As filed with the Securities and Exchange Commission on May 5, 2025.

Registration No. 333-286921

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

Amendment No.1 to

FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

bioAffinity Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**8731**	**46-5211056**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3300 Nacogdoches Road
Suite 216
San Antonio, Texas 78217
(210) 698-5334

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Maria Zannes
Chief Executive Officer
3300 Nacogdoches Road, Suite 216
San Antonio, Texas 78217
(210) 698-5334

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS Subject to Completion, dated May 5, 2025

Up to 7,014,028 Shares of Common Stock

Pre-Funded Warrants to Purchase up to 7,014,028 Shares of Common Stock

Warrants to Purchase up to 13,677,354 Shares of Common Stock

Placement Agent Warrants to Purchase up to 210,420 Shares of Common Stock

Up to 20,901,802 Shares of Common Stock Issuable Upon Exercise of

Pre-Funded Warrants, Warrants and Placement Agent Warrants

We are offering up to 7,014,028 shares (the "Shares") of our common stock, par value $0.007 per share (the "Common Stock"), together with warrants (the "May 2025 Warrants") to purchase up to 13,677,354 shares of Common Stock. The number of shares of Common Stock issuable upon exercise of the May 2025 Warrants and offered hereby is equal to 150% of the number of Shares and Pre-Funded Warrants, plus an additional 30% increase in the number of shares of Common Stock that would be issuable upon exercise of the May 2025 Warrants if a reverse stock split is effected prior to the expiration of the May 2025 Warrants (the "Reverse Stock Split Adjustment") . This registration statement does not register the issuance of up to an additional 61,397,642 shares of Common Stock which are issuable upon exercise of the May 2025 Warrants pursuant to pursuant to the Anti-Dilution Adjustment (as defined below) contained therein. The assumed combined public offering price for each share of Common Stock and accompanying May 2025 Warrant to purchase one and one-half share of Common Stock is $0.499, which is equal to the last reported sale price of our Common Stock on the Nasdaq Capital Market ("Nasdaq" or the "Nasdaq Capital Market") on April 25, 2025. Each share of our Common Stock is being sold together with one May 2025 Warrant to initially purchase one and one-half share of Common Stock.

The May 2025 Warrants will have an initial exercise price of $[*] per share (110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant) and will be immediately exercisable, except that the issuance of shares of Common Stock upon exercise of the May 2025 Warrants pursuant to the Anti-Dilution Adjustment contained therein will be subject to the filing of an amendment to our certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to increase our authorized number of shares of Common Stock to 350,000,000 shares (the "Certificate of Amendment") and the date of stockholder approval of the Anti-Dilution Adjustment (collectively, the "Warrant Stockholder Approval"). The May 2025 Warrants will expire on the five-year anniversary of the later of the date that the Company files a Current Report on Form 8-K giving public notice of the Warrant Stockholder Approval (the "Stockholder Approval Notice Date") and the effective date of the filing of the Certificate of Amendment. The terms of the May 2025 Warrants will include (i) a one-time thirty percent (30%) increase in the number of shares of Common Stock issuable upon exercise of the May 2025 Warrants if a reverse stock split is effected prior to the expiration of the May 2025 Warrants (the Reverse Stock Split Adjustment) and (ii) subject to Warrant Stockholder Approval, a decrease of the exercise price of the May 2025 Warrants, if in a subsequent offering of our securities the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering is less than the exercise price immediately prior to such subsequent offering, to an exercise price that is equal to the lowest of the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering (subject to a floor of $0.10 per share) and an increase in the number of shares of our Common Stock underlying the May 2025 Warrants upon such exercise price reset so that the reset exercise price multiplied by the increased number of shares equals the aggregate proceeds that would have resulted from the full exercise of the May 2025 Warrants immediately prior to the reset (the "Anti-Dilution Adjustment"). We have agreed not to consummate a subsequent offering of our securities at a price less than the exercise price of the May 2025 Warrants immediately prior to such subsequent offering until the earlier of (i) eight months from the closing date of this offering and (ii) later of: (a) the filing of a registration statement registering certain shares of Common Stock issuable as a result of an Anti-Dilution Adjustment (as further described under "Description of the Securities We Are Offering:" (b) the Stockholder Approval Notice Date; and (c) the effective date of the filing of the Certificate of Amendment. Based on an assumed initial exercise price of $0.5489 per share (equal to 110% of the assumed combined offering price per Share and accompanying May 2025 Warrant), if a reverse stock split is effected an additional 3,156,312 shares of Common Stock (on a pre-reverse stock split basis which number shall be adjusted based on the reverse stock split ratio) will be issuable upon exercise of the May 2025 Warrants and then, subject to obtaining Warrant Stockholder Approval, if a subsequent offering occurs for which the exercise price of the May 2025 Warrants is reset to the floor price of $0.10 per share, an additional 61,397,642 (on a pre-reverse stock split basis which number shall be adjusted based on the reverse stock split ratio) shares of Common Stock would be issuable upon exercise of the May 2025 Warrants.

We are also offering to those purchasers, if any, whose purchase of shares of Common Stock in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering, the opportunity to purchase, in lieu of the shares of our Common Stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%), pre-funded warrants (the "Pre-Funded Warrants") each to purchase one share of Common Stock at an exercise price of $0.007 per share. Each Pre-Funded Warrant is being issued together with one May 2025 Warrant to purchase one and one-half share of Common Stock. The assumed combined public offering price for each Pre-Funded Warrant and accompanying May 2025 Warrant will be equal to the public offering price per share of Common Stock and accompanying May 2025 Warrant in this offering, minus $0.007. Each Pre-Funded Warrant will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and Placement Agent Warrants (as defined herein).

For each Pre-Funded Warrant sold, the number of shares of Common Stock sold will be reduced on a one-for-one basis. The shares of Common Stock and/or Pre-Funded Warrants and the accompanying May 2025 Warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

This offering will terminate on May 15, 2025, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share of Common Stock (or Pre-Funded Warrant) and accompanying May 2025 Warrant will be fixed for the duration of this offering.

We have engaged WallachBeth Capital, LLC (the "Placement Agent"), to act as our exclusive placement agent in connection with this offering. The Placement Agent has agreed

to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The Placement Agent is not purchasing or selling any of the securities we are offering, and the Placement Agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the Placement Agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. Since we will deliver the securities to be issued in this offering upon our receipt of investor funds, there is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. Because there is no minimum offering amount required as a condition to closing in this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. In addition, because there is no escrow account, trust or similar arrangement and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. We will bear all costs associated with the offering. See "Plan of Distribution" for more information regarding these arrangements.

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 25, 2025, the last reported sale price of (i) our Common Stock on Nasdaq was $0.499 per share, and (ii) our Tradeable Warrants on Nasdaq was $0.227 per Tradeable Warrant. There is no established public trading market for the May 2025 Warrants or the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the May 2025 Warrants or the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the May 2025 Warrants and the Pre-Funded Warrants will be limited.

Certain information in this prospectus is based on an assumed public offering price of $0.499 per Share and accompanying May 2025 Warrant (the last reported sale price of our Common Stock on Nasdaq on April 25, 2025). The actual public offering price will be determined between us and the Placement Agent based on market conditions at the time of pricing, and may be at a discount to the current market price of our Common Stock. Therefore, the recent market price per share of Common Stock used throughout this prospectus as an assumed combined public offering price may not be indicative of the final offering price.

We are an "emerging growth company" and a "smaller reporting company" as defined under federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to comply with reduced public company reporting requirements in future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our securities involves a high degree of risk. See the section entitled"Risk Factors" beginning on page 7 of this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

	Per Share and accompanying May 2025 Warrant	Per Pre-Funded Warrant and accompanying May 2025 Warrant	Total
Public offering price	$	$	$
Placement Agent fees[(1)]	$	$	$
Proceeds to us, before expenses[(2)]	$	$	$

(1) We have agreed to pay the Placement Agent a total cash fee equal to 8.0% of the gross proceeds raised in this offering. We have also agreed to reimburse the Placement Agent for its legal fees and expenses and other out-of-pocket expenses in an amount up to $120,000. In addition, we have agreed to issue to the Placement Agent, or its designees, warrants (the "Placement Agent Warrants") to purchase a number of shares of our Common Stock equal to 3.0% of the aggregate number of shares of Common Stock and Pre-Funded Warrants being offered at an exercise price equal to 110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant. We refer you to "Plan of Distribution" on page 90 of this prospectus for additional information regarding Placement Agent compensation.

(2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual offering amount, Placement Agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. We refer you to "Plan of Distribution" for additional information regarding Placement Agent compensation.

The delivery of the securities offered hereby is expected to be made on or about [__], 2025, subject to satisfaction of certain customary closing conditions.

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.

WallachBeth Capital, LLC

The date of this prospectus is [ ], 2025

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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 Additional 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.

ABOUT THIS PROSPECTUS

Neither we nor the Placement Agent 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 Placement Agent 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.

For investors outside the United States: We have not, and the Placement Agent has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. 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 its 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.

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 securities. 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.

Company Overview

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

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.

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

various types of cancer and potentially other diseases.

Through our wholly owned subsidiary PPLS, we acquired the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services, including the clinical pathology laboratory it owned, and we now operate the laboratory. The laboratory is accredited by the College of American Pathologists ("CAP") and certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Recent Developments

FDA Pivotal Study

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

Case Studies

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

Targeted Strategic Actions

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

Continuation of Department of Defense Research

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

Corporate Information

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

Implications of Being an Emerging Growth Company and a Smaller Reporting 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 until such time that we are no longer an EGC. We will continue to remain an EGC until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of our initial public offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer, as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act").

We are also a "smaller reporting company" as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an EGC, certain of the exemptions available to us as an EGC may continue to be available to us as a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to the Sarbanes-Oxley Act of 2002 ("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.

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. In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these

accounting standards until they would apply to private companies. We have elected to avail ourselves of the extended transition period for complying with new or revised financial accounting standards. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not EGCs which may make comparison of our financials to those of other public companies more difficult.

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 7 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 Our Financial Position

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

Risks Related to this Offering

- Our management will have broad discretion over the use of the net proceeds from this offering.
- You may experience dilution in the net tangible book value per share of the Common Stock issued in this offering or that may be issued upon the exercise of any warrants issued in this offering.
- Future issuances of our Common Stock or rights to purchase Common Stock, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- If we issue additional securities it could adversely affect the rights of the holders of our Common Stock.
- We may not raise the amount of capital we believe is required for our business plans in this offering.
- Investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.
- Purchasers of our securities in this offering pursuant to a securities purchase agreement may have additional rights.
- There is no public market for the May 2025 Warrants or Pre-Funded Warrants.
- The May 2025 Warrants in this offering are speculative in nature.
- Holders of warrants purchased in this offering will not have rights of holders of our shares of Common Stock until exercised.
- The May 2025 Warrants are not be exercisable until we obtain Warrant Stockholder Approval.
- If we do not maintain a prospectus relating to the Common Stock issuable upon exercise of the May 2025 Warrants and Pre-Funded Warrants, public holders will only be able to exercise on a "cashless basis."
- We may be required to repurchase the May 2025 Warrants.
- If the May 2025 Warrants are exercised after a reverse stock split and/or a reset of the exercise price stockholders will suffer substantial dilution**.**

Risks Related to our Diagnostic Product

- The FDA could impose greater regulatory burdens on laboratory developed tests ("LDTs").
- Delays or difficulties in the enrollment of patients could delay or prevent regulatory approvals.
- Clinical trials are expensive, time-consuming, and may not be successful.

Risks Related to Our Diagnostic Tests

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

Risks Related to the Operation of a CAP/CLIA Laboratory

- PPLS' operations depend upon the relationship of certain of our pathologists with existing customers.
- PPLS may be unable to maintain equipment or generate revenue when its equipment is not operational.
- If our sole laboratory facility becomes damaged or inoperable, loses its accreditation, or is required to vacate the facility, PPLS' ability to sell its products or provide diagnostic assays and pursue its research and development efforts may be jeopardized.
- Disruption in the commercial courier delivery services used by PPLS to transport sputum samples could harm its business.
- Security breaches, data loss, and other disruptions could compromise sensitive information of PPLS' business.

- If PPLS uses hazardous chemicals in a manner that causes injury, PPLS could be liable for damages.
- If PPLS is unable to successfully scale its operations to support demand its business could suffer.
- PPLS must dedicate substantial time and resources to its complex billing process to be paid.
- Delays of third-party billing and collection providers and an in-house billing function to transmit claims to payors could have an adverse effect on PPLS.

Risks Related to Intellectual Property Rights

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

Risks Related to Government Regulations

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

Risks Related to Ownership of Our Common Stock and Warrants

- Our failure to meet the listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.
- We do not expect to pay dividends in the foreseeable future.
- Our Common Stock market price may never exceed the exercise price of our outstanding warrants.
- Holders of our warrants have no rights as stockholders until they exercise their warrants.
- The provisions of our outstanding warrants could limit a warrant holder's ability to choose the judicial forum for disputes.
- The financial and operational projections that we may make from time to time are subject to inherent risks.
- Our stock price has fluctuated in the past, has recently been volatile, and may be volatile in the future.
- Our Common Stock has often been thinly traded.
- An investment in our Company may involve tax implications.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- Our Board can designate classes of Preferred Stock without stockholder approval.
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company more difficult.
- Provisions in our Charter and Amended and Restated ("A&R") Bylaws could make a merger, tender offer, or proxy contest difficult.
- Certain provisions of Delaware's General Corporation Law ("DGCL") may have anti-takeover effects.
- Our Charter designates Delaware state or federal courts as the exclusive forum for disputes.
- Provisions in our Charter and A&R Bylaws may discourage stockholders from bringing a lawsuit against our directors and officers.
- Our management collectively owns a substantial percentage of our Common Stock.
- If analysts publish unfavorable research, or none at all, about our business, our stock price and trading volume could decline.
- Any inability to report and file our financial results accurately and timely could harm our business.

THE OFFERING

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus.

Common Stock Offered	Up to 7,014,028 shares of Common Stock
Pre-Funded Warrants Offered	We are also offering to those purchasers, if any, whose purchase of shares of Common Stock in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering, the opportunity to purchase, in lieu of the shares of our Common Stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%), Pre-Funded Warrants each to purchase one share of Common Stock at an exercise price of $0.007 per share. Each Pre-Funded Warrant is being issued together with one May 2025 Warrant initially to purchase one and one-half share of Common Stock. The assumed combined public offering price for each Pre-Funded Warrant and accompanying May 2025 Warrant will be equal to the public offering price per share of Common Stock and accompanying May 2025 Warrant in this offering, minus $0.007. Each Pre-Funded Warrant will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. For each Pre-Funded Warrant we sell, the number of shares of Common Stock we sell will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants. See "Description of Securities We Are Offering—Pre-Funded Warrants" for additional information.

May 2025 Warrants Offered	Each Share of Common Stock or Pre-Funded Warrant is being offered together with one May 2025 Warrant initially to purchase one and one-half share of Common Stock, which number of shares of Common Stock may be increased by 30% pursuant to the Reverse Stock Split Adjustment. The May 2025 warrants will have an exercise price of $[*] per share (110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant) and will be immediately exercisable, except that the issuance of shares of Common Stock upon exercise of the May 2025 Warrants pursuant to the Anti-Dilution Adjustment will be subject to Warrant Stockholder Approval. The May 2025 Warrants will expire on the five-year anniversary of the later of the Stockholder Approval Notice Date and the filing of the Certificate of Amendment. The terms of the May 2025 Warrants will be governed by a Warrant Agent Agreement, dated as of the effective date of this offering, between us and VStock Transfer, LLC, as the warrant agent (the "Warrant Agent") and include the Reverse Stock Split Adjustment and the Anti-Dilution Adjustment. We have agreed not to consummate a subsequent offering of our securities at a price less than the exercise price of the May 2025 Warrants immediately prior to such subsequent offering until the earlier of (i) eight months from the closing date of this offering and (ii) later of: (a) the filing of a registration statement registering certain shares of Common Stock issuable as a result of an Anti-Dilution Adjustment (as further described under "Description of the Securities We Are Offering"; (b) the Stockholder Approval Notice Date; and (c) the effective date of the filing of the Certificate of Amendment. If a reverse stock split is effected an additional 3,156,312 shares of Common Stock (on a pre-reverse stock split basis, which number shall be adjusted based on the reverse stock split ratio) will be issuable upon exercise of the May 2025 Warrants and then, subject to obtaining Warrant Stockholder Approval, if a subsequent offering occurs for which the exercise price of the May 2025 Warrants is reset to the floor price of $0.10 per share, an additional 61,397,642 (on a pre-reverse stock split basis, which number shall be adjusted based on the reverse stock split ratio) shares of Common Stock would be issuable upon exercise of the May 2025 Warrants. If, at the time a holder exercises its May 2025 Warrants a registration statement registering the issuance of the shares of Common Stock underlying the May 2025 Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the May 2025 Warrants. Those purchasers who do not enter into the Purchase Agreement and do not provide us with information required for registration of the resale of the shares of Common Stock to be issued upon an Anti-Dilution Adjustment shall not have any of their shares issuable as a result of an Anti-Dilution Adjustment included in the registration statement we will file covering the resale of the shares issuable as a result of an Anti-Dilution Adjustment and will not be able to effect a cashless exercise with respect to such shares. Because the Anti-Dilution Adjustment contained in the May 2025 Warrants is not applicable until the effective date of the Warrant Stockholder Approval or triggered until there is an issuance of securities by the Company at a purchase, exercise or conversion price below the exercise price of the May 2025 Warrants, the May 2025 Warrants may never become exercisable at an exercise price less than their original exercise price or for a number shares in excess of 13,677,354. See, "Risk Factors" for more information regarding the exercisability of the May 2025 Warrants. We intend to register the resale shares of Common Stock issuable upon the Anti-Dilution Adjustment for those stockholders that provide information required for such registration, which is subject to Warrant Stockholder Approval, after the date of the Warrant Stockholder Approval. For more information regarding the May 2025 Warrants, you should carefully read the section titled "Description of Securities We Are Offering—May 2025 Warrants" in this prospectus.
Description of the Placement Agent Warrants	The registration statement of which this prospectus is a part also registers for sale, as a portion of the Placement Agent's compensation in connection with this offering, up to 210,420 shares of Comon Stock underlying the Placement Agent Warrants to be issued at the closing of the offering, which equals 3.0% of the assumed aggregate number of shares of Common Stock and Pre-Funded Warrants sold in this offering. The Placement Agent Warrants have substantially the same terms as the May 2025 Warrants; however, they will not have any anti-dilution provisions (other than protection against pro rata distributions or share combinations), will not include a provision to increase the number of shares underlying the Placement Agent Warrants upon the occurrence of a reverse stock split, they will be immediately exercisable and will terminate five (5) years from the commencement of sales of the securities in this offering. This prospectus relates to the Placement Agent Warrants and the shares of Common Stock underlying the Placement Agent Warrants. See "Plan of Distribution—Placement Agent Warrants" in this prospectus for a description of the Placement Agent Warrants. In accordance with FINRA Rule 5110(e), the Placement Agent may not sell, transfer, assign, pledge, or hypothecate the Placement Agent Warrant or the securities underlying such warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such warrants or the underlying securities for a period of 180 days following the date of commencement of sales pursuant to this public offering.
Common stock outstanding immediately before this offering	18,246,331 shares
Common stock outstanding immediately after this offering	25,260,359 shares, based on an assumed public offering price of $0.499 per share and accompanying May 2025 Warrant, which was the closing price of our Common Stock as reported on Nasdaq on April 25, 2025, and assuming no sale of any Pre-Funded Warrants and assuming none of the May 2025 Warrants or the Placement Agent Warrants issued in this offering are exercised.
Use of proceeds	We intend to use the net proceeds from the sales of the securities offered by this prospectus primarily for working capital and other general corporate purposes. See "Use of Proceeds."
Risk Factors	An investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus and other information included or incorporated by reference in this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.
Nasdaq listing symbol	Our Common Stock is listed on the Nasdaq Capital Market under the symbol "BIAF". There is no established trading market for the May 2025 Warrants or the Pre-Funded Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the May 2025 Warrants or Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the May 2025 Warrants and Pre-Funded Warrants will be limited.
Transfer Agent and Warrant Agent	The transfer agent and registrar for our Common Stock and the Warrant Agent for the May 2025 Warrants is VStock Transfer, LLC.

