamie Platt are independent directors under the Nasdaq rules and listing standards, including with respect to each director's committee service.

EXECUTIVE AND DIRECTOR COMPENSATION

Emerging Growth Company Status

The Company qualifies as an "emerging growth company" (an "**EGC**") as defined in the Jumpstart Our Business Startups Act of 2012. As an EGC, the Company is permitted to rely on exemptions from certain disclosure requirements that are applicable to other non-EGC companies. In accordance with the SEC's disclosure rules for EGCs concerning executive compensation, the Company has provided a Summary Compensation Table and an Outstanding Equity Awards at Fiscal Year End Table, as well as limited narrative disclosures regarding executive compensation for the last completed fiscal year and a report of the Compensation Committee. In addition, for so long as the Company is an EGC, it is not required to submit certain executive compensation matters to stockholder advisory votes, such as the "say-on-pay" vote. Furthermore, the Company's reporting

obligations extend only to its “named executive officers” (the “NEOs”), which include the Company’s Chief Executive Officer and the two most highly compensated executive officers in respect of their service to the Company at the end of the last completed fiscal year. In accordance with the permitted exemptions from disclosure requirements for EGCs, the Company has not provided a Compensation Discussion and Analysis. For fiscal year 2023, the Company’s NEOs were:

- Maria Zannes, JD—President, Chief Executive Officer, and Director
- Michael Dougherty— Vice President and Chief Financial Officer
- Steven Girgenti—Executive Chairman and Director

Summary Compensation Table

The table below summarizes all compensation awarded to, earned by, or paid to our named executive officers for all services rendered in all capacities to us and our subsidiaries during the fiscal years noted below:

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) ⁽¹⁾	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Maria Zannes <i>President and CEO</i> ⁽²⁾	2023	261,671	37,500	124,996	—	—	424,168
	2022	253,343	50,000	47,944	—	—	351,287
Michael Dougherty <i>Vice President and CFO</i> ⁽³⁾	2023	158,919	80,000	100,000	—	—	338,919
Steven Girgenti <i>Executive Chairman</i> ⁽⁴⁾	2023	95,000 ⁽⁴⁾	18,750	134,995	—	—	248,745
	2022	93,333	30,000	60,000	—	—	153,333

(1) Amounts do not reflect compensation actually received by the NEO. Instead, the amounts represent aggregate grant date fair value of the restricted stock award computed in accordance with ASC 718, Stock Compensation. The valuation assumptions used in determining such amounts are consistent with those described in Note 11 of the Company’s Consolidated Financial Statements, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023.

(2) Includes for 2023 the following amounts received by Ms. Zannes for her service to the Company as a director: (i) in the Salary column - \$25,000, and (ii) in the Stock Awards column - \$74,996.

(3) Mr. Dougherty was appointed as our Chief Financial Officer effective as of May 1, 2023.

(4) Includes for 2023 the following amounts received by Mr. Girgenti for his service to the Company as a director: (i) in the Salary column - \$35,000, and (ii) in the Stock Awards column - \$74,996.

Narrative Disclosure to Summary Compensation Table

Base Salaries

The Company uses base salaries to recognize the experience, skills, knowledge, and responsibilities required of all its employees, including the NEOs. Base salaries are reviewed annually and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience. For 2023, the annual base salaries of the Company’s NEOs were:

- For Ms. Zannes: \$220,000 through July 31, 2023 and \$260,000 commencing August 1, 2023 (which amounts does not include \$25,000 in fees paid to Ms. Zannes for her service as a director in 2023);
- For Mr. Dougherty: \$250,000
- For Mr. Girgenti: \$60,000 (which amount does not include \$35,000 in fees paid to Mr. Girgenti for his service as a director in 2023).

Bonuses

On January 26, 2024, the Compensation Committee approved discretionary bonuses for each of Maria Zannes, Michael Dougherty, and Steven Girgenti for calendar year 2023 of \$75,000, \$100,000, and \$37,500, respectively to be paid 50% in cash and 50% in shares of restricted stock. The bonuses were out on January 31, 2024. The number of shares of restricted stock issued were determined by dividing the cash value of 50% of each executive’s bonus by the closing price of the Company’s Common Stock on January 31, 2024. The restricted stock awards granted on January 31, 2024 are not included in the Summary Compensation Table for 2023 and will appear in the Summary Compensation Table for 2024.

On January 26, 2024, the Compensation Committee adopted the bioAffinity Technologies, Inc. Management Incentive Bonus Plan (the “Bonus Plan”). The purpose of the Bonus Plan is to align officers’ and other employees’ efforts with the strategic goals of the Company through competitive annual incentive opportunities. The Bonus Plan is administered by the Compensation Committee. The Compensation Committee has the power to grant awards under the Bonus Plan, determine the amount of cash and/or equity to be paid pursuant to each award and the terms and conditions of each award. Awards may provide for payment in installments, or upon the satisfaction of qualitative performance standards or quantitative performance standards, on an individual, divisional or company-wide basis, as determined by the Compensation Committee. Equity awards will be issued in accordance with, and pursuant to, any equity-related incentive plan maintained by the Company.