The information above is based on 18,246,331 shares of Common Stock outstanding as of April 25, 2025, and excludes, as of that date the following:

- 12,873,602 shares of Common Stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $2.74 per share;
- 304,125 shares of Common Stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $6.95 per share; and
- 1,249,024 shares of our Common Stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the outstanding options, warrants, or pre-funded warrants described in the bullets above;
- no exercise of the May 2025 Warrants or the Placement Agent Warrants issued in this offering; and
- no sale of Pre-Funded Warrants in this offering.

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 financings;
- 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 U.S. 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, ir.bioaffinitytech.com, www.cypathlung.com and www.Precisionpath.us/) to share Company information. Information contained on or that can be accessed through our websites is not, however, incorporated by reference in this 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 Our Financial Position

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

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

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

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

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

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

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

As of December 31, 2024, we had an accumulated deficit of $53.6 million and $1.1 million cash on hand. For the year 2024, cash used in operations was $7.1 million and net loss was $9.0 million. Despite that we raised an additional $1.4 million in gross proceeds in February 2025 through a private placement offering and we intend to raise proceeds of approximately $3,500,000 in this offering, we will still need to raise additional 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. 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 May 2025. Our future is dependent upon the ability to obtain financing and upon future profitable operations from the development of new business opportunities. There can be no assurance that we will be

successful in accomplishing these objectives. Without such additional capital, we may be required to curtail or cease operations and be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. WithumSmith+Brown, PC, our independent registered public accounting firm for the fiscal year ended December 31, 2024, has included an explanatory paragraph in its opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2024, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to this Offering

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.

Our management will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management regarding 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 us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

You may experience immediate and substantial dilution in the net tangible book value per share of the Common Stock issued in this offering or that may be issued upon the exercise of any May 2025 Warrants or Pre-Funded Warrants issued in this offering.

If the price per share of our Common Stock being offered in this offering or that may be issued upon the exercise of any Pre-Funded Warrants issued in this offering is higher

than the net tangible book value per share of our Common Stock, you will suffer immediate and substantial dilution in the net tangible book value of the Common Stock you purchase in this offering or the Common Stock underlying the Pre-Funded Warrants you purchase in this offering. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you invest in this offering.

Future sales and issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our 2024 Equity Incentive Plan and outstanding warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell additional shares of our Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we may determine from time to time. If we sell Common Stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Common Stock. Pursuant to our 2024 Equity Incentive Plan, which became effective on the business day prior to the public trading date of our Common Stock, our management is authorized to grant equity awards to our employees, officers, directors and consultants.

The aggregate number of shares of our Common Stock that might be issued pursuant to stock awards under our 2024 Equity Incentive Plan is 2,000,000 shares, of which 1,239,531 remain available for grant as of the date hereof. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

At April 11, 2025, we had outstanding (i) warrants to purchase an aggregate of 12,873,602 shares of Common Stock, with a weighted average exercise price equal to $2.74 per share, which includes Tradeable Warrants and Non-Tradeable Warrants that we issued in connection with our initial public offering to purchase an aggregate of 4,305,713 shares of Common Stock, all of which have an exercise price of $3.0625 per share; and (ii) options to purchase an aggregate of 304,125 shares of Common Stock, with a weighted average exercise price equal to $6.95 per share. The issuance of the shares of Common Stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our Common Stock.

We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our Common Stock.

Our Certificate of Incorporation authorizes the issuance of 100,000,000 shares of Common Stock and 20,000,000 shares of preferred stock. The Common Stock and preferred stock, as well as the awards available for issuance under our 2024 Equity Incentive Plan, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership in us held by holders of our Common Stock and may be issued at prices below the initial price offering. In addition, the issuance of preferred stock may be used as an "anti-takeover" device without further action on the part of our stockholders, and may adversely affect the holders of the Common Stock.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations. Thus, we may not raise the amount of capital we believe is required for our operations and may need to raise additional funds. Such additional fundraises may not be available or available on terms acceptable to us.

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including (i) timely delivery of shares; (ii) agreement to not enter into variable rate transactions for 12 months from the closing of the purchase and sale of the securities in this offering (the "closing"), subject to certain exceptions; (iii) agreement to not enter into any financings for 60 days from closing; and (iv) indemnification for breach of contract. Those purchasers who do not enter into the Purchase Agreement and do not provide us with information required for registration of the shares of Common Stock to be issued upon an Anti-Dilution Adjustment shall not have any of their shares issuable as a result of an Anti-Dilution Adjustment included in the registration statement we will file covering the resale of the shares issuable as a result of an Anti-Dilution Adjustment and will not be able to effect a cashless exercise with respect to such shares.

There is no public market for the May 2025 Warrants or Pre-Funded Warrants.

There is no established public trading market for the May 2025 Warrants or Pre-Funded Warrants offered hereby, and we do not expect a market to develop. In addition, we do not intend to apply to list the May 2025 Warrants or Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system, including Nasdaq. Without an active market, the liquidity of those securities will be limited.

The May 2025 Warrants in this offering are speculative in nature.

Following this offering, the market value of the May 2025 Warrants, if any, is uncertain and there can be no assurance that the market value of the May 2025 Warrants will equal or exceed their imputed public offering price. In the event that our Common Stock price does not exceed the exercise price of the May 2025 Warrants during the period when such May 2025 Warrants are exercisable, such May 2025 Warrants may not have any value. Furthermore, each May 2025 Warrant will expire five years from the effective date of Warrant Stockholder Approval.

Except as set forth in the May 2025 Warrants and Pre-Funded Warrants, Holders of the May 2025 Warrants and Pre-Funded Warrants will not have rights of holders of our shares of Common Stock until such May 2025 Warrants and Pre-Funded Warrants are exercised.

Except as set forth in the May 2025 Warrants and Pre-Funded Warrants the May 2025 Warrants and Pre-Funded Warrants in this offering do not confer any rights of share ownership on their holders, but rather merely represent the right to acquire shares of our Common Stock at a fixed price. Until holders of May 2025 Warrants and Pre-Funded Warrants acquire shares of our Common Stock upon exercise of the May 2025 Warrants and Pre-Funded Warrants, as applicable, holders of May 2025 Warrants and Pre-Funded Warrants will have no rights with respect to our shares of Common Stock underlying such May 2025 Warrants and Pre-Funded Warrants.

We are required to obtain Warrant Stockholder Approval prior to exercise of the May 2025 Warrants and until we are able to receive such approval the May 2025 Warrants will not be exercisable. In addition, the shares of Common Stock issuable upon the Anti-Dilution Adjustment have not been registered pursuant to this prospectus. If we are unable to obtain such approval the May 2025 Warrants will have no value.

We are required to obtain Warrant Stockholder Approval prior to the exercise of the May 2025 Warrants and until, and unless, we obtain the Warrant Stockholder Approval from our stockholders, the May 2025 Warrants will not be exercisable. While we intend to promptly seek stockholder approval of both the amendment to our certificate of incorporation to increase our number of authorized shares of Common Stock and the exercise of the May 2025 Warrants and the issuance of the shares of Common Stock upon such exercise, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the May 2025 Warrants will have no value. In addition, we will incur substantial cost, and management will devote substantial time and attention, in attempting to obtain the Warrant Stockholder Approval. Furthermore, the shares of Common Stock issuable upon the Anti-Dilution Adjustment have not been registered and although we intend to register them after obtaining the Warrant Stockholder Approval, we cannot guarantee that they will be registered.

If we do not maintain a current and effective prospectus relating to the Common Stock issuable upon exercise of the May 2025 Warrants, public holders will only be able to exercise such May 2025 Warrants on a "cashless basis."

If we do not maintain a current and effective prospectus relating to the shares of Common Stock issuable upon exercise of the May 2025 Warrants at the time that holders wish to exercise such warrants, they will only be able to exercise them on a "cashless basis," and under no circumstances would we be required to make any cash payments or settle such warrants to the holders. The Pre-Funded Warrants are exercisable on a "cashless basis" at all times. As a result, if exercised on a "cashless basis" the number of shares of Common Stock that holders will receive upon exercise of the May 2025 Warrants and Pre-Funded Warrants will be fewer than it would have been had such holders exercised their May 2025 Warrants or Pre-Funded Warrants for cash. We will do our best efforts to maintain a current and effective prospectus relating to the shares of Common Stock issuable upon exercise of such warrants until the expiration of such warrants. However, we cannot assure you that we will be able to do so. If we are unable to do so, the potential "upside" of the holder's investment in our company may be reduced.

We may be required to repurchase the May 2025 Warrants, which may prevent or deter a third party from acquiring us.

The May 2025 Warrants provide that in the event of a "Fundamental Transaction" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our Common Stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black-Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

If the May 2025 Warrants are exercised after a reverse stock split or reset of the exercise price stockholders will suffer substantial dilution.

If the May 2025 Warrants are exercised after a reverse stock split is effected and/or after the a reset of the exercise price, assuming receipt of Warrant Stockholder Approval, such exercising holder will receive 7.1 shares of Common Stock for each May 2025 Warrant they exercise and a total of 75,074,993 shares of Common Stock would be issuable upon exercise of all of the May 2025 Warrants if the exercise price is reset to the floor price of $0.10, and you will suffer immediate and substantial dilution in the net tangible book value of the Common Stock you purchase in this offering or the Common Stock underlying the Pre-Funded Warrants you purchase in this offering.

Risks Related to our Diagnostic Product

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

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

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

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

Patient enrollment is affected by many other factors, including:

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

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

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

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

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

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

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

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

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

Risks Related to Our Diagnostic Tests

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

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

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

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

We cannot be certain that:

- any tests that we may enhance or develop will prove to be effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, regulatory approvals, if needed;

- any tests that we may enhance or develop will be ordered and used by healthcare providers;
- any tests that we may enhance or develop can be provided at acceptable cost and with appropriate quality; or
- any of our tests can be successfully marketed.

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

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

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

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

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

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

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

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

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

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

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

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

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

commercializing our diagnostic tests or therapeutic products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants, or stock options

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

We face intense competition in the biotechnology and pharmaceutical industries.

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

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

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

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

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

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

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

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

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

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

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs, and the development of our diagnostic tests and therapeutic product candidates could be delayed. In addition, the loss of clinical trial data for our diagnostic tests and therapeutic product candidates could result in delays in our marketing approval efforts and

significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Like all businesses we may be increasingly subject to ransomware or other malware that could significantly disrupt our business operations or disable or interfere with necessary access to essential data or processes. Numerous recent attacks of this nature have also involved exfiltration and disclosure of sensitive or confidential personal or proprietary information, or intellectual property, when victim companies have not paid the cyber criminals substantial ransom payments. For example, any such event that leads to unauthorized access, use, disclosure, unavailability, or compromised integrity of personal or other sensitive or essential information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, increase the costs we incur to protect against such information security breaches, such as increased investment in technology, render key personnel unable to perform duties or communicate throughout the organization, and otherwise subject us to fines and other liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

Risks Related to the Operation of a CAP/CLIA Laboratory

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

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

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

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

compromised on account of equipment malfunctions or a cybersecurity-related attack, PPLS's ability to provide services and to fulfill its contractual arrangements would be adversely affected and our revenue could decline.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

will be successful in responding to the growing complexity of testing operations.

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

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

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

Several factors make the billing process complex, including:

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

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

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

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

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

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

Risks Related to Intellectual Property Rights

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

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

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

- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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

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

- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests and products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that are directed to our diagnostic tests and product candidates or uses thereof in the U.S. or foreign countries;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing diagnostic tests and product candidates;

- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; and

- if enforced, a court may not hold that our patents are valid, enforceable, and infringed.

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

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

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

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

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

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

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

Our competitive position depends on protection of our intellectual property.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, or other forms of intellectual property, particularly those relating to biotechnology tests and products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing tests and products in violation of our proprietary rights

generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic tests and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our diagnostic tests and product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

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

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

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

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

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

Risks Related to Government Regulations

CyPath® Lung is currently being offered as an LDT by PPLS. The FDA's regulatory approach and authority over LDTs is being litigated, and should the federal courts issue a ruling finding that the FDA has authority over LDTs and the agency changes its approach to LDTs thereafter, 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 federal Food, Drug and Cosmetic Act (the "FDCA"), but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, *de novo* classification, or clearance of LDTs, it has generally chosen not to enforce those requirements. The FDA has, on occasion, sent warning letters to laboratories offering LDTs that the agency believed were not eligible for enforcement discretion because of how they were developed, validated, performed, or marketed and consequent risks to the public.

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

Within weeks of the FDA issuing the LDT Final Rule, lawsuits were filed challenging the rule claiming it is "in excess of the agency's statutory jurisdiction, authority, or limitations and is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law". On March 31, 2025, the U.S. District Court for the Eastern District of Texas entered a judgment in favor of the plaintiffs. In its Opinion and Order, the Court states that, "the text, structure, and history of the FDCA and CLIA make clear that FDA lacks the authority to regulate laboratory-developed test services". Throughout its opinion, the Court outlines its disagreement with the FDA's expansion and interpretation of the definition of "device" and the agency's overall interpretation of its authority to regulate LDTs under the FDCA. (*See* 5 U.S.C. § 706(2)).

Specifically, the Court states LDTs are services regulated under CLIA, for which CMS is primarily responsible for issuing implementing regulations. The Court notes that Congress created a separate statutory and regulatory framework for laboratory test services under CLIA. In its opinion, the Court defines an LDT as "a methodology or process by which a laboratory generates biochemical, genetic, molecular, or other forms of clinical information about a patient specimen for use by the treating physician" and that "[e]ach laboratory uses its own unique knowledge of the protocols, performance characteristics, and means of analysis to develop such methodologies and processes".

By employing this particular definition of LDTs, the Court claims that LDTs are services that laboratory professionals perform rather than a physical product sold by a laboratory that could be subject to FDA jurisdiction as a device. As a result, the Court vacated and set aside the LDT Final Rule in its entirety, holding that the LDT Final Rule exceeds the FDA's statutory authority and violates the Administrative Procedures Act (APA). Due to the Court's order, the LDT Final Rule will not go into effect as planned in May 2025. Unless appealed by the government, this ruling essentially halts the FDA's ability to promulgate further regulations or guidance regulating LDTs.

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

The FDCA requires that medical devices introduced to the U.S. market, unless exempted by regulation, be authorized by the FDA pursuant to either the premarket notification

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the demand for our diagnostic tests or therapeutic product candidates, if we or our licensors obtain regulatory approval;

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

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

Risks Related to Ownership of Our Common Stock and Warrants

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our diagnostic tests and therapeutic products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts;

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

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

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

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

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

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

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

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

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

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

designated and issued, then depending upon the designation and preferences, the holders of the Preferred Stock may exercise voting control. As a result, our stockholders would have no control over the operations of our Company.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 26% 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 SOX ("Section 404") 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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $2.9 million, assuming a public offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrants (which is equal to the last reported sale price per share of our Common Stock on the Nasdaq Capital Market, on April 25, 2025), and the sale of all the securities offered under this prospectus, after deducting the Placement Agent fees and estimated offering expenses payable by us, assuming no sale of any Pre-Funded Warrants. However, because this is a "best efforts" offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the Placement Agent fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus. The combined public offering price per share of Common Stock (or Pre-Funded Warrant) and accompanying May 2025 Warrants will be fixed for the duration of this offering.

These estimates exclude the proceeds, if any, from the exercise of May 2025 Warrants issued in this offering. If all of the May 2025 Warrants issued in this offering were to be exercised in cash at an assumed exercise price of $0.5489 per share of Common Stock (equal to 110% of the assumed combined offering price per Share and accompanying May 2025 Warrant), we would receive additional proceeds of approximately $5.8 million. We cannot predict when or if these May 2025 Warrants will be exercised. It is possible that these May 2025 Warrants may expire and may never be exercised. Additionally, the May 2025 Warrants contain a cashless exercise provision that permit exercise of these warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act covering the issuance of the underlying shares of Common Stock, subject to certain exceptions.