Each participant in the Bonus Plan will be entitled to receive payment of the award for a plan year only after certification by the Compensation Committee that the targets associated with such award have been satisfied. Final payments with respect to awards will vary based on the level of achievement measured against the pre-determined performance measures. Except as may be approved by the Compensation Committee, each participant must be employed full-time on the date of payment, and not under a notice of termination, to receive the amount earned under the award. Except as otherwise provided by the Compensation Committee, awards will be paid on or before March 15th following the end of the plan year in which payment under the award is earned. The Compensation Committee will have the discretion to reduce or eliminate the amount otherwise payable to a participant if it determines that such a reduction or elimination is in the best interests of the Company.

Retirement Plans

The Company established a defined contribution plan for all employees age 21 and older who have completed one month of service for payrolls after April 1, 2022. The Company does not currently make a matching contribution.

Employee Benefits

The Company's NEOs are eligible to participate in employee benefit plans and programs, including medical and dental benefit plans.

Employment Agreements

The following discussion contains a summary of the terms of the NEOs employment agreements currently in effect.

Zannes Employment Agreement. The Company entered into an employment agreement with Ms. Zannes on February 1, 2015, which sets forth the terms and conditions of her employment (the "**Zannes Agreement**"). Pursuant to the Zannes Agreement, Ms. Zannes serves as the Company's Chief Executive Officer and was entitled to an annual base salary of \$220,000. On July 26, 2023, the Company and Ms. Zannes entered into an amendment to the Zannes Agreement to provide for the payment of an annual base salary of \$260,000 effective August 1, 2023. The Zannes Agreement may be terminated by either party at any time, provided that Ms. Zannes is required to give the Company at least 90 days advance notice of termination.

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In the event the Company terminates Ms. Zannes' employment without "Cause" (as defined in the Zannes Agreement) she is entitled to receive the following payments and benefits, in addition to any accrued obligations: (i) an amount of cash equal to the sum of 12 months of her then-current annual base salary, payable in the form of salary continuation in regular installments, in accordance with our normal payroll practices, over a period of 12 months from the termination date, and (ii) reimbursement for her healthcare insurance premiums for a period of up to 12 months.

Dougherty Offer Letter. Pursuant to the terms of an offer letter dated April 11, 2023, entered into between the Company and Mr. Dougherty, Mr. Dougherty will receive an annual base salary of \$250,000. The offer letter provided that Mr. Dougherty would receive a one-time signing bonus, comprised of both cash and equity. The cash portion of the signing bonus would equal \$30,000 and the equity portion of the signing bonus would be a grant of restricted stock with the number of shares to be issued to be equal to the quotient obtained by dividing \$100,000 by the average of the closing stock price of the Company's Common Stock on each of the 30 trading days prior to the date of grant. In addition, the offer letter states that Mr. Dougherty will be eligible to receive further equity grants under the Company's equity incentive plan at the discretion of the Compensation Committee and to participate in the Company's health insurance and the 401K retirement plans on the same basis and at the same rates as the Company's similarly situated employees. In addition, on January 26, 2024, the Compensation Committee approved an amendment (the "Amendment") to Mr. Dougherty's offer letter to amend the terms of the restricted stock award previously granted to Mr. Dougherty pursuant to the offer letter (the "Prior Restricted Stock Award"). The Amendment provides that upon a Change in Control (as defined in the Company's Amended and Restated 2014 Equity Incentive Plan, as amended), any outstanding and unvested portion of the Prior Restricted Stock Award shall vest in full immediately prior to such Change in Control.

Girgenti Employment Agreement. The Company entered into an employment agreement with Mr. Girgenti on January 1, 2020, which sets forth the terms and conditions of his employment (the "**Girgenti Agreement**"). Pursuant to the Girgenti Agreement, Mr. Girgenti serves as the Company's Executive Chairman and is entitled to an annual base salary of \$120,000, one-half of which is paid in cash and one-half of which is paid in the form of restricted stock grants. The cash portion of his compensation is deferred and credited to an unfunded bookkeeping account established on his behalf and is payable to Mr. Girgenti on the earlier of: (i) a Change in Control of the Company (as defined in the Girgenti Agreement); (ii) his termination as Chairman of the Board; (iii) the termination of his employment without Cause (as defined in the Girgenti Agreement); (iv) his death; or (v) the third anniversary of the payroll date when such compensation would have been paid but for the deferral. The Girgenti Agreement may be terminated by either party at any time, provided that Mr. Girgenti is required to give the Company at least 30 days advance notice of termination.

In the event the Company terminates Mr. Girgenti's employment without "Cause" or Mr. Girgenti terminates his employment for "Good Reason" (as defined in the Girgenti Agreement) he is entitled to receive the following payments and benefits, in addition to any accrued obligations: (i) all deferred payments of his cash compensation, and (ii) the immediate vesting of any unvested shares of restricted stock granted to him under the Girgenti Agreement. In the event the Company terminates Mr. Girgenti's employment for "Cause," Mr. Girgenti will not be entitled to any of his deferred cash compensation or vesting of his restricted stock.

Clawback Policy

The Board has adopted a clawback policy which requires the clawback of erroneously awarded incentive-based compensation of past or current executive officers awarded during the three full fiscal years preceding the date on which the issuer is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the federal securities laws. There is no fault or misconduct required to trigger a clawback.

The Compensation Committee shall determine, in its sole discretion, the timing and method for promptly recouping such erroneously awarded compensation, which may include without limitation: (a) seeking reimbursement of all or part of any cash or equity-based award, (b) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (c) cancelling or offsetting against any planned future cash or equity-based awards, (d) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations promulgated thereunder, and (e) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Compensation Committee may affect recovery under this policy from any amount otherwise payable to the executive officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the executive officer.

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Outstanding Equity Awards at December 31, 2023

The table below summarizes the outstanding equity awards awarded to the Company's NEOs during the fiscal year ended December 31, 2023.

Name	Grant Date	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) ⁽¹⁾	Market Value of Shares of Stock That Have Not Vested (\$) ⁽²⁾
Maria Zannes	4/28/2014	64,848	-	1.16	4/27/2024	-	-
	7/27/2015	3,571	-	4.20	7/26/2025	-	-
	7/25/2016	3,571	-	7.00	7/24/2026	-	-
	4/24/2027	3,571	-	7.00	4/23/2027	-	-
	5/7/2018	7,142	-	7.70	5/6/2028	-	-
	2/25/2019	2,857	-	7.70	2/24/2029	-	-
	7/26/2029	7,142	-	7.70	7/25/2029	-	-
	2/5/2020	7,142	-	7.70	2/4/2030	-	-

	7/27/2020	7,142	-	7.70	7/26/2030		
	7/26/2021	7,142	-	7.70	7/26/2031	-	-
	12/16/2031	7,142	-	4.20	12/15/2031	-	-
	7/26/2021	-	-	-	-	698	989
	6/6/2023	-	-	-	-	13,092	18,553
Michael Dougherty	6/6/2023	-	-	-	-	52,356	74,194
Steven Girgenti	4/28/2014	64,848	-	1.16	4/27/2024		
	7/27/2015	3,571	-	4.20	7/26/2025		
	7/25/2016	3,571	-	7.00	7/24/2026		
	4/24/2017	3,571	-	7.00	4/23/2027		
	5/7/2018	7,142	-	7.70	5/6/2028		
	7/26/2019	7,142	-	7.70	7/25/2029		
	7/27/2020	7,142	-	7.70	7/26/2030		
	12/16/2021	7,142	-	4.20	12/15/2031		
	2/19/2021	-	-	-	-	3,896	5,521
	12/31/2021	-	-	-	-	14,285	20,243
	8/9/2023	-	-	-	-	26,315	37,291

(1) The following table shows the vesting schedule for restricted stock awards in this column vest:

Name	Grant Date	Vesting Schedule
M. Zannes	7/26/2021	Vests in equal monthly installments over the 36 months following the date of grant
	6/6/2023	Vests in equal monthly installments over the 12 months following the date of grant
M. Dougherty	6/6/2023	Vests in equal monthly installments over the 36 months following the date of grant, subject to the closing price of the Company's common stock averaging at least \$5.00 per share for 30 consecutive trading days
S. Girgenti	2/19/2021	Vests on third anniversary of the grant date, February 19, 2024
	12/31/2021	Vests on third anniversary of the grant date, December 31, 2024
	8/9/2023	Vests on third anniversary of the grant date, August 9, 2026

(2) Calculated by multiplying the closing price per share of the Company's common stock on December 29, 2022, \$1.471 by the number of shares.

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Director Compensation

2023 Director Compensation Program

The Board adopted a compensation plan for directors on November 21, 2022, pursuant to which directors are compensated for services as a director of the Company. Beginning on January 1, 2023, each director will receive compensation in accordance with the following:

- each director will be paid \$25,000 per year in cash with payments to be made in four quarterly installments of \$6,250 on each of January 1, April 1, July 1, and October 1;
- the Chairman of the Board will be paid an additional \$10,000 per year in cash, with payments to be made to the chairman in four quarterly installments of \$2,500 on each of January 1, April 1, July 1, and October 1;
- the chairman of the Audit Committee will be paid an additional \$5,000 per year in cash, with payments to be made to the Audit Committee chairman in four quarterly installments of \$1,250 on each of January 1, April 1, July 1, and October 1;
- the chairmen of the Compensation Committee and the Nominating and Governance Committee will be paid an additional \$2,500 per year in cash, with payments to be made to such committee chairmen in four quarterly installments of \$625 on each of January 1, April 1, July 1, and October 1; and
- each director will be granted a quarterly restricted stock award valued at \$18,750 based on the fair market value of the Company's Common Stock on the date of grant (which shall be deemed to be the greater of (a) the average closing price of the Company's Common Stock on the Nasdaq Stock Market over the 30 trading days prior to the date of grant, or (b) the closing price of the Company's Common Stock on the Nasdaq Stock Market on the trading date immediately prior to the date of grant) on each of January 1, April 1, July 1, and October 1. The restricted stock awards will vest after three months of continued service by the director.