We intend to use the net proceeds from the sales of the securities offered by this prospectus primarily for working capital and other general corporate purposes. Pending these uses, we expect to invest the net proceeds in short-term, interest-bearing securities. We have broad discretion in determining how the proceeds of this offering will be used, and our discretion is not limited by the aforementioned possible uses. Our board of directors believes the flexibility in application of the net proceeds is prudent.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2024:

- on an actual basis, based on 15,576,674 shares of Common Stock issued and outstanding at December 31, 2024;
- on a pro forma basis to give effect to: (i) an aggregate of 1,136,391 shares of Common Stock upon the exercise of common warrants that we issued on October 21, 2024, at the reduced exercise price of $0.58 per share, and our receipt of approximately $755,000 in proceeds upon such exercise, and (ii) an aggregate of 1,302,082 shares of Common Stock upon the exercise of common warrants that we issued on August 5, 2024, at the reduced exercise price of $0.58 per share, and our receipt of approximately $659,000 in proceeds upon such exercise; (iii) an aggregate of 235,908 shares of restricted Common Stock to officers, directors, employees and/or consultants; and (iv) 4,724 shares of restricted Common Stock that were cancelled related to grants issued prior to December 31, 2024; and
- on a pro forma, as adjusted basis to give effect to the pro forma adjustments and the issuance and sale of 7,014,028 Shares of Common Stock in this offering at an assumed offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrant, after deducting the Placement Agent fees and estimated offering expenses payable by us, assuming no sale of any Pre-Funded Warrants.

The information set forth in the table below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual offering price, the number of securities sold in this offering, and other terms of this offering determined at pricing. You should read the following table in conjunction with our consolidated financial statements and related notes appearing at the end of this prospectus as well as the MD&A and "Description of Our Securities" sections of this prospectus.

	As of December 31, 2024		
	Actual	Pro Forma	Pro Forma, As Adjusted
Cash and cash equivalents	$ 1,105,291	$ 2,276,460	$ 5,198,960
Stockholders' equity:			
Preferred stock, par value $0.001 per share; 20,000,000 shares authorized; no shares issued and outstanding at December 31, 2024, no shares issued and outstanding pro forma, and no shares issued and outstanding pro forma, as adjusted			
Common stock, par value $0.007 per share; 100,000,000 shares authorized; 15,576,674 issued and outstanding at December 31, 2024, 18,246,311 shares issued and outstanding pro forma, and 25,260,359 shares issued and outstanding pro forma, as adjusted	106,593	123,662	172,760
Additional paid-in capital	56,139,753	57,293,853	60,167,255
Accumulated deficit	(53,644,310)	(53,644,310)	(53,644,310)
Total stockholders' equity	$ 2,602,036	$ 3,773,205	$ 6,695,705
Total capitalization	$ 2,602,036	$ 3,773,205	$ 6,695,705

Each $0.10 increase (decrease) in the assumed public offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrant, would increase (decrease) each of our pro forma, as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $645,000, assuming that the number of shares of Common Stock and accompanying May 2025 Warrants offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting Placement Agent fees and estimated offering expenses payable by us, and assuming no sale of any Pre-Funded Warrants in this offering, and no exercise of the May 2025 Warrants or Placement Agent Warrants being offered in this offering. Similarly, each increase (decrease) of 1,000,000 in the number of shares of Common Stock offered by us would increase (decrease) each of our pro forma, as adjusted cash, cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $459,000, assuming the assumed combined offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrant remains the same and after deducting Placement Agent fees and estimated offering expenses payable by us, and assuming no sale of any Pre-Funded Warrants in this offering, no exercise of the May 2025 Warrants or Placement Agent Warrants being offered in this offering.

The information above is based on 15,576,674 shares of Common Stock outstanding as of December 31, 2024, and excludes, as of that date:

- 12,298,124 shares of Common Stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $2.95 per share;
- 304,125 shares of Common Stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $6.95 per share;
- 1,480,208 shares of our Common Stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan;
- 75,074,993 shares of Common Stock issuable upon the exercise of May 2025 Warrants sold in this offering; and
- 210,420 shares of Common Stock issuable upon the exercise of Placement Agent Warrants issued in connection with this offering.

DILUTION

If you invest in our securities in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price paid by the purchasers of the shares of Common Stock (or Pre-Funded Warrants) and accompanying May 2025 Warrants sold in this offering and the pro forma as adjusted net tangible book value per share of Common Stock after 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, 2024, we had a net tangible book value of approximately $0.4 million or $0.03 per share of Common Stock based upon 15,576,674 shares of Common Stock outstanding as of that date.

Our pro forma net tangible book value as of December 31, 2024 was approximately $1.6 million or $0.09 per share of Common Stock, based upon 18,246,331 shares of Common Stock outstanding as of April 25, 2025. Pro forma net tangible book value represents net tangible book value adjusted to take into account the issuance, subsequent to December 31, 2024, of: (i) an aggregate of 1,302,082 shares of Common Stock upon the exercise of common warrants that we issued on August 5, 2024, at the reduced exercise price of $0.58 per share, and our receipt of approximately $755,000 in proceeds upon such exercise, and (ii) an aggregate of 1,136,391 shares of Common Stock upon the exercise of common warrants that we issued on October 21, 2024, at the reduced exercise price of $0.58 per share, and our receipt of approximately $659,000 in proceeds upon such exercise; (iii) an aggregate of 235,908 shares of restricted Common Stock to officers, directors, employees and/or consultants; and (iv) 4,724 shares of restricted Common Stock that were cancelled related to grants issued prior to December 31, 2024.

Dilution represents the difference between the amount per share paid by purchasers in this offering and the as adjusted net tangible book value per share of Common Stock after the offering. After giving effect to the sale of shares of Common Stock and accompanying May 2025 Warrants in this offering at an assumed offering price of $0.499 per share, which was the closing price of our Common Stock as reported on the Nasdaq Capital Market on April 25, 2025, and after deducting Placement Agent fees and estimated offering expenses payable by us, and assuming no sale of any Pre-Funded Warrants in this offering, no exercise of the May 2025 Warrants or Placement Agent Warrants being offered in this offering, that no value is attributed to such warrants and that such warrants are classified as and accounted for as equity, our as adjusted net tangible book value

would have been $0.18 per share. This represents an immediate increase in net tangible book value of $0.09 per share to existing stockholders and an immediate dilution in net tangible book value of $0.299 per share to investors purchasing securities in this offering at the assumed offering price.

The following table illustrates the dilution on a per share basis:

Assumed public offering price per share			$	0.499
Historical net tangible book value per share as of December 31, 2024	$	0.03		
Pro forma net tangible book value per share	$	0.09		
Increase in pro forma net tangible book value per share attributable to this offering	$	0.09		
Pro forma as adjusted net tangible book value per share after this offering			$	0.18
Dilution in net tangible book value per share to new investors in this offering			$	0.319

Each $0.10 increase (decrease) in the assumed public offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrant would increase (decrease) the as adjusted net tangible book value by $684,000 per share of Common Stock and the dilution to new investors by $0.319 per share, after deducting the estimated Placement Agent fees and estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 shares in the number of shares of Common Stock offered by us would increase our as adjusted net tangible book value by approximately $0.5 million, or approximately $0.01 per share of Common Stock, and decrease the dilution per share to investors in this offering by approximately $0.01 per share, assuming that the number of shares of Common Stock and accompanying May 2025 Warrants offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated Placement Agent fees and estimated offering expenses payable by us. Similarly, a decrease of 1,000,000 shares in the number of shares of Common Stock offered by us would decrease our as adjusted net tangible book value by approximately $0.5 million, or approximately $0.01 per share, and increase the dilution per share to investors in this offering by approximately $0.01 per share, assuming the assumed combined offering price of $0.499 per share of Common Stock and accompanying May 2025 Warrant remains the same and after deducting the estimated Placement Agent fees and estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the Placement Agent at pricing.

The information above is based on 15,576,674 shares of Common Stock outstanding as of December 31, 2024, and excludes, as of that date:

- 12,298,124 shares of Common Stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $2.95 per share;
- 304,125 shares of Common Stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $6.95 per share;
- 1,480,208 shares of our Common Stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan;
- 75,074,993 shares of Common Stock issuable upon the exercise of May 2025 Warrants sold in this offering; and
- 210,420 shares of Common Stock issuable upon the exercise of Placement Agent Warrants issued in connection with this offering.

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 25, 2025, 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, (3) each of our named executive officers, and (4) all of the Company's current executive officers and directors 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 will become 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 or become exercisable within 60 days of April 25, 2025. 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 18,246,331 shares of Common Stock outstanding as of April 25, 2025.

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]	440,249	2.39%
James Michael Edwards[3]	134,787	*
Steven Girgenti[4]	1,806,080	9.52%
Robert Anderson[5]	223,215	1.22%
Stuart Diamond[6]	126,228	*
Jamie Platt[7]	54,748	*
Peter Knight[8]	186,022	1.02%
Gary Rubin[9]	1,369,849	7.23%
Roby Joyce[10]	669,744	3.67%
All Directors and Current Executive Officers as a Group (11 Individuals):	5,120,422	25.56%

* Ownership of less than 1%.

(1) Unless otherwise indicated, the address for each person is c/o bioAffinity Technologies, Inc., 3300 Nacogdoches Road, Suite 216, San Antonio, Texas 78217.

(2) Includes (i) 280,259 shares of Common Stock owned by Ms. Zannes, including 42,128 shares of unvested restricted stock as to which Ms. Zannes has the right to vote, but not to dispose; (ii) 56,422 shares of Common Stock issuable upon the exercise of stock options that are currently exercisable; and (iii) 103,568 shares of Common Stock issuable upon the exercise of warrants that are currently exercisable.

(3) Includes (i) 120,128 shares of Common Stock owned by Mr. Edwards, including 80,143 shares of Common Stock issued to Mr. Edwards as restricted stock; and (ii) an aggregate of 14,658 shares of Common Stock issuable upon exercise warrants that are currently exercisable.

(4) Includes (i) 1,079,963 shares of Common Stock owned by Mr. Girgenti, including 89,398 shares of Common Stock issued to Mr. Girgenti as restricted stock; (ii) 8,955 shares of Common Stock owned directly by the Cranye Girgenti Testamentary Trust, for which Mr. Girgenti serves as trustee; (iii) an aggregate of 669,549 shares of Common Stock issuable upon exercise of warrants owned by Mr. Girgenti; (iv) 8,332 shares of Common Stock issuable upon exercise of warrants owned by the Cranye Testamentary Trust, for which Mr. Girgenti serves as trustee; and (v) 39,281 shares of Common Stock issuable upon exercise of options held by Mr. Girgenti that are immediately exercisable. As the trustee of the Cranye Girgenti Testamentary Trust, Mr. Girgenti has sole voting and dispositive power over the shares beneficially owned by the Cranye Girgenti Testamentary Trust.

(5) Includes (i) 163,936 shares of Common Stock owned by Mr. Anderson, including 11,264 shares of unvested restricted stock as to which Mr. Anderson has the right to vote, but not to dispose; (ii) 39,281 shares of Common Stock issuable upon exercise of options that are currently exercisable; and (iv) 19,998 shares of Common Stock issuable upon exercise of warrants that are currently exercisable.

(6) Includes (i) 99,088 shares of Common Stock owned by Mr. Diamond, including 11,264 shares of unvested restricted stock as to which Mr. Diamond has the right to vote, but not to dispose; (ii) 7,142 shares of Common Stock issuable upon exercise of options that are currently exercisable; and (iii) 19,998 shares of Common Stock issuable upon exercise of warrants that are currently exercisable.

(7) Includes 54,748 shares of Common Stock issued to Dr. Platt as restricted stock, including 11,264 shares of unvested restricted stock as to which Dr. Platt has the right to vote, but not to dispose.

(8) Includes (i) 117,455 shares of Common Stock owned by Mr. Knight, including 11,264 shares of unvested restricted stock as to which Mr. Knight has the right to vote, but not to dispose; (ii) 28,568 shares of Common Stock issuable upon exercise of options that are currently exercisable; and (iii) 39,999 shares of Common Stock issuable upon exercise of warrants that are currently exercisable.

(9) Includes (i) 146,597 shares of Common Stock owned by Mr. Rubin, including 11,264 shares of unvested restricted stock as to which Mr. Rubin has the right to vote, but not to dispose; (ii) 32,139 shares of Common Stock issuable upon exercise of options held by Mr. Rubin that are currently exercisable; (iii) 17,137 shares of Common Stock issuable upon exercise of warrants held by Mr. Rubin that are currently exercisable; (iv) 522,606 shares of Common Stock owned by the Phyllis Sandler Revocable Trust; and (v) an aggregate of 651,370 shares of Common Stock issuable upon exercise of warrants owned by the Harvey Sandler Revocable Trust that are currently exercisable. Mr. Rubin serves as co-trustee of the Phyllis Sandler Revocable Trust and the Harvey Sandler Revocable Trust. As a co-trustee, Mr. Rubin has the sole power to vote and dispose of the shares beneficially owned by the Phyllis Sandler Revocable Trust and the Harvey Sandler Revocable Trust.

(10) Includes (i) 66,615 shares of Common Stock owned by Dr. Joyce, including 11,264 shares of unvested restricted stock as to which Dr. Joyce has the right to vote, but not to dispose; (ii) 583,130 shares of Common Stock owned by the Joyce Living Trust; and (iii) an aggregate of 19,999 shares of Common Stock issuable upon exercise of warrants held by the Joyce Living Trust that are currently exercisable. 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.

MARKET INFORMATION FOR SECURITIES AND DIVIDEND POLICY

Market Information

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 25, 2025 was $0.499 per share of Common Stock and $0.227 per Tradeable Warrant.

Holders of Record

As of April 25, 2025, there were approximately 92 holders of record of shares of our Common Stock. This number does not reflect the beneficial holders of our Common Stock who hold shares in street name through brokerage accounts or other nominees.

Dividends

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

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

Company Overview

Business

We develop noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung using flow cytometry and automated analysis developed by machine learning, a form of artificial intelligence ("AI"). Our diagnostic tests, including our commercial test CyPath® Lung and those tests in our pipeline for development, analyzes cell populations that are indicative of a specific diseased state.

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

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

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

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

Current Year Financial Highlights

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

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

Recent Financial Developments

Targeted Strategic Actions

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

Public and Private Offerings

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

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

Financial

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

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

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

Results of Operations

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

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

Revenue

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

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

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

Operating Expenses

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

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

Direct Costs and Expenses

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

Research and Development

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

Clinical Development

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

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately $9.9 million and $6.8 million for the years ended December 31, 2024 and 2023, respectively. The increase of approximately $3.1 million, or 46% was primarily attributable to the laboratory operations of PPLS being owned for the full fiscal year 2024, compared to approximately 3.5

months in fiscal year 2023. Additionally, the increase was due to the expansion of sales efforts for CyPath® Lung, partially offset by a reduction in legal and professional fees.

Other Income (Expense)

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

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

Interest income (expense)

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

Liquidity and Capital Resources

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

Recent Financings

February 2025 Warrant Inducement

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

October 2024 Registered Direct Offering and Concurrent Private Placement

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

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

On August 5, 2024, pursuant to the terms of the warrant inducement agreement, dated August 2, 2024 (the "August Inducement Agreement) certain holders of existing warrants, exercised for cash common warrants to purchase an aggregate of up to 1,041,667 shares of Common Stock that we issued on March 8, 2024 (the "March 2024 Warrants"), at the reduced exercise price of $1.25 per share. We received aggregate gross proceeds of approximately $1.3 million, before deducting advisory fees and other expenses payable by us. In consideration of the immediate exercise of the March 2024 Warrants by the holders thereof in accordance with the August Inducement Agreement, we issued unregistered common warrants to purchase an aggregate of up to 1,302,082 shares of Common Stock (120% of the number of shares of Common Stock issuable upon exercise of the March 2024 Warrants) to such holders.

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

March 2024 Registered Direct Offering and Concurrent Private Placement

On March 8, 2024, we issued to certain investors, pursuant to a Securities Purchase Agreement (1) 1,600,000 shares of Common Stock in a registered direct offering, and (2) warrants to purchase an aggregate of 1,600,000 shares of Common Stock with an exercise price of $1.64, in a concurrent private placement. The direct offering resulted in gross proceeds of $2.5 million.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic test or therapeutic products to generate revenue. During 2024 and 2023, we had net losses of $9.0 million and $7.9 million, respectively, and we expect to incur substantial additional losses in future periods. We have an accumulated deficit of approximately $53.6 million as of December 31, 2024. Based on our current expected level of operating expenditures and the cash on hand of approximately $390 thousand at the time of this filing, management concludes that there is substantial doubt about our ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that our cash resources are sufficient to continue operations through May 2025.

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

Cash Flows

The following information reflects cash flows for the years presented:

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

Net Cash Used in Operating Activities

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

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

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

Critical Accounting Estimates

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

Patient Fee Revenues

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

Patient Fee Receivables and Considerations for Credit Losses

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

Discount Rate for Finance Leased Equipment

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

Share-Based Compensation

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

Accounting for Income Taxes

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

ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which the related temporary difference becomes deductible.

Assessment of Goodwill and Intangible Assets

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

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

Going Concern

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

Off-Balance Sheet Arrangements

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

BUSINESS

Business Overview

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

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

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

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

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

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

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

Current Year Financial Highlights

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

- Consolidated revenue increased approximately 270% to $9.4 million as compared to $2.5 million for the year ended December 31, 2023, primarily as a result of the acquisition of PPLS in September 2023.

- CyPath® Lung testing revenue increased approximately 1,400% to $0.5 million as compared to $35 thousand for the year ended December 31, 2023, due to an increase in total test results delivered of more than 600 for the current year.

- Raised approximately $6.9 million in gross proceeds from equity transactions to fund operating activities.