The table below summarizes the compensation paid to the Company's non-NEO directors who served on the Board during the fiscal year ended December 31, 2023.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) ⁽¹⁾	Total (\$)
Robert Anderson	25,000	74,996	99,996
Stuart Diamond	30,000	74,996	104,996
Peter Knight	27,500	74,996	102,496
Mohsin Meghji ⁽²⁾	25,000	74,996	99,996
Gary Rubin	27,500	74,966	102,496
Roby Joyce ⁽³⁾	6,250	18,750	25,000
Jamie Platt ⁽⁴⁾	—	—	—

(1) Amounts do not reflect compensation actually received by the directors. Instead, the amounts represent aggregate grant date fair value of the restricted stock award computed in accordance with ASC 718, Stock Compensation. The valuation assumptions used in determining such amounts are consistent with those described in Note 11 of the Company's Consolidated Financial Statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. As of December 31, 2023, the aggregate number of outstanding exercisable options held by each individual who served as a non-NEO director during 2023 was as follows: Robert Anderson—104,129; Stuart Diamond—7,142; Peter Knight—28,568; Mohsin Meghji—21,426; Gary Rubin—32,139; Roby Joyce—0; and Jamie Platt—0.

(2) Mr. Meghji resigned on December 1, 2023

(3) Dr. Joyce was appointed as a director on September 18, 2023.

(4) Dr. Platt was appointed as a director on December 1, 2023.

Changes to Program in Fiscal 2024

In March 2024, on the recommendation of the Compensation Committee, our Board amended the terms of the equity grants from quarterly to annually as follows: beginning July 1, 2024, each Board member shall receive an annual equity grant of restricted stock on July 1st of each year with a grant date value (which shall be equal to the closing price of a share of the Company's common stock as of the date of grant on the principal established stock exchange or national market system on which the Company's common stock is then traded) of approximately \$75,000 that will vest pro rata on a monthly basis for 12 months commencing on August 1st of each year.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2023, with respect to the Company's 2014 Incentive Compensation Plan, which was approved by the Company's stockholders:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	676,553	\$ 3.98	683,175
Total	676,553	\$ 3.98	683,175

(1) The number of shares of Common Stock that may be issued pursuant to awards under the 2014 Equity Incentive Plan shall not exceed in the aggregate the greater of (i) 8,000,000 shares of Common Stock, or (ii) that number of shares equal to 20% of the total issued and outstanding shares of Common Stock.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Zannes Purchase of Bridge Note and Accompanying Bridge Warrant

In August 2022, Maria Zannes, the President, CEO, and a director of the Company, purchased a convertible promissory note (a "**Bridge Note**") in the principal amount of \$99,000, which accrued interest at a rate of 6% per year. Originally, all principal and unpaid interest on the Bridge Note was due, if not settled prior, on May 31, 2022. Upon the IPO Closing on September 6, 2022, the Bridge Note automatically converted into 23,672 shares of Common Stock.

In connection with her Bridge Note purchase, Ms. Zannes was issued an accompanying warrant (a "**Bridge Warrant**") to purchase one share of the Company's Common Stock for each conversion share based on the principal balance of the Bridge Note at an exercise price equal to \$5.25 per share. The Bridge Warrant issued to Ms. Zannes entitled her to purchase 23,571 shares of Common Stock at an exercise price of \$5.25 per share.

Girgenti Purchase of Bridge Note and Accompanying Bridge Warrant

In August 2022, Steven Girgenti, the Executive Chairman and a director of the Company, purchased a Bridge Note in the principal amount of \$150,000. Upon the IPO closing, Mr. Girgenti's Bridge Note automatically converted into 35,866 shares of Common Stock.

In connection with his Bridge Note purchase, Mr. Girgenti received a Bridge Warrant to purchase 35,714 shares of Common Stock at an exercise price of \$5.25 per share.

PPLS Acquisition of the Laboratory

On September 18, 2023, PPLS consummated the Acquisition of the Laboratory Assets pursuant to the terms of the Asset Purchase Agreement with Village Oaks. As a result of the Acquisition, the CAP-accredited CLIA-certified clinical pathology laboratory is owned by PPLS. Dr. Joyce was the Medical Director and Laboratory Director of the clinical pathology laboratory prior to the Acquisition and he continues to serve as Medical Director and Laboratory Director after the Acquisition. Founded in 2007 by Dr. Roby Joyce, Village Oaks has provided pathology services to physicians practicing in a variety of outpatient settings. Since September 2021, Village Oaks, under the trade name Precision Pathology Services, has offered CyPath[®] Lung for sale as an LDT for the detection of early-stage lung cancer. In addition to CyPatf[®] Lung, PPLS intends to continue to offer a range of laboratory services including respiratory testing for SARS-CoV-2 and influenza, anatomical pathology, morphological stains, histological services, DNA extractions, STI testing and women's and men's health testing.

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

The Asset Purchase Agreement contains customary representations, warranties and covenants made by PPLS and Village Oaks and consummation of the transaction was subject to customary closing conditions, including, among other things, entry into the other ancillary agreements described below.

Pursuant to the Asset Purchase Agreement, PPLS assumed all liabilities and obligations under and obtained any and all rights, title and interest of Village Oaks in and to (i) the Assumed Leases under the Assumption Agreement; (ii) the Assumed Contracts under the Assumption Agreement; (iii) all accounts payable of Village Oaks as of September 18, 2023 that were incurred in the ordinary course of business consistent with past custom and practice; and (iv) the lease of the premises used in connection with operation of the CLIA-certified and CAP-accredited clinical pathology laboratory, pursuant to the Assignment and Assumption of Lease, which Assignment of Lease was consented to by the landlord of the leased premises. The monthly rent is currently \$10,143.83 per month and the term of the Lease is five years.

In connection with the Asset Purchase Agreement, PPLS entered into the Management Services Agreement with Village Oaks, pursuant to which PPLS will provide comprehensive management and administrative services to Village Oaks in connection with the operation of Village Oaks' professional cytopathology, histopathology, clinical and anatomic pathology interpretation medical services practice. PPLS will provide space, equipment, administrative, management and clinical personnel, billing and collection, and related management services to Village Oaks in exchange for a management fee of 70% of the net revenues received by Village Oaks from the provision of the medical services. The Management Services Agreement has an initial term of 20 years and provides that upon expiration of the initial term, it will be automatically extended for two additional successive terms of five years each, unless either party delivers written notice of its intention not to extend the term of the agreement not less than 90 days prior to the expiration of the preceding term. The Management Services Agreement also provides that until the fifth anniversary of its effective date, Village Oaks will not, without the prior written approval of PPLS own, operate or have any financial interest in any other person or entity that operates an independent laboratory or an enterprise within the United

In connection with the Asset Purchase Agreement, PPLS entered into the Succession Agreement, pursuant to which Dr. Joyce, as holder of 100% of the issued and outstanding stock of Village Oaks, and Village Oaks are restricted from disposing of their equity interests in Village Oaks, subject to certain exceptions, without the prior written consent of us and Village Oaks. The Succession Agreement further provides that the entire equity interest held by Dr. Joyce in Village Oaks will be automatically assigned and transferred to a successor who meets the Eligibility Requirements of a Designated Physician, as such terms are defined and described in the Succession Agreement, in the event of, among other things, the death, disability, retirement, or a court's determination of incompetence of Dr. Joyce, as well as Dr. Joyce's failure to satisfy the eligibility requirements of a Designated Physician, exclusion or disqualification from participation in the Medicare program, conviction of a felony or crime or moral turpitude, bankruptcy filing, or material breach of the Succession Agreement. In the event of the automatic transfer of Dr. Joyce's equity interests in Village Oaks as provided in the Succession Agreement, such agreement provides that the board of directors of Village Oaks shall nominate a group of three candidates as the Designated Physician who satisfy the Eligibility Requirements. In the event the Company desires not to select any of such candidates, the Company shall select and appoint a successor Designated Physician from any other physicians that satisfy the Eligibility Requirements. Subject in all cases to the Management Services Agreement, Dr. Joyce shall not cause any voluntary interruption of the conduct of Village Oaks' business and operations, and shall use commercially reasonable efforts to preserve (or assist us in preserving) all rights, privileges and franchises held by Village Oaks, including the maintenance of all contracts, copyrights, trademarks, licenses and registrations.

In connection with the Asset Purchase Agreement, PPLS entered into the Professional Services Agreement with Village Oaks, pursuant to which Village Oaks will provide pathology interpretation services as requested on behalf of PPLS based on the professional fees approved for the CPT code for the services provided under the Medicare Physician Fee Schedule in the locality where the test is performed. The Professional Services Agreement has an initial term of 20 years and provides that upon expiration of the initial term, it will be automatically extended for successive terms of 12 months each, unless either party delivers written notice of its intention not to extend the term of the agreement not less than 30 days prior to the expiration of the preceding term.

In connection with the Asset Purchase Agreement, we entered into the Executive Employment Agreement with Dr. Joyce, for a term of three years, to serve as the Medical Director and Laboratory Director of PPLS at a base salary of \$333,333.34 per year. Pursuant to the Joyce Employment Agreement, Dr. Joyce was also appointed to serve on our Board. Dr. Joyce will be eligible to participate in or receive benefits under our benefit plans generally made available to executives of similar status and responsibilities and will be provided use of a company car. In the event the Joyce Employment Agreement is terminated for any reason, including by Dr. Joyce upon 60 days' notice, by us for cause or by reason of Dr. Joyce's death, Dr. Joyce (or his estate as applicable) will receive his base salary for the remainder of the three-year employment term. However, the Joyce Employment Agreement provides that if Dr. Joyce breaches any of the restrictive covenants set forth in the Joyce Employment Agreement, including a covenant not to compete during his term of employment and a covenant not to knowingly disclose confidential information, such breach will be grounds for the immediate termination of Dr. Joyce and will result in the forfeiture of all compensation and benefits otherwise due to Dr. Joyce.

One of the Assumed Leases is the Hologic Equipment Lease, pursuant to which PPLS leases reagent equipment from Hologic and is required to purchase a minimum number of specified testing kits each year. The total monthly minimum purchase commitment PPLS is required to pay Hologic, inclusive of the lease of the reagent equipment, is \$16,914 per month. The term of the Hologic Equipment Lease currently expires on December 20, 2027.