Recent Developments

FDA Pivotal Study

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

Case Studies

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

Targeted Strategic Actions

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

Continuation of Department of Defense Research

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

Public and Private Offerings

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

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

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

Our First Diagnostic Test – CyPath® Lung

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

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

A study authored by two pulmonologists and published in 2024 in the peer-reviewed *Journal of Health Economics and Outcomes Research* reported that adding CyPath® Lung

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

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

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

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

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

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

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

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

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

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

The CyPath® Lung technology is based on scientific work originating at Los Alamos National Laboratory in collaboration with St. Mary's Hospital in Colorado. In the Los Alamos research study, sputum samples from lung cancer patients were differentiated from non-cancer samples with 100% accuracy. This early research was conducted with sputum from 12 uranium miners. Microscope slides of sputum samples were labeled with the synthetic fluorescent porphyrin TCPP. The Los Alamos research study of 12 uranium miners included eight men with cancer and four healthy individuals. Researchers were blinded to the sample origin and looked for the presence of highly fluorescent cells indicating uptake of TCPP as an indicator of lung cancer. The length of the study and specific follow-up was not reported, but researchers did report that one patient in the study who had been incorrectly considered to be a healthy subject was correctly diagnosed with cancer by the test. Later, a blinded clinical trial was conducted and results published September 2015 in an article titled "Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum" in the *Journal of Thoracic Oncology*. This study reported on an earlier version of CyPath® Lung that used a fluorescent microscope to directly identify cells labeled with TCPP in one-third or less of the

sputum sample. For each trial participant, researchers manually scanned 12 microscope slides labeled with TCPP for the presence of red fluorescent cells ("RFCs") displaying a spectral signature that indicated uptake of TCPP in the cell. In addition to measuring the spectral signature, the fluorescent intensity and cell size of RFCs were measured. The test data, including fluorescent intensity over cell size, was analyzed. The trial was conducted over 24 months and resulted in 81% test accuracy, 77.9% sensitivity, and 65.7% specificity in the ability to correctly differentiate between samples from lung cancer patients and those at high risk who were cancer-free. The earlier trial required participants to provide a sputum sample and CT imaging of the lungs. Those in the cancer cohort underwent a biopsy to confirm lung cancer. High-risk patients displaying indeterminate nodules were followed for 18 months to confirm they were cancer-free. The study concluded that optimizing the test to provide for analysis of the entire sputum sample would improve results.

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

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

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

The Cancer Diagnostics Market and CyPath® Lung

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

Comparison of CyPath® Lung to Current Standards of Care

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

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

for males the highest in Eastern European countries and a five-year survival rate of only 13%, as reported by a May 2021 article, "Lung cancer screening in Europe: where are we in 2021?" published in *Translational Lung Cancer Research.* We expect to pursue CE marking of CyPath® Lung for sale in the European Union ("EU").

CyPath® Lung Business Development Plan

We believe in the viability of our business plan based on the circumstances surrounding our business that are known to us as of the date of this 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 was completed in 2024 with a limited market launch of our LDT CyPath® Lung in Texas. This limited test market launch was designed to evaluate our marketing program and help us ensure each step in the care pathway – from the initial order by physicians to sputum collection and processing, to generating and delivering the patient report – is efficient and effective. This limited test market approach allowed us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market.

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

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

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

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

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

The Competition for CyPath® Lung

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

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

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

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

Delphi's First Look was recently launched to assist in determining whether a person should be screened by LDCT. While CyPath® Lung is positioned to help diagnose lung

nodules in patients who have already undergone screening by LDCT, First Look is intended to be used *prior* to LDCT. As such, this test may increase lung cancer screening uptake and potentially increase the need for CyPath® Lung.

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

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

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

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

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

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

OncoSelect® Therapeutics Research

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

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

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

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 3300 Nacogdoches, Suite 216, San Antonio, Texas 78217, and our telephone number at that address is (210) 698-5334. Our website address is https://www.bioaffinitytech.com/. Information contained on or that can be accessed through our website is not incorporated by reference into this 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 ours are generally uncertain and can involve complex legal, scientific, and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties.

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

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

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

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

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

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

Government Regulation

United States

Diagnostic Products (including Medical Devices and Tests)

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

Laboratory Developed Tests

CyPath® Lung completed its certification as an LDT in accordance with CAP and CLIA regulations and guidance in 2023. The FDA considers LDTs to be tests that are

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

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

Within weeks of the FDA issuing the LDT Final Rule, lawsuits were filed challenging the rule claiming it is "in excess of the agency's statutory jurisdiction, authority, or limitations and is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law". On March 31, 2025, the U.S. District Court for the Eastern District of Texas entered a judgment in favor of the plaintiffs. In its Opinion and Order, the Court states that, "the text, structure, and history of the FDCA and CLIA make clear that FDA lacks the authority to regulate laboratory-developed test services". Throughout its opinion, the Court outlines its disagreement with the FDA's expansion and interpretation of the definition of "device" and the agency's overall interpretation of its authority to regulate LDTs under the FDCA. (*See* 5 U.S.C. § 706(2)).

Specifically, the Court states LDTs are services regulated under CLIA, for which CMS is primarily responsible for issuing implementing regulations. The Court notes that Congress created a separate statutory and regulatory framework for laboratory test services under CLIA. In its opinion, the Court defines an LDT as "a methodology or process by which a laboratory generates biochemical, genetic, molecular, or other forms of clinical information about a patient specimen for use by the treating physician" and that "[e]ach laboratory uses its own unique knowledge of the protocols, performance characteristics, and means of analysis to develop such methodologies and processes".

By employing this particular definition of LDTs, the Court claims that LDTs are services that laboratory professionals perform rather than a physical product sold by a laboratory that could be subject to FDA jurisdiction as a device. As a result, the Court vacated and set aside the LDT Final Rule in its entirety, holding that the LDT Final Rule exceeds the FDA's statutory authority and violates the Administrative Procedures Act (APA). Due to the Court's order, the LDT Final Rule will not go into effect as planned in May 2025. Unless appealed by the government, this ruling essentially halts the FDA's ability to promulgate further regulations or guidance regulating LDTs.

Clinical Laboratory Improvement Amendments of 1988

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

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

Medical Devices

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

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

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

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

Premarket Authorization and Notification

While most Class I and some Class II devices may be marketed without prior FDA authorization, many Class II and most Class III medical devices can be legally sold within

the U.S. only if the FDA has: (1) approved a PMA application prior to marketing, generally applicable to most Class III devices; (2) cleared the device in response to a premarket notification (a "510(k) submission"), generally applicable to some Class I and most II devices; or (3) authorized the device to be marketed through the *de novo* classification process, generally applicable for novel low- or moderate-risk devices. PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of user fees.

510(k) Premarket Notification

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

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

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

De Novo Classification

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

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

PMA Approval

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

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

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

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

Clinical Trials

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

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

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

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

manufacturing.

Postmarket Requirements

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

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

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

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

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

Therapeutic Products

FDA Approval Process

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

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

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

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

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

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

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

patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

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

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

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

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

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

Disclosure of Clinical Trial Information

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

Post-Approval Requirements

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

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

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

European Union

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

European Data Collection

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

Rest of the World Regulation

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

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

Human Capital

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

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

Facilities

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

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

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

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

Legal Proceedings

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

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

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

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

We may take advantage of some or all of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the first fiscal year in which our annual gross revenues exceed $1.235 billion, (3) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this 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 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 25, 2025.

Name	Age	Position(s)
Maria Zannes, JD	69	President, Chief Executive Officer, and Director
James Michael Edwards	58	Chief Financial Officer
Xavier Reveles	56	Chief Operating Officer
Timothy P. Zannes, JD	72	Executive Vice President, Secretary, and General Counsel
Steven Girgenti	79	Executive Chairman and Director
Robert Anderson	84	Director
Stuart Diamond	64	Director
Peter Knight	74	Director
Gary Rubin	69	Director
Roby Joyce, MD	77	Director
Jamie Platt, PhD	58	Director

Biographical Information

Maria Zannes, JD - ***President, Chief Executive Officer, and Director***

Maria 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.

James Michael Edwards - ***Chief Financial Officer***

James Edwards was appointed as our Chief Financial Officer effective November 5, 2024, after serving as our Interim Chief Financial Officer since September 2024. Mr. Edwards has more than 25 years of experience in corporate finance and accounting. Since 2009, Mr. Edwards has provided consulting services through his company J. Michael Edwards, LLC. Mr. Edwards served as the Company's Chief Financial Officer from April 2014 until November 2016 and again from June 2017 to May 1, 2023. He was the CFO for CytoBioscience, Inc. from 2016 until 2017 and previously he was the CFO for OncoVista Innovative Therapies, Inc. He was an assistant controller at ILEX Oncology, Inc. and controller at Bionumerik Pharmaceuticals Inc. and U.S. Global Investors, Inc. Mr. Edwards started his career at PricewaterhouseCoopers. He is a Certified Public Accountant and holds a BBA from The University of Texas at San Antonio and an MBA from The University of Texas McCombs School of Business.

Xavier Reveles- ***Chief Operating Officer***

Xavier 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 Laboratory Developed Tests ("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***

Timothy Zannes was appointed as Executive Vice President, General Counsel and Secretary in March 2014. He 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***

Steven 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***

Robert Anderson was appointed to serve on our Board of Directors in March 2014. 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***

Stuart Diamond was appointed to serve on our Board of Directors January 2022. Stuart Diamond has advised us that he will not stand for re-election at the 2025 annual meeting of stockholders (the "Annual Meeting"). Therefore, Mr. Diamond's term will expire at the Annual Meeting. Upon the recommendation of the Nominating and Corporate Governance Committee, our Board has reduced the size of the Board to seven directors as of the conclusion of the Annual Meeting. 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 that Mr. Diamond's substantial business and financial acumen made him qualified to serve as Chairman of the Audit Committee and on the Board.

Peter S. Knight - ***Director***

Peter Knight was appointed to serve on our Board of Directors in May 2018. Mr. Knight is a retired 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***

Gary Rubin was appointed to serve on our Board of Directors October 2017. Mr. Rubin is 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 was appointed to our Board of Directors in December 2023. Dr. 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 DxTerity 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.

Family Relationships

Maria Zannes is the sister of Timothy P. Zannes, J.D., the Company's Executive Vice President, Secretary, and General Counsel. Other than the sibling relationship between Maria Zannes and Timothy Zannes, there are no other family relationships among any of the Company's director nominees or executive officers.

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

We are an "emerging growth company" and a "smaller reporting company" under applicable federal securities laws and therefore permitted to take advantage of certain reduced public company reporting requirements. As such, we provide in this prospectus the scaled disclosure permitted under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, including the compensation disclosures required of a "smaller reporting company," as that term is defined in Rule 12b-2 promulgated under the Exchange Act.

The Company's executive officers named in the Summary Compensation Table below are referred to herein as the "named executive officers" or "NEOs". These named executive officers are:

- Maria Zannes, J.D. - *President, Chief Executive Officer, and Director*
- J. Michael Edwards - *Chief Financial Officer* (beginning November 5, 2024); *Interim Chief Financial Officer* (September 16, 2024 through October 31, 2024)
- 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 ($) (1)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Maria Zannes	2024	291,666	—	149,998	—	30,000	5,491	477,155
President and CEO (4)	2023	261,671	37,500	124,996	—	—	—	424,168
J. Michael Edwards	2024	50,000	50,000	134,000	—	5,000	34,213	273,213
Chief Financial Officer (5)								
Steven Girgenti	2024	95,000	—	191,249		12,000	8,430	306,679
Executive Chairman (6)	2023	95,000	—	134,995	—	—	—	248,745

(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 elsewhere in this prospectus.

(2) Represents annual performance-based cash bonuses which have been earned with respect to that fiscal year's performance that will be paid in fiscal 2025 despite that they were accrued in fiscal 2024. All incentive cash bonus awards issued in 2024 to our named executive officers were issued pursuant to the Company's Management Incentive Bonus Plan (the "Bonus Plan").

(3) The amounts in the "All Other Compensation" column for the year ended December 31, 2024 includes the following compensation items: (i) for Ms. Zannes, $5,491 in reimbursements of payroll tax obligations related to restricted stock grants; (ii) for Mr. Edwards, is comprised of (a) $31,438 of consulting fees paid to Mr. Edwards during 2024 and (b) $2,775 in reimbursements of payroll tax obligations related to restricted stock grants; (iii) for Mr. Girgenti, $8,430 in reimbursements of payroll tax obligations related to restricted stock grants.

(4) Salary is comprised of (i) $266,666 of salary, of which $6,666 is accrued and to be paid in fiscal 2025, and (ii) $25,000 for services to the Company as a director. Stock awards include: (i) $37,500 for an annual bonus, and (ii) $112,498 for services to the Company as a director.

(5) Mr. Edwards served as the Interim Chief Financial Officer of the Company from September 16, 2024 through October 31, 2024 and began serving as Chief Financial Officer of the Company, effective November 5, 2024.

(6) Includes for 2024 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 — $148,377.

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 2024, the annual base salaries of the Company's NEOs were:

- For Ms. Zannes: $260,000 through October 31, 2024 and $300,000 commencing November 1, 2024 (which amounts do not include $25,000 in fees paid to Ms. Zannes for her service as a director in 2024);
- For Mr. Edwards: $300,000[(1)]; and
- For Mr. Girgenti: $120,000 (which amount does not include $35,000 in fees paid to Mr. Girgenti for his service as a director in 2024).

(1) Mr. Edwards' employment agreement provides that he will receive an annual base salary of $300,000. Mr. Edwards was employed pursuant to such agreement as of November 5, 2024, accordingly, he received a pro-rated portion of such salary in 2024. In addition, he served as a consultant to Company from September 16, 2024 through October 31, 2024 for which he was paid consulting fees of $31,438.

Bonuses

On January 26, 2024, the Compensation Committee adopted the bioAffinity Technologies, Inc. Management Incentive 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 15 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.

The annual bonus awards for fiscal 2024 under the Bonus Plan for all of our named executive officers were based on the following performance measures: (i) securing adequate financing with a performance weighting of 25%, (ii) generating sales and profit from Precision Pathology Laboratory Services with a performance weighting of 45%, (iii) advancing a collaborative relationship with the Department of Defense with a performance weighting of 25%; and (iv) timely SEC filings with a performance weighting of 5%.

For 2024, our Compensation Committee set award levels for each of named executive officers as percentages of their base salaries as shown in the following table:

Participant	Base Salary	Target %	Max. Payout of Base Salary
Maria Zannes	$ 300,000[(1)]	20%	30%
J. Michael Edwards	$ 50,000[(2)]	20%	30%
Steven Girgenti	$ 120,000	20%	30%

(1) Bonus metric for Ms. Zannes was updated to be based on amended salary.
(2) Pro-rated for his time employed.

On January 10, 2025, the Compensation Committee met to determine and certify the extent to which the fiscal 2024 performance measures under the Bonus Plan were achieved. For 2024, the Compensation Committee determined that each of the performance measures were achieved at the target level. Accordingly, based on the formula previously adopted, the Compensation Committee approved bonuses for each of Maria Zannes. Xavier Reveles and Steven Girgenti for calendar year 2024 of $60,000, $35,000 and $24,000, respectively to be paid 50% in cash and 50% in shares of restricted stock. The cash bonuses have not been paid out as the date of the filing. 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 10, 2025.

The restricted stock awards granted on January 10, 2025, are not included in the Summary Compensation Table for 2024 and will appear in the Summary Compensation Table for 2025.

Retirement Plans

The Company established a defined contribution plan for all employees aged 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 and on January 10, 2025, the Company and Ms. Zannes entered into an amendment to the Zannes Agreement to increase her annual salary to $300,000, effective as of November 1, 2024. 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.

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.

Edwards Consulting Agreement and Employment Agreement. On August 21, 2024, the Company entered into a consulting agreement with Mr. Edwards, which provided for Mr. Edwards to serve as the Company's Interim Chief Financial Officer reporting to the Company's Chief Executive Officer for a monthly salary of $10,000 plus expenses. On October 9, 2024, the Company and Mr. Edwards entered into an employment agreement (the "Edwards Employment Agreement") pursuant to which Mr. Edwards, effective as of November 5, 2024, began serving as the Company's Chief Financial Officer. The Edwards Employment Agreement provides for an annual base salary of $300,000. The initial term of Mr. Edwards' employment is one year, commencing November 5, 2024, which shall be automatically renewed for successive one (1) year periods thereafter, unless his employment is terminated in accordance with the terms of the Edwards Employment Agreement. Mr. Edwards received a one-time signing bonus, comprised of both cash and equity. The cash portion of the signing bonus was $50,000 and the equity portion of the signing bonus was a grant of a restricted stock award of 100,000 shares of Common Stock, which vested 25% on November 5, 2024 and vests 25% on each of the first, second and third anniversary of such date. In addition, Mr. Edwards is eligible to receive cash and equity bonus awards at the discretion of the Company's compensation committee and to participate in the Company's benefit plans made available by the Company to similarly situated employees.

In the event the Company terminates Mr. Edwards' employment without "Cause" (as defined in the Edwards Employment Agreement) he 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 his 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 his healthcare insurance premiums for a period of up to 12 months. Upon a change of control or termination of Mr. Edwards' employment without "Cause," any outstanding and unvested portion of the restricted stock award granted to Mr. Edwards as part of his signing bonus will immediately vest.

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.