Another of the Assumed Leases is the Leica Equipment Lease, pursuant to which PPLS leases reagent equipment from Leica and is required to purchase a minimum number of specified testing kits. The total monthly minimum purchase commitment PPLS is required to pay to Leica, inclusive of the lease of the reagent equipment, is \$19,790 per month. The term of the Leica Equipment Lease currently expires on March 23, 2026.

One of the Assumed Contracts is the License Agreement. Pursuant to the License Agreement, Pathology Watch granted a license to its digital imaging cloud-based pathology platform to facilitate remote interpretation and billing of pathology specimens by qualified professionals to PPLS for a monthly fee of \$25,000. In connection with the License Agreement, Pathology Watch also provides certain support services and marketing vendor services to PPLS for the monthly fee of \$38,000, for a total monthly fee paid by PPLS to Precision Watch of \$63,000. The License Agreement is for an initial term of 12 months, unless terminated by either party upon 90 days' notice, and provides that upon expiration of the initial term (or any renewal term), it will be automatically extended for successive 12-month terms, unless either party notifies the other party of its intention not to renew the License Agreement not less than 90 days prior to the expiration of the current term.

In connection with the Asset Purchase Agreement, Dr. Joyce, on behalf of Village Oaks, executed the Bill of Sale, pursuant to which all rights, title, and interest of Village Oaks in and to the permits listed on Exhibit A attached thereto, inclusive of the CLIA-certificate and CAP-accreditation, notwithstanding the transfer of the CLIA certificate by operation of law to PPLS upon consummation of the Acquisition, were confirmed to have been transferred and assigned to PPLS.

Amendment to Warrants

On September 17, 2023, Mr. Girgenti, the Cranye Girgenti Testamentary Trust, Gary Rubin, The Harvey Sandler Revocable Trust, a trust of which Mr. Rubin is a co-trustee, Ms. Zannes and Dr. Joyce consented to an amendment of the terms of the outstanding warrants that they own. Such warrants include warrants (i) Tradeable Warrants to purchase 98,198, 39,182, and 39,182 shares of Common Stock owned by Mr. Girgenti, The Harvey Sandler Revocable Trust, and Ms. Zannes, respectively); (ii) Non-Tradeable Warrants to purchase 102,286, 40,813, and 40,813 shares of Common Stock owned by Mr. Girgenti, The Harvey Sandler Revocable Trust, and Ms. Zannes, respectively; and (iii) Pre-IPO Warrants to purchase 469,063, 8,332, 571,373, 23,571, 17,137, and 14,285 shares of Common Stock owned by Mr. Girgenti, the Cranye Girgenti Testamentary Trust, Mr. Rubin, The Harvey Sandler Revocable Trust, Ms. Zannes and Dr. Joyce, respectively. The warrant amendment provides that such warrants will not be exercisable until the date that we file a certificate of amendment to our certificate of incorporation with the State of Delaware which increases the number of shares of our authorized Common Stock to allow for sufficient authorized and unissued shares of Common Stock for the full exercise of all of the outstanding Pre-IPO Warrants, Tradeable Warrants and Non-Tradeable Warrants of the Company and the issuance of all of the shares of Common Stock underlying such warrants.

Timothy Zannes Compensation

Timothy Zannes, brother of Maria Zannes, our Chief Executive Officer, has been employed by the Company as General Counsel and Secretary since 2014. Mr. Zannes received (i) a salary of \$70,008 and an equity award valued at \$9,997 in 2002 and (ii) a salary of \$70,008 and a bonus of \$21,000, which was paid on January 31, 2024, 50% in cash and 50% in shares of restricted stock. The number of shares of restricted stock issued was determined by dividing the cash value of 50% of Mr. Zannes bonus by the closing price of the Company's common stock on January 31, 2024. Mr. Zannes is scheduled to receive an annual salary in 2024 of \$80,000.

Policies and Procedures for Related Party Transactions

The Board has adopted a written Code of Ethics and Business Conduct, which includes a policy on conflicts of interest that requires the Company's directors and executive officers to seek determination and prior authorizations or approvals of potential conflicts of interest exclusively from the Board. In reviewing and approving any such transactions, the Company's General Counsel and Board consider all relevant facts and circumstances. The Code of Ethics and Business Conduct is available on the Investor Relations section of the Company's website at ir.bioaffinitytech.com and can be accessed through the "Governance Documents" hyperlink under the "Governance" tab. The Company intends to disclose any amendments to the Code of Ethics and Business Conduct, or any waivers of its requirements, on its website to the extent required by the applicable rules and exchange requirements.

Policies and Procedures for Related Party Transactions

The Board has adopted a written Code of Ethics and Business Conduct, which includes a policy on conflicts of interest that requires our directors and executive officers to seek determination and prior authorizations or approvals of potential conflicts of interest exclusively from the Board. In reviewing and approving any such transactions, the Company's General Counsel and Board consider all relevant facts and circumstances. The Code of Ethics and Business Conduct is available on the Investor Relations section of the Company's website at ir.bioaffinitytech.com and can be accessed through the "Governance Documents" hyperlink under the "Governance" tab. We intend to disclose any amendments to the Code of Ethics and Business Conduct, or any waivers of its requirements, on its website to the extent required by the applicable rules and exchange requirements.

Insider Trading Policy

We maintain a policy on insider trading that applies to any and all transactions in our securities held by any director, officer, or employee. The policy prohibits all of our directors, officers, and employees from trading in our securities while in possession of material nonpublic information ("**MNPI**") about us and from giving MNPI to others who may trade on the basis of such information. Under the policy, Timothy Zannes, the Company's Executive Vice President, Secretary, and General Counsel, is designated as our Insider Trading Compliance Officer (the "**Compliance Officer**"). Prior to engaging in transfers of our securities intended to comply with the affirmative defense provided under Rule 10b5-1 promulgated under the Exchange Act, employees, officers, and directors must receive the Compliance Officer's approval.

Transfer Agent

The transfer agent and registrar for the Company's Common Stock is VStock Transfer, LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598.

DESCRIPTION OF SECURITIES

Authorized Capital Stock

We are currently authorized to issue up to 25,000,000 shares of Common Stock, par value \$0.007 per share, and 20,000,000 shares of Preferred Stock, par value \$0.001 per share.

As of April 4, 2024, there were 11,514,354 shares of Common Stock issued and outstanding that were held of record by 79 stockholders. As permitted by the Company's Charter, the Company has designated 5,400,000 shares of Preferred Stock as "Series A Convertible Preferred Stock," par value \$0.001 per share (the "**Series A Preferred Stock**"), of which no shares are outstanding.

Common Stock

Voting Rights

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

Dividend Rights

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

Rights upon Liquidation

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

No Preemptive or Similar Rights

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

Series A Preferred Stock

Voting Rights

Holders of the shares of Series A Preferred Stock have the right to one vote for each share of Common Stock into which such Series A Preferred Stock could then be converted. In addition, for so long as 30% of the shares of Series A Preferred Stock remain outstanding, the Series A Preferred Stock holders, voting together as a single class, may exercise the Series A Director Designation Right, pursuant to which they are entitled to elect one director of the Company as the Series A Representative. Any Series A Representative elected by the holders of Series A Preferred Stock may be removed from office only by the Series A Preferred Stockholders, and any vacancy of a Series A Representative may be filled only by the holders of the Series A Preferred Stock. If at any time fewer than 30% of the shares of Series A Preferred Stock remain outstanding, then the director position previously held by the Series A Representative will be elected by all of the holders of Preferred Stock and Common Stock acting together.

Dividend Rights

Holders of shares of the Series A Preferred Stock are entitled to receive dividends, in preference to any declaration or payment of a dividend to holders of the Common Stock, of 8% per share per annum when, as and if declared by the Board. Such dividends are not cumulative. See "Description of Securities—Dividend Policy" below.

Rights Upon Liquidation

In the event of any liquidation, dissolution or similar event, the holders of shares of Series A Preferred Stock are entitled to receive in preference to any distribution of any of the assets of the Company to the holders of the Common Stock, \$7.70 per share (subsequent to the reverse-stock-split calculation). Unless otherwise decided by holders of a majority of the Preferred Stock outstanding, a liquidation includes a sale of substantially all of the assets of the Company and a merger, unless such merger is solely for the purpose of changing the Company's state of incorporation or a majority of the voting power of the surviving entity will be owned by persons who were stockholders of the Company prior to the merger. Holders of shares of Preferred Stock will not participate with the holders of Common Stock in the distribution of the remainder of the Company's assets.

Conversion Rights

Shares of Series A Preferred Stock are convertible, at the option of the holder thereof, into shares of Common Stock at any time. Shares of Series A Preferred Stock are automatically converted into shares of Common Stock following the closing of an underwritten initial public offering of our Common Stock in which at least \$10,000,000 in shares of Common Stock are sold at a price of \$3.00 per share or more on such other date as agreed to by a holders of the majority of the outstanding shares of Series A Preferred Stock. The holders of a more than a majority of our outstanding shares of Series A Preferred Stock executed a written consent such that all of the issued and outstanding shares of Series A Preferred Stock automatically converted into fully paid and nonassessable shares of Common Stock immediately prior to the closing of the initial public offering at the then-effective conversion rate of the Series A Preferred Stock. The conversion rate of Series A Preferred Stock into Common Stock is initially 1 for 7 (as adjusted for the 1-for-7 reverse stock split) but is subject to further adjustment in the event of a stock split, stock dividend or similar event.

Following the automatic conversion of the Series A Preferred Stock shares into Common Stock immediately prior to the closing of our initial public offering, the Company does not intend to issue any further shares of Series A Preferred Stock. Furthermore, the Series A Director Designation Right ceased to exist because no shares of Series A Preferred Stock are outstanding. The director who currently serves as the Series A Representative, Gary Rubin, will continue to serve as a director until his earlier resignation or removal or until his successor is duly elected and qualified. The number of Board seats for election by the holders of the Common Stock will be expanded by one so that the director position that the holders of the Series A Preferred Stock were previously entitled to elect will be subject to election the holders of the Common Stock following the conversion of the Series A Preferred Stock into Common Stock.