Equity Compensation Policy and Practices

While we do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure of material nonpublic information, the Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. It has been our practice to grant equity awards to our officers and directors upon their appointment. We intend to issue equity grants to our officers and directors at

the same time each year. It is our policy to grant our executive officers annual equity awards of restricted stock in the first quarter of each year and to grant our directors annual equity awards of restricted stock on July 1 of each year. Option grants, if any, are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our Common Stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

During the fiscal year ended December 31, 2024, we did not award any options to a named executive officer, and we did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Outstanding Equity Awards at December 31, 2024

The table below summarizes the outstanding equity awards awarded to the Company's NEOs during the fiscal year ended December 31, 2024.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares of Units of Stock That Have Not Vested ($)
Maria Zannes	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	—	—
	1/31/2024	—	—	—	—	1,995	1,815
	7/1/2024	—	—	—	—	19,709	17,935
J. Michael Edwards	11/5/2024	—	—	—	—	75,000	68,250
Steven Girgenti	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		
	8/9/2023	—	—	—	—	26,315	23,947
	1/31/2024	—	—	—	—	998	908
	2/16/2024	—	—	—	—	39,474	35,921
	7/1/2024	—	—	—	—	19,709	17,935

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

Name	Grant Date	Vesting Schedule
M. Zannes	1/31/2024	Vests in equal monthly installments over the 12 months following the date of grant
	7/1/2024	Vests in equal monthly installments over the 12 months following the date of grant
J. M. Edwards	11/5/2024	Vests in equal annual installments over the 3 years following the date of grant
S. Girgenti	8/9/2023	Vests on third anniversary of the grant date, August 9, 2026
	1/31/2024	Vests in equal monthly installments over the 12 months following the date of grant
	2/16/2024	Vests on third anniversary of the grant date, February 16, 2027
	7/1/2024	Vests in equal monthly installments over the 12 months following the date of grant

(2) Calculated by multiplying the closing price per share of the Company's common stock on December 31, 2024, $0.91 by the number of shares.

Director Compensation

2024 Director Compensation Program

Our 2024 director compensation program included the following components:

- an annual cash retainer of $25,000 (payable in four quarterly installments of $6,250);
- an additional annual cash retainer of $10,000 for the Chairman of the Board (payable in four quarterly installments of $2,500);
- an additional annual cash retainer of $5,000 for the Audit Committee Chair (payable in four quarterly installments of $1,250);
- an additional annual cash retainer of $2,500 for the Compensation Committee Chair (payable in four quarterly installments of $625);
- an additional annual cash retainer of $2,500 for the Nominating and Governance Committee Chair (payable in four quarterly installments of $625); and

- an annual equity grant of restricted stock with a grant date value of approximately $75,000 that vests pro rata on a monthly basis for 12 months.

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, 2024.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Other Compensation ($)	Total ($)
Robert Anderson	25,000	112,498	—	137,498
Stuart Diamond	30,000	112,498	—	142,498
Peter Knight	27,500	112,498	—	139,998
Gary Rubin	27,500	112,498	—	139,998
Roby Joyce	25,000	112,498	474,407	611,905
Jamie Platt	26,875	112,498	—	139,373

(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 elsewhere in this prospectus. As of December 31, 2024, the aggregate number of outstanding options, all of which are currently exercisable, held by each individual who served as a non-NEO director during 2024 was as follows: Robert Anderson – 39,281; Stuart Diamond – 7,142; Peter Knight – 28,568; Gary Rubin – 32,139; Roby Joyce – 0; and Jamie Platt – 0. As of December 31, 2024, the aggregate number of unvested shares of restricted stock held by each non-NEO director was 8,449.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Related-Party Transactions

In addition to the compensation arrangements with directors and executive officers described under "Executive and Director Compensation," the following is a description of each transaction since January 1, 2023, and each currently proposed transaction in which:

- the Company was or is to be a participant;
- the amount involved exceeds the lesser of $120,000 or one percent of the average of the Company's total assets at year end for the last two completed fiscal years; and
- any related person had or will have a direct or indirect material interest.

PPLS Acquisition of the Laboratory

On September 18, 2023, the Company's wholly owned subsidiary, PPLS, consummated the acquisition of the laboratory assets of Village Oaks Pathology Services, P.A., d/b/a Precision Pathology Services, 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. Roby 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 of PPLS after the acquisition. Founded in 2007 by Dr. 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, had offered CyPath® Lung for sale as an 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, 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 States that provides or promotes management or administrative services or any product or services substantially similar to those provided by PPLS.

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 the Company 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, the Company 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 (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 provided that such warrants will not be exercisable until the date that we filed a certificate of amendment to our certificate of incorporation with the State of Delaware which increased 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. On June 5, 2024, we filed an amendment to our certificate of incorporation to increase the number of shares of Common Stock authorized for issuance from 25,000,000 to 100,000,000, after receiving the approval of our stockholders of such certificate of amendment at our 2024 annual meeting of stockholders. Upon the filing of the certificate of amendment, the aforementioned warrants became exercisable and the warrant amendment was rendered moot.

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) for the fiscal year ended December 31, 2023, 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; and (ii) for the fiscal year ended December 31, 2024, a salary of $80,000 and a bonus of $21,000. The number of shares of restricted stock issued as equity compensation for 2023 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 2025 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.

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 us and 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. VStock Transfer, LLC is also the warrant agent for the May 2025 Warrants to be issued in this offering. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598.

DESCRIPTION OF OUR SECURITIES

Authorized Capital Stock

We are currently authorized to issue up to 100,000,000 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 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 Stockholders, 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 Our 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 or 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

As of April 25, 2025, we have outstanding warrants to purchase an aggregate of 12,873,602 shares of Common Stock, with a weighted average exercise price equal to $2.74 per share, which includes Tradeable Warrants and Non-Tradeable Warrants that we issued in connection with our initial public offering to purchase an aggregate of 4,305,713 shares of Common Stock, all of which have an exercise price of $3.0625 per share.

Stock Options

As of April 25, 2025, we had outstanding options to purchase an aggregate of 304,125 shares of Common Stock, with a weighted average exercise price equal to $6.95 per share.

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.

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

Our Charter and our A&R Bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL. In addition, as permitted by Delaware law, our Charter includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of these provisions is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director or officer for breach of fiduciary duties as a director or officer, subject to certain exceptions in which case the director or officer would be personally liable. An officer may not be exculpated for any action brought by or in the right of the corporation. A director may not be exculpated for improper distributions to stockholders. Further, pursuant to Delaware law a director or officer may not be exculpated for:

- any breach of his or her duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; and
- any transaction from which the director or officer derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 7,014,028 shares of our Common Stock at an assumed combined public offering price of $0.499 per share and accompanying May 2025 Warrant (the last reported sale price of our Common Stock on Nasdaq on April 25, 2025). We are also offering Pre-Funded Warrants to those purchasers whose purchase of shares of our Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock following the consummation of this offering in lieu of the shares of Common Stock that would result in such excess ownership. For each Pre-Funded Warrant sold, the number of shares of Common Stock sold will be reduced on a one-for-one basis. Each share of our Common Stock or Pre-Funded Warrant is being sold together with one May 2025 Warrant to purchase one and one-half share of Common Stock. The shares of Common Stock and/or Pre-Funded Warrants and the accompanying May 2025 Warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. We are also registering the shares of our Common Stock issuable from time to time upon exercise of the Pre-Funded Warrants, May 2025 Warrants and Placement Agent Warrants offered hereby.

Common Stock

The description of our Common Stock under the section "Description of Our Securities—Common Stock" in this prospectus is incorporated herein by reference.

May 2025 Warrants

The following summary of certain terms and provisions of the May 2025 Warrants included with the shares of Common Stock and the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement between us and VStock Transfer, LLC, as Warrant Agent, and the form of the May 2025 Warrants, both of which will be filed as exhibits to the registration statement of which this prospectus forms a part. Prospective

investors should carefully review the terms and provisions of the Warrant Agent Agreement, including the annexes thereto, and the form of May 2025 Warrant for a complete description of the terms and conditions of the May 2025 Warrants.

Warrant Stockholder Approval

The May 2025 Warrants are exercisable after issuance.

We have agreed to hold a stockholders' meeting no later than 90 days from the closing date of this offering in order to seek Warrant Stockholder Approval. If we do not obtain Warrant Stockholder Approval at the first meeting, the Company shall call a meeting every three (3) months thereafter to seek Stockholder Approval until the earlier of the date Stockholder Approval is obtained or the May 2025 Warrants are no longer outstanding. We cannot assure you that we will be able to hold the meeting in this timeframe or obtain Stockholder Approval. In the event that we are unable to obtain the Warrant Stockholder Approval, the Anti-Dilution Adjustment will not be permitted. "Warrant Stockholder Approval" means approval from the stockholders of the Company: (a) of Anti-Dilution Adjustments and (b) to an increase in the number of authorized shares of Common Stock to 350,000,000 shares of Common Stock under the Company's Certificate of Incorporation, as amended.

Duration and Exercise Price

Each May 2025 Warrant offered hereby will have an exercise price of $[*] per share (110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant). The May 2025 Warrants will expire on the five-year anniversary of the later of the Stockholder Approval Notice Date and the effective date of the filing of the Certificate of Amendment. The exercise price and number of shares of Common Stock issuable upon exercise of the May 2025 Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price, provided however that, in the event of a reverse stock split, the number of shares underlying the May 2025 Warrants and the exercise price thereof will each be appropriately adjusted according to the reverse stock split ratio. The May 2025 Warrants will be issued separately from the Common Stock and Pre-Funded Warrants and may be transferred separately immediately thereafter. The exercise price is also subject to voluntary adjustment. The May 2025 Warrants will be issued in certificated form only.

The terms of the May 2025 Warrants will also include (i) a one-time thirty percent increase in the number of shares of Common Stock issuable upon exercise of the May 2025 Warrants if a reverse stock split is effected prior to the expiration of the May 2025 Warrants and (ii) subject to Warrant Stockholder Approval, a decrease of the exercise price of the May 2025 Warrants, if in a subsequent offering of our securities the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering is less than the exercise price immediately prior to such subsequent offering (a "Dilutive Issuance"), to an exercise price that is equal to the lowest of the price paid for Common Stock, the exercise price of any options or warrants or the conversion price of any convertible securities issued in such subsequent offering (subject to a floor of $0.10 per share) and an increase in the number of shares of our Common Stock underlying the May 2025 Warrants so that the reset exercise price multiplied by the increased number of shares equals the aggregate proceeds that would have resulted from the full exercise of the May 2025 Warrants immediately prior to the reset (the "Anti-Dilution Adjustment"). We have agreed not to consummate a subsequent Dilutive Issuance until the earlier of (i) eight months from the closing date of this offering and (ii) later of: (a) the filing of a registration statement registering the resale of the shares issuable as a result of an Anti-Dilution Adjustment, which registration statement we agree to use our commercially reasonable efforts to become effective; (b) the Stockholder Approval Notice Date; and (c) the effective date of the filing of the Certificate of Amendment. If a reverse stock split is effected an additional 3,156,312 (on a pre-reverse split basis which number shall be adjusted based on the reverse stock split ratio) shares of Common Stock will be issuable upon exercise of the May 2025 Warrants and then, subject to obtaining Warrant Stockholder Approval, if a subsequent offering occurs for which the exercise price of the May 2025 Warrants is reset to the floor price of $0.10 per share, an additional 61,397,642 (on a pre-reverse split basis which number shall be adjusted based on the reverse stock split ratio) shares of Common Stock would be issuable upon exercise of the May 2025 Warrants. Those purchasers who do not enter into the Purchase Agreement and do not provide us with information required for registration of the resale of shares of Common Stock shall not have any of their shares issuable as a result of an Anti-Dilution Adjustment included in the registration statement we will file covering shares issuable as a result of an Anti-Dilution Adjustment and will not be able to effect a cashless exercise with respect to such shares

Exercisability

The May 2025 Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the May 2025 Warrants, 9.99%) of the outstanding Common Stock immediately after exercise. Following the issuance of the May 2025 Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding stock after exercising the holder's warrants up to 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 the May 2025 Warrants and in accordance with the rules and regulations of the SEC, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise

If, at the time after the date of issuance of the May 2025 Warrants and the date of Warrant Stockholder Approval, a holder exercises its May 2025 Warrants and a registration statement registering the issuance of the shares of Common Stock underlying the May 2025 Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the May 2025 Warrants, provided however that those purchasers who do not enter into the Purchase Agreement and do not provide us with information required for registration of the shares of Common Stock to be issued upon an Anti-Dilution Adjustment shall not be able to effect a cashless exercise with respect to Warrant Shares issuable upon the triggering of the Anti-Dilution Adjustment.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the May 2025 Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the May 2025 Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the May 2025 Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the May 2025 Warrants will be extremely limited. The Common Stock issuable upon exercise of the May 2025 Warrants is currently listed on the Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the May 2025 Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the May 2025 Warrants do not

have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their May 2025 Warrants.

Warrant Agent; Global Certificates.

The May 2025 Warrants will be issued in registered form under a Warrant Agent Agreement between the Warrant Agent and us. The May 2025 Warrants will be unregistered securities and will be evidenced by a global certificate, which shall be deposited on behalf of the Company with the Warrant Agent. Our transfer agent, VStock Transfer, LLC, will serve as the Warrant Agent.

Fundamental Transaction

In the event of a fundamental transaction, as described in the May 2025 Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the May 2025 Warrants will be entitled to receive upon exercise of the May 2025 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the May 2025 Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board of directors, the holders of the May 2025 Warrants have the right to require us or a successor entity to redeem the May 2025 Warrant for cash in the amount of the Black-Scholes Value (as defined in the warrant) of the unexercised portion of the warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the May 2025 Warrants have the right to require us or a successor entity to redeem the warrant for the consideration paid in the fundamental transaction in the amount of the Black-Scholes Value of the unexercised portion of the warrant on the date of the consummation of the fundamental transaction.

Amendments

The May 2025 Warrants may be modified or amended with the written consent of the holder of such warrant and us.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Duration and Exercise Price

Each Pre-Funded Warrant offered hereby will have an initial exercise price per share equal to $0.007. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price. The Pre-Funded Warrants will be issued separately from the accompanying May 2025 Warrants, in certificated form only.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the Pre-Funded Warrant, 9.99%) of the outstanding Common Stock immediately after exercise. Following the issuance of the Pre-Funded Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding stock after exercising the holder's Pre-Funded Warrants up to 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 the Pre-Funded Warrants and in accordance with the rules and regulations of the SEC. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants.

Transferability

Subject to applicable law, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Pre-Funded Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment to such fraction multiplied by the exercise price to the holder.

Trading Market

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Pre-Funded Warrants will be extremely limited. The Common Stock issuable upon exercise of the Pre-Funded Warrants is currently listed on the Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Pre-Funded Warrants. The Pre-Funded Warrants will provide that holders have the right to participate in distributions or dividends paid on our Common Stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our

Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Amendments

The Pre-Funded Warrants may be modified or amended with the written consent of the holder of such Pre-Funded Warrant and us.

Placement Agent Warrants

We have also agreed to issue to the Placement Agent (or its designees) Placement Agent Warrants to purchase up to 210,420 shares of Common Stock, which equals 3.0% of the assumed aggregate number of shares of Common Stock and Pre-Funded Warrants sold in this offering,. The Placement Agent Warrants will have substantially the same terms as the May 2025 Warrants described above, including that they will have an exercise price of $[*] per share (representing 110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant), except that the Placement Agent Warrants will not have any anti-dilution (other than protection against pro rata distributions or share combinations) provisions, will not include a provision to increase the number of shares underlying the Placement Agent Warrants upon the occurrence of a reverse stock split, will be immediately exercisable and will have a termination date that will be five years from the commencement of the sales pursuant to this offering. In accordance with FINRA Rule 5110(e), the Placement Agent may not sell, transfer, assign, pledge, or hypothecate the Placement Agent Warrant or the securities underlying such warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such warrants or the underlying securities for a period of 180 days following the date of commencement of sales pursuant to this public offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrants is included as an exhibit to this registration statement of which this prospectus forms a part. See “Plan of Distribution” below.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a general discussion of the material U.S. federal income tax considerations applicable to the ownership and disposition of shares of our Common Stock and the Pre-Funded Warrants and May 2025 Warrants acquired in this offering. The Pre-Funded Warrants and the May 2025 Warrants are collectively referred to as, the “Warrants”). This discussion is for general information only and is not tax advice. Accordingly, all prospective holders of our Common Stock and Warrants should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our Common Stock and Warrants. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences described in this prospectus. We assume in this discussion that each holder holds shares of our Common Stock and Warrants as capital assets within the meaning of Section 1221 of the Code (generally property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular holder in light of that holder’s individual circumstances, does not address the alternative minimum or Medicare contribution taxes, and does not address any aspects of U.S. state, local or non-U.S. taxes or any U.S. federal taxes other than income tax. This discussion also does not consider any specific facts or circumstances that may apply to a holder and does not address aspects of U.S. federal income taxation that may be applicable to holders that are subject to special tax rules, including without limitation:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- real estate investment trusts;
- pension plans, individual retirement accounts and other tax deferred accounts;
- persons that mark their securities to market;
- controlled foreign corporations;
- passive foreign investment companies;
- “dual resident” corporations;
- persons that receive our Common Stock or Warrants as compensation for the performance of services;
- owners that hold our Common Stock or Warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- owners that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- persons that have a functional currency other than the U.S. dollar; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or other pass-through entities for U.S. federal income tax purposes, or persons who hold our Common Stock or Warrants through partnerships or other pass-through entities for U.S. federal income tax purposes. A partner in a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or other pass-through entity that will hold our Common Stock or Warrants should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our Common Stock or Warrants through a partnership or other pass-through entity, as applicable.

As used in this prospectus, the term “U.S. holder” means a beneficial owner of Common Stock or Warrants that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity properly classified as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state within the United States, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (i) a U.S. court is able to exercise primary supervision over the trust’s administration and one or more “United States persons” (as defined in the Code) have the authority to control all substantial decisions of the trust, or (ii) in the case of a trust that was treated as a domestic trust under the laws in effect before 1997, a valid election is in place under applicable U.S. Treasury regulations to treat such trust as a domestic trust.

The term “non-U.S. holder” means any beneficial owner of shares of Common Stock or Warrants that is not a U.S. holder and is not a partnership or other entity properly classified as a partnership for U.S. federal income tax purposes. For the purposes of this prospectus, U.S. holders and non-U.S. holders are referred to collectively as “holders.” There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the U.S. federal income tax consequences of the purchase, ownership or disposition of our Common Stock or Warrants.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a Pre-Funded Warrant should be treated as a share of our Common Stock for U.S. federal income tax purposes and a holder of Pre-Funded Warrants should generally be taxed in the same manner as a holder of Common Stock, as described below.

Accordingly, no gain or loss should be recognized upon the exercise of a Pre-Funded Warrant and, upon exercise, the holding period of a Pre-Funded Warrant should carry over to the share of Common Stock received. Similarly, the tax basis of the Pre-Funded Warrant should carry over to the share of Common Stock received upon exercise, increased by the exercise price of $0.01 per share. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of Pre-Funded Warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above will be respected for U.S. federal income tax purposes.

Allocation of Purchase Price

Each share of Common Stock or Pre-Funded Warrant, as applicable, and accompanying May 2025 Warrants will be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our Common Stock or Pre-Funded Warrant, as applicable, and an accompanying May 2025 Warrant to purchase our Common Stock. In determining their tax basis for the Common Stock or Pre-Funded Warrant and the May 2025 Warrants constituting an investment unit, holders of these securities should allocate their purchase price for the investment unit between the Common Stock or Pre-Funded Warrant, as applicable, and the May 2025 Warrants on the basis of their relative fair market values at the time of issuance. We do not intend to advise holders of the Common Stock or Pre-Funded Warrant and accompanying May 2025 Warrants with respect to this determination, and holders of these securities are advised to consult their tax and financial advisors with respect to the relative fair market values of the Common Stock or Pre-Funded Warrant, as applicable, and the May 2025 Warrants for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Exercise or Expiration of Warrants

Subject to the discussion below with respect to the cashless exercise of a Warrant, a U.S. holder will not recognize income, gain or loss on the exercise of a Warrant. A U.S. holder's tax basis in the Common Stock received upon the exercise of a Warrant will equal the sum of (i) the initial tax basis of the Warrant exercised (as determined pursuant to the rules discussed above under "Allocation of Purchase Price") and (ii) the exercise price of the Warrant. The U.S. holder's holding period for the Common Stock received upon exercise of a Warrant will begin on the day after such exercise (or possibly on the date of exercise) and will not include the period during which the U.S. holder held the Warrant.

If a registration statement registering the issuance of the Common Stock underlying the Warrants under the Securities Act is not effective or available the holder may, in its sole discretion, elect to exercise the Warrant through a cashless exercise. The tax consequences of a cashless exercise of a Warrant are not clear under current U.S. tax law. U.S. holders should consult their own tax advisors regarding the tax consequences of a cashless exercise.

If a Warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the Warrant. The deductibility of capital losses is subject to significant limitations.

Distributions on Our Common Stock

We have never paid cash dividends on our Common Stock, and we do not anticipate paying any cash dividends in the foreseeable future. See "Dividend Policy." If we do make distributions on our Common Stock to a U.S. holder, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to (and in reduction of) such U.S. holder's tax basis in the Common Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "— Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants." Dividends paid by us generally will be eligible for the reduced rates of tax for qualified dividend income allowed to individual U.S. holders and for the dividends received deduction allowed to corporate U.S. holders, in each case assuming that certain holding period and other requirements are satisfied.

Constructive Distributions on Our Warrants

Under Section 305 of the Code, an adjustment to the number of shares of Common Stock that will be issued on the exercise of our Warrants (whether Pre-Funded Warrants or Warrants), or an adjustment to the exercise price of such Warrants, may be treated as a constructive distribution to a U.S. Holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to holders of our Common Stock). Adjustments to the exercise price of a Warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holder of the Warrant should generally not result in a constructive distribution. Any constructive distributions generally would be subject to the tax treatment described above under "— Distributions on our Common Stock".

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

Upon the sale, exchange, or other taxable disposition of our Common Stock or Warrants (whether Pre-Funded Warrants or Warrants), a U.S. holder will recognize gain or loss equal to the difference between the amount realized upon the disposition and the U.S. holder's tax basis in the Common Stock or Warrants sold or exchanged.

Any gain or loss generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder's holding period for the Common Stock or Warrants exceeded one year at the time of the disposition. Certain U.S. holders (including individuals) are currently eligible for preferential rates of U.S. federal income taxation in respect of long-term capital gains. The deductibility of capital losses is subject to significant limitations.

Information Reporting and Backup Withholding

In general, information reporting requirements may apply to distributions (whether actual or constructive) paid to a U.S. holder on our Common Stock or Warrants, and to the proceeds of the sale, exchange or other disposition of our Common Stock and Warrants, unless the U.S. holder is an exempt recipient. Backup withholding will apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Consequences to Non-U.S. Holders

Exercise or Expiration of Warrants

In general, a non-U.S. holder will not be required to recognize income, gain or loss upon the exercise of a Warrant by payment of the exercise price. To the extent that a cashless exercise results in a taxable exchange, the consequences would be similar to those described below under "Sale, Exchange or Other Taxable Disposition of our

Common Stock or Warrants".

The expiration of a Warrant will be treated as if the non-U.S. holder sold or exchanged the Warrant and recognized a capital loss equal to the non-U.S. holder's basis in the Warrant. A non-U.S. holder will not be able to utilize a loss recognized upon expiration of a Warrant against the Non-U.S. holder's U.S. federal income tax liability, however, unless the loss (i) is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a "permanent establishment" or "fixed base" in the United States) or (ii) is treated as a U.S. source loss and the non-U.S. holder is present in the United States 183 days or more in the taxable year of disposition and certain other conditions are met.

Distributions on Our Common Stock

We have never paid cash dividends on our Common Stock, and we do not anticipate paying any cash dividends in the foreseeable future. See "Dividend Policy." If we do make distributions to holders of our Common Stock or if we are treated as making a constructive distribution to holders of our Warrants or Pre-Funded Warrants, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the Common Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "— Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants."

Distributions (including constructive distributions) made to a non-U.S. holder that are treated as dividends generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence, unless such dividends are effectively connected with a trade or business conducted by a non-U.S. holder within the United States (as discussed below). A non-U.S. holder of our Common Stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W- 8BEN-E (or successor form), as applicable, and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may be able to obtain a refund or credit of any excess amounts withheld by timely filing the required information with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a "permanent establishment" or a "fixed base" maintained by the non-U.S. holder within the United States, generally are exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements.

U.S. effectively connected income, net of specified deductions and credits, is generally taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Constructive Distributions on Our Warrants

As described above under "—Tax Consequences to U.S. Holders—Constructive Distributions on our Warrants," an adjustment to the Warrants could result in a constructive distribution to a non-U.S. holder, which would be treated as described under "—Distributions on Our Common Stock" above. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the non-U.S. holder. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the Warrants.

In addition, regulations governing "dividend equivalents" under Section 871(m) of the Code may apply to the Pre-Funded Warrants. Under those regulations, an implicit or explicit payment made to the holder of Pre-Funded Warrants that references a distribution on our Common Stock would generally be taxable to a non-U.S. holder in the manner described under "Distributions on our Common Stock" above. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property, and we may satisfy any withholding obligations by withholding from other amounts due to the non-U.S. holder. Non-U.S. holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the Pre-Funded Warrants.

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

In general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other taxable disposition of shares of our Common Stock or Warrants (whether Pre-Funded Warrants or Warrants) unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a "permanent establishment" or a "fixed base" maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on such gain at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "— Tax Consequences to Non-U.S. Holders — Distributions on Our Common Stock" also may apply to such gain;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the taxable disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the taxable disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or

- we are, or have been, at any time during the five-year period preceding such taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our Common Stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding Common Stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the taxable disposition or the period that the non-U.S. holder held our Common Stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our Common Stock will be regularly traded on an established securities market for purposes of the rules described above.

Information Reporting and Backup

Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions paid on our Common Stock (and constructive distributions on our Warrants) to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our Common Stock or Warrants. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Non-U.S. Holders—Distributions on Our Common Stock,"

generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our Common Stock and Warrants by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends (including constructive dividends) on our Common Stock and Warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a "foreign financial institution," the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a "foreign financial institution," the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Withholding under FATCA generally will apply to payments of dividends (including constructive dividends) on our Common Stock and Warrants.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. While withholding described in this paragraph would have applied also to payments of gross proceeds from the sale or other disposition of our securities on or after January 1, 2019, proposed Treasury Regulations eliminate such withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury regulations are issued. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our Common Stock or Warrants. **The preceding discussion of material U.S. federal income tax considerations is for informational purposes only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our Common Stock or Warrants, including the consequences of any proposed changes in applicable laws.**

PLAN OF DISTRIBUTION

Pursuant to a placement agency engagement agreement, dated [___], 2025, we have engaged WallachBeth Capital, LLC to act as our exclusive Placement Agent to solicit offers to purchase the securities offered pursuant to this prospectus on a best efforts basis. The engagement agreement does not give rise to any commitment by the Placement Agent to purchase any of our securities, and the Placement Agent will have no authority to bind us by virtue of the engagement agreement. The Placement Agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. This is a "best efforts" offering and there is no minimum offering amount required as a condition to the closing of this offering. The Placement Agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. Therefore, we may not sell all of the shares of Common Stock, Pre-Funded Warrants and May 2025 Warrants being offered. The terms of this offering are subject to market conditions and negotiations between us, the Placement Agent and prospective investors. The Placement Agent does not guarantee that it will be able to raise new capital in any prospective offering. The Placement Agent may engage sub-agents or selected dealers to assist with the offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the investors which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with a means to enforce the following covenants uniquely available to them under the securities purchase agreement, including: (i) timely delivery of shares; (ii) a covenant to not enter into variable rate transactions for a period of 12 months following the closing of the offering, subject to certain exceptions, including that the prohibition against entering into an "at the market" offering will expire 45 days following the closing of the offering; (iii) a covenant to not enter into any financings for 60 days from closing of the offering; and (iv) indemnification for breach of contract. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and

- covenants regarding matters such as registration of warrant shares, no integration with other offerings, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of shares of Common Stock, and no subsequent equity sales for 45 days, subject to certain exceptions.

This offering will terminate on May 15, 2025, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share (or Pre-Funded Warrant) and May 2025 Warrants will be fixed for the duration of this offering.

We expect to deliver the shares and other securities to the purchasers in the offering on or about [___], 2025, subject to satisfaction of certain conditions. There is no minimum number of securities or amount of proceeds that is a condition to closing of this offering.

Fees and Expenses

The following table shows the per share and accompanying May 2025 Warrants and per Pre-Funded Warrant and accompanying May 2025 Warrants Placement Agent fees we will pay in connection with the sale of the securities in this offering, assuming the purchase of all of the securities we are offering.

Per share of Common Stock and accompanying May 2025 Warrant–Placement Agent cash fees	$
Per Pre-Funded Warrant and accompanying May 2025 Warrant –Placement Agent cash fees	$
Total	$

We have agreed to pay the Placement Agent a total cash fee equal to 8.0% of the gross proceeds of this offering. We will also reimburse the Placement Agent's legal fees and expenses in an amount up to $120,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the Placement Agent fees and expenses, will be approximately $148,000. After deducting the Placement Agent fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $2.9 million.

Placement Agent Warrants

We have also agreed to issue to the Placement Agent (or its designees) Placement Agent Warrants to purchase up to 210,420 shares of Common Stock. The Placement Agent Warrants will have substantially the same terms as the May 2025 Warrants described above, including that they will have an exercise price of $[*] per share (representing 110% of the combined public offering price per share of Common Stock and accompanying May 2025 Warrant, except that the Placement Agent Warrants will not have any anti-dilution (other than protection against pro rata distributions or share combinations) provisions, will not include a provision to increase the number of shares underlying the Placement Agent Warrants upon the occurrence of a reverse stock split, will be immediately exercisable and will have a termination date that will be five years from the commencement of the sales pursuant to this offering. In accordance with FINRA Rule 5110(e), the Placement Agent may not sell, transfer, assign, pledge, or hypothecate the Placement Agent Warrant or the securities underlying such warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such warrants or the underlying securities for a period of 180 days following the date of commencement of sales pursuant to this public offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrants is included as an exhibit to this registration statement of which this prospectus forms a part.

Right of First Refusal

In addition, with certain exceptions, for a period of six months following the closing of this offering, if we decide to raise funds by means of a public offering (including "at the market offering" facility) the right to act as sole book-running manager, sole underwriter or sole placement agent for such financing.

Tail

We have also agreed to pay the Placement Agent a tail fee equal to both the cash and warrant compensation in this offering, if this offering is not consummated and any potential investor who was brought over-the-wall by the Placement Agent with respect to an offering other than a public offering or contacted by the Placement Agent with respect to a public offering during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the twelve-month period following expiration or termination of our engagement with the Placement Agent. Notwithstanding anything to the contrary contained in the agreement with the Placement Agent, if the engagement of the Placement Agent is terminated for cause, the Placement Agent shall not have the right to receive any tail fee pursuant to FINRA Rule 5110(g)(5).

Determination of Offering Price

The public offering price per share (or Pre-Funded Warrant) and accompanying May 2025 Warrant we are offering and the exercise prices and other terms of the May 2025 Warrants were negotiated between us and the investors, in consultation with the Placement Agent based on the trading of our Common Stock prior to this offering, among other things. Other factors considered in determining the public offering prices of the securities we are offering and the exercise prices and other terms of the May 2025 Warrants include the history and prospects of our Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant. The combined public offering price per share (or Pre-Funded Warrant) and warrants will be fixed for the duration of this offering.

Indemnification

We have agreed to indemnify the Placement Agent against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the Placement Agent may be required to make for these liabilities.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of our securities offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the Placement Agent and the Placement Agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the Placement Agent and should not be relied upon by investors.

Lock-up Agreements

We and each of our officers and directors have agreed with the Placement Agent to be subject to a lock-up period of 60 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of Common Stock or any securities convertible into, or exercisable or exchangeable for, shares of Common Stock, subject to customary exceptions. The Placement Agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our Common Stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of twelve months following the closing date of this offering, subject to an exception. The Placement Agent may waive this prohibition in its sole discretion and without notice.

Support Agreement

Each of our officers and directors will agree to vote in favor of the Warrant Stockholder Approval.

Other Relationships

Except as described below, the Placement Agent and its designees have not had any material relationship with us within the past three years. The Placement Agent served as: (i) the placement agent in connection with our sale of convertible bridge notes in 2021 and 2022, (ii) the underwriter for our initial public offering that closed on September 6, 2022; (iii) the placement agent for a registered direct offering and concurrent private placement consummated in March 2024; (iv) financial advisor and placement agent for a warrant inducement private placement and a registered direct offering and concurrent private placement, all of which were consummated in August 2024, (v) as placement agent for a registered direct offering and concurrent private placement consummated in October 2024, and (vi) as financial advisor for a warrant inducement private placement

consummated in February 2025, pursuant to which the Placement Agent received cash compensation and warrants. The warrants issued to the Placement Agent in October 2024 and February 2025 have been terminated.

From time to time, the Placement Agent may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which it may receive customary fees and commissions. Except as disclosed in this prospectus, we have no present arrangements with the Placement Agent for any services.

In addition, in the ordinary course of their business activities, the Placement Agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The Placement Agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

EXPERTS

The consolidated financial statements of bioAffinity Technologies, Inc. as of December 31, 2024 and 2023, and for the years ended December 31, 2024 and 2023, 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. The Placement Agent is being represented by Sichenzia Ross Ference Carmel LLP, New York, New York in connection with this offering.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the information and periodic reporting requirements of the Exchange Act, and we file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains these periodic 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/*. You may access our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. 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 with respect to the securities being offered by this prospectus. 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.

GLOSSARY OF SELECTED TERMS

Adenocarcinoma	A form of cancer that forms in the tissue that lines certain internal organs. Most cancers of the breast, pancreas, lung, prostate, colon, esophagus, and stomach are adenocarcinomas.
Antibody	A protein that is produced by a person's immune system to target and destroy alien substances in the blood such as bacteria or viruses.
Bio-label	A tag that is chemically attached to an individual cell. These tags, or bio-labels, help to identify or track the cell on basis of its color or radioactivity depending on the type of bio-label used.
Cancerization	The act of transforming a normal cell or tissue to a cancerous state.
CAP	The College of American Pathologists (CAP). CAP is a professional association that, among other things, issues guidance for commercial laboratories. CAP guidance must be followed by the laboratory to receive CAP certification. CAP often works in collaboration with regulations issued by the U.S. Centers for Medicare and Medicaid under authority granted the Agency by the Clinical Laboratory Improvement Amendments (CLIA). (See also "CLIA" and "Laboratory Developed Test (LDT)").
CD320 Gene	A gene that provides instructions for making CD320 receptors. The CD320 receptor on the surface facilitates the uptake of vitamin B12, an important nutrient for human cells. Cancer cells can express large numbers of CD320 receptors on their cell surface.
Cell surface receptors	Proteins that are located on the cell surface that interact, or bind, with specific molecules outside the cell called ligands.
CE-marked	The letters 'CE' (Conformitè Europëenne) on a product signifies that products sold in the European Union have been assessed to meet high safety, health, and environmental protection requirements.
CLIA	The Clinical Laboratory Improvement Amendments of 1989 (CLIA). These amendments to U.S. law grant authority to the Centers for Medicare and Medicaid to issue regulations and guidance governing commercial laboratories. CLIA regulations are often associated with CAP guidance. (See also "Laboratory Developed Test (LDT)").
Cobalamin	Another name for vitamin B12.
Cytology	A branch of biology that deals with the structure, function, multiplication, pathology, and life history of cells.
Endocytosis	The process of actively transporting a molecule into a cell by engulfing the molecule with the cell's membrane.