Warrants

Warrants Issued In the Private Placement

In connection with our private placement that closed on March 8, 2024, we issued to the Selling Stockholders, Common Warrants and Placement Agent Warrants, as applicable to purchase 1,632,000 shares of Common Stock. See “Description of The Private Placement Offering” for additional information regarding the terms of the Common Warrants and Placement Agent Warrants.

Warrants Issued In Connection with Our Initial Public Offering

In connection with our initial public offering, we sold Tradeable Warrants to purchase up to 1,392,767 shares of our Common Stock at an exercise price equal to \$7.35, which Tradeable Warrants were adjusted as a result of our registered direct offering such that we currently have outstanding Tradeable Warrants to purchase 1,601,258 shares of Common Stock at a reduced exercise price of \$3.0625 per warrant, and Non-Tradeable Warrants to purchase up to 1,392,767 shares of our Common Stock at an exercise price equal to \$7.656 per share, which Non-Tradeable Warrants were adjusted as a result of our registered direct offering such that we currently have outstanding 2,701,554 shares of our Common Stock at an exercise price equal to \$3.0625. As of the date of this prospectus, there are an aggregate of 4,305,812 shares of Common Stock issuable upon the exercise of outstanding Tradeable Warrants and Non-Tradeable Warrants, all of which have an exercise price of \$3.0625 per share and expire five years from the date of issuance. The Tradeable Warrants are currently listed on Nasdaq and trade under the symbol “BIAFW.” This summary of certain terms and provisions of the warrants offered in our initial public offering is not complete and is subject to, and qualified in its entirety by the provisions of the form of warrants, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

In connection with the sale of our convertible bridge notes, we issued Placement Agent’s Warrants to the Placement Agent, or their designees, to purchase an aggregate of 54,464 shares of our Common Stock. The Placement Agent’s Warrants have a five-year term commencing 180 days after the commencement of the sales in the initial public offering and have an exercise price of \$7.35 per share.

In connection with our initial public offering, we agreed to issue to the representative of the underwriters or their designees warrants to purchase an aggregate of 26,652 shares of our Common Stock as additional consideration to the underwriters. The underwriters’ warrants have an exercise price of \$7.044 per share, are exercisable during the period commencing 180 days after the commencement of sales in our initial public offering and expire five years from the effective date of our initial public offering and contain customary “cashless” exercise and registration rights provisions.

Other Outstanding Warrants

We also have outstanding warrants to purchase up to 2,900,904 shares of our Common Stock, having a weighted average exercise price of \$5.31 expiring between October 14, 2026 and July 25, 2027, issued prior to consummation of our initial public offering and 1,600,000 warrants outstanding that we issued in our March 2024 registered direct offering having an exercise price of \$1.64 per share.

Stock Options

As of the date of this prospectus, we had reserved the following shares of Common Stock for issuance:

- 806,392 shares of our Common Stock reserved for issuance under stock option agreements with a weighted average exercise price of \$4.33 per share; and
- 658,294 shares of our Common Stock reserved for future issuance under the Plan.

Exchange Listing.

Our Common Stock and the Tradeable Warrants trade on The Nasdaq Capital Market under the symbols “BIAF” and “BIAFW,” respectively.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business. We do not anticipate paying any cash dividends in the foreseeable future, and it is unlikely that investors will derive any current income from ownership of our stock.

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

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

Delaware Anti-Takeover Statute

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

- before the stockholder became interested, the corporation’s board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by the corporation’s board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

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

Provisions of Our Charter and A&R Bylaws

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

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Director Vacancies

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

Special Meetings of Stockholders

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

Prohibition of Stockholder Action by Written Consent

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

Advance Notice Requirements

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

Amendment to Charter and Bylaws

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

Exclusive Forum

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

Limitations on Liability and Indemnification of Officers and Directors

For a discussion of liability and indemnification, see the section entitled “Management—Limitations on Liability and Indemnification of Officers and Directors.”

PLAN OF DISTRIBUTION

The Selling Stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction, a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities are “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholders have informed us that they do not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the Selling Stockholders do not own any Common Warrants, Common Warrants Shares, Placement Agent Warrants or Placement Agent Warrant Shares, as applicable.

Pursuant to applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

EXPERTS

The consolidated financial statements of bioAffinity Technologies, Inc. as of December 31, 2023 and 2022, and for the years ended December 31, 2023 and 2022, appearing in this prospectus and registration statement have been audited by WithumSmith+Brown, PC, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about bioAffinity Technologies, Inc.’s ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Blank Rome LLP, New York, New York.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information filed electronically with the SEC, which is available at <http://www.sec.gov>. We also make these documents available on our website at

<https://www.bioaffinitytech.com/>. Our website and the information contained, or connected to, our website is not incorporated by reference in this prospectus and you should not consider it part of this prospectus.

This prospectus forms part of the registration statement on Form S-1 we filed with the SEC under the Securities Act. This prospectus does not contain all of the information set forth in the registration statement or the exhibits and schedules filed as part of the registration statement. For further information about us and our securities offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

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1,632,000 Shares of Common Stock



bioAffinity Technologies, Inc.

PROSPECTUS

April 15, 2024