Flow cytometry	A technique that can distinguish individual cells in a fluid such as blood or sputum. In the flow cytometry process, cells flow individually past a laser and this produces data to be analyzed to distinguish different cell types. Cells can be labeled to identify different types of cells. Flow cytometry has applications in fields like immunology, virology, molecular biology, cancer biology, disease diagnosis, and infectious disease monitoring.
Gene expression	A biological process taking place in a cell by which the information encoded in our DNA (i.e., our genes) is converted into a product, like a protein, that can perform different cell functions. Proteins carry out most of the active functions of a cell.
Gene silencing	A biological process by which an mRNA molecule is destroyed and prevented from delivering its instructions for producing a protein.
Heme	The deep red, nonprotein component of hemoglobin that carries oxygen in the blood. Heme is a porphyrin.
IVD	Diagnostic tests whose process of detection is performed outside the body, or in vitro.
Knock-down of CD320 and LRP2	bioAffinity uses siRNA to target and destroy the instructions encoded by the CD320 and LRP2 Genes that lead to a cessation in CD320 and LRP2 receptor production, thereby killing cancer cells with little or no harm to healthy cells.
Laboratory reagent	A substance that is used in a laboratory to measure, detect, or create other substances during a chemical reaction. Reagents are the substances added to the laboratory tests to carry out a chemical reaction or to check whether any reaction occurs or not.
Laboratory Developed Test (LDT)	An LDT is a type of diagnostic test that is designed, manufactured and used within a single laboratory. LDTs are performed in vitro, that is, outside the body (See also "IVD").
Low-dose computed tomography (LDCT)	A medical imaging test that uses a low-dose of radiation to create high-quality images of the inside of the human body. The radiation exposure in LDCT scans is more than a standard X-ray, but up to 90% less than a conventional CT chest scan. The only recommended screening test for lung cancer is LDCT.
LRP2 Gene	A gene that provides instructions for making the LRP2 receptor that facilitates the uptake of many proteins and some nutrients that includes vitamin B12. Cancer cells can express a large number of LRP2 receptors on their cell surface.

Metabolism	The set of life-sustaining chemical reactions used by organisms to convert the energy in food to energy available for the body to stay alive, grow and reproduce, maintain the body's structures, and respond to its environments.
Negative predictive value	The probability that a patient with a negative diagnostic or screening test truly does not have the disease. Negative predictive value is a function of the incidence of a disease in a population (i.e., the estimated percentage of people who are expected to have the disease in the population) and the specificity of a test (See "Specificity").
Nodules	Abnormal tissue growths that can be found anywhere in the body. Although they are often benign, some nodules are symptoms of an underlying health condition such as cancer.
Organic compound	Organic compounds are the complex compounds of carbon. These compounds can occur naturally or can be man-made (synthesized) in a laboratory.
Pathology	The branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic or forensic purposes.
Pivotal trial	A clinical study seeking to demonstrate the efficacy of a new diagnostic test in order to obtain approval by the U.S. FDA to market the test directly by its manufacturer.
Plasma	The liquid portion of blood. Its main role is to take nutrients, hormones, and proteins to the parts of the body that need it. Cells also excrete their waste products into the plasma.
Porphyrins	A class of pigments that can be either lab-produced or naturally occurring, many of which are essential to life, such as the green chlorophyll for photosynthesis in plants and the oxygen carrier, hemoglobin, that gives blood its red color. The molecular structure of all porphyrins is a large ring composed of four linked nitrogen-containing rings known as pyrroles.
Positive predictive value	The probability that a patient with a positive diagnostic or screening test truly has the disease. Positive predictive value is a function of the incidence of a disease in a population (i.e., the estimated percentage of people who are expected to have the disease in the population) and the sensitivity of a test (See "Sensitivity").
Pre-malignant	A term used to describe a condition that may (or is likely to) become cancer. Also called precancerous.
RNA interference (RNAi)	A natural process in which small pieces of RNA shut down a cell's ability to make certain proteins. To do so, RNAi binds to the messenger RNA (mRNA) that carries instructions for that protein.
RNA	Ribonucleic acid, a naturally occurring chemical compound present in all living cells. RNA's principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins. Several types of RNA sequences are often mentioned, including:
mRNA	Messenger RNA (mRNA), the molecule that carries protein-building instructions from DNA to the ribosome, the part of the cell where proteins are assembled.
siRNA	Small interfering RNA (siRNA), short molecules that bind to an mRNA and target it for destruction.
Sensitivity	In a diagnostic test, sensitivity is a measure of how well a test can identify true positives, meaning the test's ability to detect a disease in a person with that disease. There is a trade-off between sensitivity and specificity, such that higher sensitivities will mean lower specificities and vice versa.
Specificity	Specificity is a measure of how well a test can identify someone who does not have a disease is negative for that disease.

Squamous cell carcinoma	A type of cancer that begins in squamous cells. Squamous cells are thin, flat cells that look like fish scales, and are found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the lining of the respiratory and digestive tracts. Most cancers of the anus, cervix, head and neck, and vagina are squamous cell carcinomas.
Stage I–IV	Staging describes where cancer is located, how far the primary tumor (where the cancer started) has spread and to where, and its size. This is one method used to define how cancer is growing and advancing in the body. The lower the number, the less advanced the disease. Stage I is when cancer is relatively small and is contained where it started. Stage II is when cancer has started to spread, but is still in the early stage of disease. In Stage III, cancer has spread more so than Stage II, and may be considered a regional cancer, as opposed to local, meaning the cancer has metastasized to nearby lymph nodes, lymph vessels, or another organ. By Stage IV, cancer is advanced and has spread to multiple areas in the body. It is important to take note that each case of cancer is different, even within the same stage.
Synthesis	The making of a chemical compound by combining simpler materials. Synthesis can occur both naturally and in the laboratory.
Synthetic	A chemical or compound that is produced artificially in a laboratory rather than a natural system. Naturally occurring molecules can be made synthetically, and have the same molecular structure and properties as the nature-made material.
TCPP	A specific synthetic (i.e., man-made) porphyrin molecule whose chemical name is *meso*-tetra (4-carboxyphenyl) porphine.
Transfection	A laboratory technique that is used to insert foreign nucleic acid (DNA or RNA) into a cell, typically with the intention of producing a specific protein within the cell.
Vitamin B12	An essential dietary nutrient that the body needs daily in small amounts to function and stay healthy. Vitamin B12 helps make red blood cells, DNA, RNA, energy, and tissues, and keeps nerve cells healthy. It is found in liver, meat, eggs, poultry, shellfish, milk, and milk products. Chronic lack of vitamin B12 can result in anemia and central nervous system problems.

INDEX TO FINANCIAL STATEMENTS

bioAffinity Technologies, Inc.
Index to the Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

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

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

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

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing

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

/s/ WithumSmith+Brown, PC

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

New York, New York
March 31, 2025

PCAOB ID Number 100

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

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

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

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

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

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

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

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

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

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

	2024	2023

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

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

bioAffinity Technologies, Inc.
Notes to Consolidated Financial Statements
For the Years Ended December 31, 2024 and 2023

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

Description of Business

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

Organization

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

Basis of Presentation

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

Liquidity and Capital Resources

In accordance with Accounting Standards Update ("ASU") 2014-15, *Presentation of Financial Statements – Going Concern* (Subtopic 205-40), the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern for at least one year after the date the consolidated financial statements are issued.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to continue to incur losses and negative cash flows for the foreseeable future. As a result, the Company had an accumulated deficit of $53.6 million at December 31, 2024. The Company's cash and cash equivalents at December 31, 2024, were approximately $1.1 million. Based on the Company's current expected level of operating expenditures and the cash and cash equivalents on hand at December 31, 2024, management concludes that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements. Without funding from the proceeds of a capital raise or strategic relationship or grant, management anticipates that the Company's cash resources are sufficient to continue operations through May 2025. The Company may need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations, if revenue from operations does not significantly increase. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan may be curtailed. Furthermore, an alternative source of funding to the sale of additional equity or debt securities is the exercise of outstanding warrants for which there can be no guarantee. No adjustments have been made to the presented consolidated financial statements as a result of this uncertainty.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Principles of Consolidation

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

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

Business Combination

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

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

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

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

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

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

Cash and Cash Equivalents

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

Concentration of Risk

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

Advertising Expense

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

Loss Per Share

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

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

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

Revenue Recognition

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

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

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

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

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

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

Reclassifications

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

Property and Equipment, Net

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

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

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

Intangible Assets

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

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

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

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

Recent Accounting Pronouncements

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

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

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which the related temporary difference becomes deductible. The Company includes interest and penalties related to uncertain tax positions as part of income tax expense, if any. No such interest or penalties were recognized during the years ended December 31, 2024 and 2023, and the Company had no accruals for interest and penalties at December 31, 2024 or 2023.

Segment Information

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

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

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

Net loss before income taxes	(9,028,181)	(7,916,018)
Income tax expense	(11,650)	(20,993)
Net loss	$ (9,039,831)	$ (7,937,011)

Research and Development

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

Accrued Research and Development Costs

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

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

Regulatory Matters

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

Note 3. ACCOUNTS AND OTHER RECEIVABLES, NET

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

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

Note 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

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

Note 5. PROPERTY AND EQUIPMENT, NET

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

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

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

Note 6. ACCRUED EXPENSES

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

	December 31,	
	2024	2023
Compensation	$ 1,079,839	$ 857,037
Legal and professional	98,477	257,926
Clinical	160,371	15,350

Other	60,035	19,498
Total accrued expenses	$ 1,398,722	$ 1,149,811

Note 7. UNEARNED REVENUE

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

Note 8. FAIR VALUE MEASUREMENTS

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

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

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

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

Note 9. LEASES

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

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

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

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

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

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

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

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

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

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

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

Note 10. NOTES PAYABLE

Toyota Corolla - 2024

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

Directors and Officers Insurance Policy – 2024

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

Note 11. COMMITMENTS AND CONTINGENCIES

Legal Matters

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

Note 12. COMMON STOCK

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

Note 13. STOCK-BASED COMPENSATION

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

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

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

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

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

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

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

Restricted Stock Awards

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

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

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

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

Note 14. WARRANTS

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

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

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

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

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

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

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

Note 15. INCOME TAXES

Deferred tax assets and valuation allowance

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

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

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

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

Unrecognized tax benefits

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

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

Note 16. SUBSEQUENT EVENTS

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

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

Pre-Funded Warrants to Purchase up to 7,014,028 Shares of Common Stock

Warrants to Purchase up to 13,677,354 Shares of Common Stock

Placement Agent Warrants to Purchase up to 210,420 Shares of Common Stock

Up to 20,901,802 Shares of Common Stock Issuable Upon Exercise of

Pre-Funded Warrants, Warrants and Placement Agent Warrants

WallachBeth Capital, LLC

, 2025

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses to be paid by the registrant, other than estimated underwriting discounts and commissions, in connection with this Offering. All of the amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

	Amount
SEC registration fee	$ 1,703
FINRA filing fee	2,169
Legal fees and expenses	150,000
Accounting fees and expenses	30,000
Miscellaneous fees and expenses	16,128
Total	$ 200,000

Item 14. Indemnification of Directors and Officers

bioAffinity Technologies, Inc. is incorporated under the laws of the State of Delaware. Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends or unlawful stock purchase or redemptions, or (4) for any transaction from which the director derived an improper personal benefit.

Section 145(a) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the adjudicating court shall deem proper.

Section 145(g) of the DGCL provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether the corporation would have the power to indemnify the person against such liability under Section 145 of the DGCL.

In addition, as permitted by Delaware law, our Charter includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director, except to the extent such an exemption from liability thereof is not permitted under the DGCL. The effect of these provisions is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director, subject to certain exceptions in which case the director would be personally liable. If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our Charter does not eliminate the duty of care owed by our directors and officers and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect the responsibilities of directors and officers under any other laws, such as the federal securities laws or other state or federal laws.

Our Charter also provides that any amendment, repeal or modification of such article unless otherwise required by law will not adversely affect any right or protection existing at the time of such repeal or modification with respect to any acts or omissions occurring before such repeal or amendment of a director serving at the time of such repeal or modification.

Our Charter and A&R Bylaws provides that we shall indemnify each of our directors, officers, employees and agents, to the fullest extent permitted by the DGCL as the same may be amended (except that in the case of an amendment, only to the extent that the amendment permits us to provide broader indemnification rights than the DGCL permitted us to provide prior to such the amendment) against any and all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by the director, officer or such employee or on the director's, officer's or employee's behalf in connection with any threatened, pending or completed proceeding or any claim, issue or matter therein, to which he or she is or is threatened to be made a party because he or she is or was serving as a director, officer or employee of our Company, or at our request as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of our Company and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Charter and A&R Bylaws further provide for the advancement of expenses.

In addition, the A&R Bylaws provide that the right to indemnification and advancement of expenses shall not be exclusive of any other right now possessed or hereafter acquired under any statute, provision of the Charter or A&R Bylaws, agreement, vote of stockholders or otherwise. Furthermore, our A&R Bylaws authorize us to provide insurance for our directors, officers, employees and agents against any liability, whether we would have the power to indemnify such person against such liability under the DGCL or the A&R Bylaws.

We also maintain a general liability insurance policy which covers certain liabilities of directors and officers of our Company arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 15. Recent Sales of Unregistered Securities

The Company has not issued unregistered securities to any person within the last three years, except as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and, unless otherwise indicated below, the Company believes that each transaction was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof, Rule 701 of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder. All recipients had adequate access, though their relationships with the Company, to information about the Company.

In July of 2022, we issued 729,658 warrants to the holders of our convertible promissory notes that agreed to an extension of the maturity date of such notes to October 31, 2022. The warrants are exercisable to purchase Common Stock at an exercise price of $5.25 per share. The warrants have a term of five years.

In August of 2022, we issued and sold unsecured, convertible promissory notes to two investors pursuant to a note purchase agreement with an aggregate principal amount of $249,000. These notes bear interest at 6% per annum and have a maturity date of October 31, 2022. The principal and accrued interest under these notes automatically converted into shares of the Company's Common Stock upon completion of our initial public offering at the initial public offering price of $6.125. Holders of these notes also, at their option, prior to our initial public offering, could have converted the principal and accrued interest under their notes (or any portion thereof) into shares of the Company's Common Stock at a price per share equal to $4.20 per share. Pursuant to the terms of the note purchase agreement, each of these notes was accompanied by warrants to purchase that number of shares of the Company's Common Stock equal to the principal amount of the note divided by $4.20. Accordingly, warrants to purchase up to 59,285 shares of the Company's Common Stock were issued to the noteholders. These warrants have an exercise price equal to $5.25 per share. The warrants have a term of 5 years.

On January 1, 2023, we issued an aggregate of 57,589 restricted shares of the Company's Common Stock to our seven directors, which shares of restricted stock will vest ratably over three months of continued service and which represents a restricted stock award to each director valued at $18,750 granted by us to each of our directors each quarter during the calendar year as part of our director compensation policy.

On April 15, 2023, we issued an aggregate of 69,440 restricted shares of the Company's Common Stock to our seven directors, which shares of restricted stock will vest one-third on the date of grant, one-third on May 1, 2023 and the remaining shares on June 1, 2023, provided each individual continues to service as a director, and which represents a restricted stock award to each director valued at $18,750 granted by us to each of our directors each quarter during the calendar year as part of our director compensation policy.

On April 1, 2023, we issued 2,645 shares of the Company's Common Stock to a consultant pursuant to the terms of a consulting agreement in consideration of services provided.

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

In November 2023, we issued to an investor relations firm of 50,000 shares of Common Stock for services provided. The investor relations firm was a sophisticated investor, received shares that had a restricted legend and had adequate access, though their relationships with the Company, to information about the Company.

On March 8, 2024, we issued: (i) in a private placement offering, warrants to purchase up to an aggregate of 1,600,000 shares of Common Stock, which are exercisable, at an exercise price of $1.64, commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of such warrants, which approval was obtained on June 4, 2024, and will expire on the fifth anniversary of such date; and (ii) warrants to purchase up to an aggregate of 32,000 shares of Common Stock to designees of the placement agent for such private placement offering, which were immediately exercisable, at an exercise price of $1.64 per share, for a term of five years from the date of issuance. Subsequently, on August 2, 2024, we agreed to reduce the exercise price of certain of such warrants issued to investors in the private placement offering to $1.25.

On August 5, 2024, we issued: (i) warrants to purchase an aggregate of 1,302,082 shares of Common Stock, exercisable at $1.50 per share, commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of such warrants, which approval was obtained on October 2, 2024, and will expire on the fifth anniversary of such date, pursuant to a warrant inducement letter agreement; and (ii) warrants to purchase up to 39,062 shares of Common Stock to designees of the financial advisor for such warrant inducement, which were immediately exercisable, an exercise price of $1.50 per share, for a term of five years from the date of issuance. Subsequently, on February 25, 2025, we agreed to reduce the exercise price of certain of such warrants issued to investors in the private placement offering to $0.58.

On August 5, 2024, we issued: (i) in a private placement offering, warrants to purchase up to 450,000 shares of Common Stock, which are exercisable, at an exercise price of $1.50 per share, commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of such warrants, which approval was obtained on October 2, 2024, and will expire on the fifth anniversary of such date; and (ii) warrants to purchase up to 10,800 shares of Common Stock to designees of the placement agent for such private placement offering, which were immediately exercisable, an exercise price of $1.50 per share, for a term of five years from the date of issuance.

On October 21, 2024, we issued: (i) in a private placement offering, warrants to purchase an aggregate of 2,662,782 shares of Common Stock, which are exercisable, at an exercise price of $1.50 per share, commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of such warrants, which approval was obtained on December 20, 2024, and will expire on the fifth anniversary of such date; and (ii) warrants to purchase up to 61,448 shares of the Company's Common Stock to designees of the placement agent for such private placement offering, which were immediately exercisable, an exercise price of $1.50 per share, for a term of five years from the date of issuance. Subsequently, on February 25, 2025, we agreed to reduce the exercise price of certain of such warrants issued to investors in the private placement offering to $0.58.

On February 26, 2025, we issued: (i) warrants to purchase an aggregate of up to 2,926,166 shares of Common Stock, which are exercisable, at an exercise price of $0.85 per share, commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of such warrants, and will expire on the fifth anniversary of such date, pursuant to a warrant inducement letter agreement that we entered into with certain holders of existing warrants, in exchange for such holders' exercise for cash of certain of their October 2024 Warrants and August 2024 Warrants at a reduced exercise price of $0.58.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is

incorporated herein by reference.

(b) Financial Statement Schedules

Schedules not listed have been omitted because the information required to be set forth therein is not applicable, not material or is shown in the financial statements or notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. to include any prospectus required by Section 10(a)(3) of the Securities Act;

ii. to reflect in the prospectus any acts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement (notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of a prospectus filed with the Commission pursuant to Rule 424(b) under the Securities Act if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement); and

iii. to include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement; provided, however, that subparagraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those subparagraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration, by means of a post-effective amendment, any of the securities being registered which remain unsold at the termination of the offering.

(4) That each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter);

ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a Registrant of expenses incurred or paid by a director, officer or controlling person of a Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, that Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(7) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering.

EXHIBIT INDEX

Exhibit Number	Description
1.1	Placement Agency Agreement, dated March 6, 2024, by and among the Company and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Form 8-K filed with the SEC on March 8, 2024)

1.2	Placement Agency Agreement, dated August 2, 2024, by and between bioAffinity Technologies, Inc. and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
1.3	Placement Agency Agreement, dated October 18, 2024, by and between bioAffinity Technologies, Inc. and WallachBeth Capital LLC (Incorporated by reference as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
1.4**	Form of Placement Agency Agreement
3.1	Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (Incorporated by reference as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-41463) filed with the SEC on April 1, 2024)
3.2	Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on June 16, 2022)
3.3	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016 (Incorporated by reference as Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-41463) filed with the SEC on April 1, 2024)
3.4	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.5	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021 (Incorporated by reference as Exhibit 3.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-41463) filed with the SEC on April 1, 2024)
3.6	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.7	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)
3.8	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 5, 2024 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 5, 2024)
3.9	Amendment to Amended and Restated By-Laws of bioAffinity Technologies Inc., dated October 17, 2024 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
4.1	Form of Registrant's Common Stock Certificate (Incorporated by reference as Exhibit 4.1 to the Registrant's Form S-1/A filed with the SEC on June 16, 2022)
4.2	Common Stock Purchase Warrant issued to San Antonio Economic Development Corporation dated March 17, 2017 (Incorporated by reference as Exhibit 4.2 to the Registrant's Form S-1/A filed with the SEC on May 25, 2022).
4.3	Form of Common Stock Purchase Warrant issued to Holders of the Registrant's Convertible Promissory Notes (Incorporated by reference as Exhibit 4.3 to the Registrant's Form S-1/A filed with the SEC on May 25, 2022)
4.4	Form of Placement Agent's Warrant issued to WallachBeth Capital, LLC (Incorporated by reference as Exhibit 4.4 to the Registrant's Form S-1/A filed with the SEC on August 5, 2022)

4.5	Form of Representative's Warrant issued to WallachBeth Capital, LLC, in connection with the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.5 to the Registrant's Form S-1/A filed with the SEC on July 28, 2022).
4.6	Form of (Tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.1 to the Registrant's Form 8-K filed with the SEC on September 6, 2022)
4.7	Form of Warrant Agent Agreement for the Warrants issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.3 to the Registrant's Form 8-K filed with the SEC on September 6, 2022)
4.8	Form of (Non-tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's Initial Public Offering (Incorporated by reference as Exhibit 4.2 to the Registrant's Form 8-K filed with the SEC on September 6, 2022)
4.9	Form of Amendment to Common Share Purchase Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
4.10	Form of Amendment to Initial Public Offering Warrants with schedule of warrant holders and warrants (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
4.11	Form of Warrant to Purchase Common Stock (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)
4.12	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024
4.13	Form of Purchase Warrant (New Warrant and Private Warrant) (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
4.14	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
4.15	Form of Common Warrant (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)

4.16	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
4.17	Form of New Warrant (Incorporated by reference as Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)
4.18	Form of Advisor Warrant (Incorporated by reference as Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)
4.19*	Form of May 2025 Warrant
4.20*	Form of Pre-Funded Warrant
4.21**	Form of Placement Agent Warrant
4.22**	Form of Warrant Agent Agreement for the May 2025 Warrants
5.1*	Opinion of Blank Rome LLP
10.1+	2014 Equity Incentive Plan of Registrant, as amended. (Incorporated by reference as Exhibit 10.1 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.2+	Executive Chairman Employment Agreement dated January 1, 2020, by and between Registrant and Steven Girgenti, as amended. (Incorporated by reference as Exhibit 10.2 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.3+	Employment Agreement dated February 1, 2015, by and between Registrant and Maria Zannes. (Incorporated by reference as Exhibit 10.3 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.4+	Employment Agreement dated April 4, 2016, by and between Registrant and Vivienne Rebel, as amended. (Incorporated by reference as Exhibit 10.4 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)
10.5+	Employment Agreement dated February 1, 2015, by and between Registrant and Timothy Zannes. (Incorporated by reference as Exhibit 10.5 to the Registrant's Form S-1 filed with the SEC on May 25, 2022)

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

10.20	Assignment and Assumption of Lease Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.21	Office Lease, dated July 31, 2019, by and between Village Oaks Pathology Services, P.A. and 343 West Sunset, LLC (Incorporated by reference as Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.22	Assignment and Assumption Agreement, effective September 18, 2023, by and between Precision Pathology Laboratory Services, LLC and Village Oaks Pathology Services, P.A. (Incorporated by reference as Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)

10.23	Equipment Usage Attachment, dated effective as of August 9, 2019, by and between Gen-Probe Sales & Service, Inc., together with its subsidiaries and affiliates and Village Oaks Pathology Services, P.A. d/b/a Precision Pathology, as amended by that certain Amendment No. 1 to Equipment Usage Attachment dated November 2, 2020, as further amended by that certain Amendment No. 2 to Equipment Usage Attachment dated November 2, 2020, and as further amended by that certain Amendment No. 3 to Equipment Usage Attachment dated December 21, 2022 (Incorporated by reference as Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.24	Master Agreement, dated as of January 29, 2015, by and between Leica Microsystems, Inc. and Precision Pathology, as amended by Amendment No. 1 to the Master Agreement, dated on or about April 4, 2018, as further amended by that certain Amendment No. 2 to Master Agreement, dated March 23, 2021 (Incorporated by reference as Exhibit 10.11 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.25	Strategic Relationship License Agreement, dated December 1, 2022, by and between Pathology Watch, Inc. and Precision Pathology Services (Incorporated by reference as Exhibit 10.12 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.26	Bill of Sale signed by Village Oaks Pathology Services, P.A., effective as of September 18, 2023 (Incorporated by reference as Exhibit 10.13 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on September 20, 2023)
10.27+	Jamie Platt Offer Letter (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on December 5, 2023)
10.28+	bioAffinity Technologies, Inc. Management Incentive Bonus Plan (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 31, 2024)
10.29+	Amendment to Michel Dougherty Offer Letter (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 31, 2024)
10.30	Form of Securities Purchase Agreement, dated as of March 6, 2024, by and among the Company and the investors parties thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)
10.31	Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on March 8, 2024)
10.32+	bioAffinity Technologies, Inc. 2024 Incentive Compensation Plan (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 5, 2024)
10.33	Form of Securities Purchase Agreement, dated as of August 2, 2024, by and among the Company and the investor listed on the signature page thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.34	Form of Warrant Inducement Agreement (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.35	Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 5, 2024)
10.36+	Consulting Agreement between the Company and Michael Edwards dated August 21, 2024 (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on August 23, 2024)
10.37+	Employment Agreement between the Company and Michael Edwards dated as of October 9, 2024 (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 10, 2024)
10.38	Form of Securities Purchase Agreement, dated as of October 18, 2024, by and among the Company and the investor listed on the signature page thereto (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
10.39	Form of Support Agreement with schedule of signatories (Incorporated by reference as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on October 21, 2024)
10.40	Amendment No. 2 to Employment Agreement with Maria Zannes (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on January 14, 2025)
10.41	Form of Warrant Inducement Agreement (Incorporated by reference as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on February 27, 2025)
10.42*	Form of Securities Purchase Agreement
21.1	List of Subsidiaries of the Registrant (Incorporated by reference as Exhibit 21.1 to the Registrant's Form 10-K filed with the SEC on April 1, 2024)
23.1**	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for bioAffinity Technologies Inc.
23.2*	Consent of Blank Rome LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page of the initial Registration Statement)

107*	Filing Fee Table.

* Filed herewith.
** Previously file.
# To be filed by amendment
+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of San Antonio, Texas, on the 5th day of May, 2025.

bioAffinity Technologies, Inc.

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

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Maria Zannes Maria Zannes	Founder, President, Chief Executive Officer, and Director (Principal Executive Officer)	May 5, 2025
/s/ James Michael Edwards James Michael Edwards	Chief Financial Officer	May 5, 2025
* Steven Girgenti	Founder, Executive Chairman, and Director	May 5, 2025
* Robert Anderson	Director	May 5, 2025
* Stuart Diamond	Director	May 5, 2025
* Peter S. Knight	Director	May 5, 2025
* Gary Rubin	Director	May 5, 2025
* Roby Joyce, MD	Director	May 5, 2025
* Jamie Platt, PhD	Director	May 5, 2025

By: */s/ Maria Zannes*
Name: Maria Zannes
Title: Attorney-in-fact

Exhibit 4.19

FORM OF

COMMON STOCK PURCHASE WARRANT

BIOAFFINITY TECHNOLOGIES, INC.

Warrant Shares:

Issue Date: [*], 2025

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, **[ ]** or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Issuance Date (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on a date that is five years after the later of (i) the Stockholder Approval Notice Date and (ii) the Charter Effectiveness Date (the " Termination Date") but not thereafter, to subscribe for and purchase from bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), up to **[ ]** shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized but undefined terms used herein have the meanings set forth in the Purchase Agreement.

"Charter Effectiveness Date" means the effective date of the filing of an amendment to the Company's Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase the Company's authorized number of shares of Common Stock to 350,000,000 shares.

"Common Stock Equivalents" means any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Convertible Securities" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for Common Stock.

"Excluded Securities" means (a) shares of Common Stock or options to employees, officers or directors or consultants of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities;, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibition period in Section 4.12(a) of the Purchase Agreement, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"Floor Price" means $0.10 per share (subject to adjustment for reverse and forward stock splits, recapitalizations and similar transactions following the date of the Purchase Agreement).

"Non-Executing Holder" means any Holder who does not execute the Purchase Agreement.

"Options" means any rights, warrants or options to subscribe for or purchase (i) Common Stock or (ii) Convertible Securities.

"Option Value" means the value of an Option based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of (A) the Trading Day prior to the public announcement of the issuance of the applicable Option, if the issuance of such Option is publicly announced or (B) the Trading Day immediately following the issuance of the applicable Option if the issuance of such Option is not publicly announced, for pricing purposes and reflecting (i) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of the applicable Option as of the applicable date of determination, (ii) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of (A) the Trading Day immediately following the public announcement of the applicable Option if the issuance of such Option is publicly announced or (B) the Trading Day immediately following the issuance of the applicable Option if the issuance of such Option is not publicly announced, (iii) the underlying price per share used in such calculation shall be the highest Weighted Average Price of the Common Stock during the period beginning on the Trading Day prior to the execution of definitive documentation relating to the issuance of the applicable Option and ending on (A) the Trading Day immediately following the public announcement of such issuance, if the issuance of such Option is publicly announced or (B) the Trading Day immediately following the issuance of the applicable Option if the issuance of such Option is not publicly announced, (iv) a zero cost of borrow and (v) a 360 day annualization factor

"Purchase Agreement" means the Securities Purchase Agreement dated May [*], 2025 between the Company and the investors that are signatory thereto.

"Registrable Securities" means any Warrant Shares that could become issuable under the Warrants on and after the later of the Charter Effectiveness Date and the Stockholder Approval Date pursuant to Section 3(b) of the Warrants.

"Secondary Registration Statement" shall mean the registration statement on Form S-1 (or other appropriate form) covering all the additional shares that could be underlying the Warrants as a result of a Dilutive Issuance by the Company.

"Stockholder Approval" means approval from the stockholders of the Company: (a) to the adjustments in Section 3(b) hereof thereby giving full effect to the adjustment in the Exercise Price and/or number of shares of Common Stock underlying this Warrant following any Dilutive Issuance, and (b) to consent to an increase in the number of authorized shares of Common Stock to 350,000,000 shares of Common Stock under the Company's Certificate of Incorporation, as amended.

"Stockholder Approval Notice Date" means the date during which the Company files a Current Report on Form 8-K with the Securities and Exchange Commission giving public notice of the Stockholder Approval.

"Subscription Date" means the date of the Purchase Agreement.

"Stockholder Approval Date" means the date of such approval as may be required by the applicable rules and regulations of The Nasdaq Stock Market LLC (or any

successor entity) from the stockholders of the Company to consent to any exercise of the Warrant and issuance of Warrant Shares.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) one (1) Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **$[ ]**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of Exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares by the Company, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the highest Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") within two (2) hours of the time of Holder's delivery of the Notice of Exercise pursuant to Section 2(a) hereof if such Notice of Exercise is delivered during "regular trading hours" or within two (2) hours thereafter the close of "regular trading hours" on a Trading Day or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is delivered pursuant to Section 2(a) hereof within two (2) hours after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

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

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall have the registered characteristics of the Warrants to be exercised (except, subject to Section 5, that any Warrant Shares issuable as a result of a Dilutive Issuance in accordance with Section 3(b) shall only be registered on and after the date the Secondary Registration Statement is declared effective by the Commission). The Company agrees not to take any position contrary to this Section 2(c).

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the OTCQB Venture Market ("OTCQB") or the OTCQX Best Market ("OTCQX") is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market ("Pink Market") operated by the OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

This Section 2(c) shall not apply with respect to Registrable Securities held by Non-executing Holders that are not included in the Secondary Registration Statement because such non-executing Holder failed to submit the Registration Materials to the Company in the time frame provided for in Section 5.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the

Holder in the Notice of Exercise by the date that is the earliest of (i) one (1) Trading Day after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date") provided that payment of the aggregate Exercise Price (other than in the instance of a cashless exercise) is received by the Company by such date. Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) one (1) Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise by delivering written notice to the Company at any time prior to the delivery of such Warrant Shares (in which case any liquidated damages payable under Section 2(d)(i) shall no longer be payable.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date(other than any such failure that is solely due to any action or inaction by the Holder with respect to such exercise), and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same- day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares. For the avoidance of doubt, nothing in this Section 2(d)(vi) shall require the Company to deliver the Warrant Shares on a date earlier than the Warrant Share Delivery Date.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a

Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Adjustment Upon Issuance of Common Stock. If and whenever on or after the Subscription Date, as long as this Warrant is outstanding, the Company issues or sells, or in accordance with this Section 3 is deemed to have issued or sold, any Common Stock (including the issuance or sale of Common Stock owned or held by or for the account of the Company, but excluding Common Stock deemed to have been issued or sold by the Company in connection with any Excluded Securities) for a consideration per share (the "New Issuance Price") less than a price (the "Applicable Price") equal to the Exercise Price in effect immediately prior to such issue or sale or deemed issuance or sale (the foregoing a "Dilutive Issuance"), then immediately after such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the New Issuance Price; provided that if the New Issuance Price is less than the Floor price, the New Issuance Price shall be deemed to be the Floor Price (such adjusted price, the "Base Share Price") and the number of shares of Common Stock issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant on the Issuance Date for the Warrant Shares then outstanding shall remain unchanged. Notwithstanding the foregoing, if one or more Dilutive Issuances occurred prior to the later of the Stockholder Approval Notice Date and the Charter Effectiveness Date (such later date being the "Approved Reset Date"), instead of the adjustment in the prior sentence being made on the date of the Dilutive Issuance on the Approved Reset Date, the Exercise Price will automatically be reduced to equal the greater of (x) the lowest Base Share Price with respect to any Dilutive Issuance that occurred prior to the Stockholder Approval being obtained, and (y) the Floor Price. For the avoidance of doubt, (x) for the purposes of this Section 3(b), pre-funded warrants to purchase Common Stock shall be treated as Common Stock with the aggregate consideration received or receivable by the Company upon the issuance and the exercise of such pre-funded warrants deemed the consideration per share and (y) if any sale or issuance, or deemed issuance, if determined to be for a consideration per share less than the par value of a share of Common Stock, the New Issuance Price shall be deemed to be equal the par value of a share of Common Stock. For purposes of determining the adjusted Exercise Price under this Section 3(b), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants or sells any Options and the lowest price per share for which one share of Common Stock is issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting or sale of such Option for such price per share. For purposes of this Section 3(b)(i), the "lowest price per share for which one share of Common Stock is issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option" shall be equal to the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting or sale of the Option, upon exercise of the Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option less any consideration paid or payable by the Company with respect to one share of Common Stock upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option. No further adjustment of the Exercise Price shall be made upon the actual issuance of such Common Stock or of such Convertible Securities upon the exercise of such Options or upon the actual issuance of such Common Stock upon conversion, exercise or exchange of such Convertible Securities.

(ii) Issuance of Convertible Securities. If the Company in any manner issues or sells any Convertible Securities and the lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale of such Convertible Securities for such price per share. For the purposes of this Section 3(b)(ii), the "lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange thereof" shall be equal to the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the issuance or sale of the Convertible Security and upon conversion, exercise or exchange of such Convertible Security less any consideration paid or payable by the Company with respect to such one share of Common Stock upon the issuance or sale of such Convertible Security and upon conversion, exercise or exchange of such Convertible Security. No further adjustment of the Exercise Price shall be made upon the actual issuance of such Common Stock upon conversion, exercise or exchange of such Convertible Securities, and if any such issue or sale of such Convertible Securities is made upon exercise of any Options for which adjustment of this Warrant has been or is to be made pursuant to other provisions of this Section 3(b), no further adjustment of the Exercise Price shall be made by reason of such issue or sale.

(iii) Change in Option Price or Rate of Conversion. If the purchase price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or exercisable or exchangeable for Common Stock increases or decreases at any time, the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price, which would have been in effect at such time had such Options or Convertible Securities provided for such increased or decreased purchase price, additional consideration or

increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 3(b)(iii), if the terms of any Option or Convertible Security that was outstanding as of the Issue Date are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 3(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(iv) Calculation of Consideration Received. In case any Option is issued in connection with the issue or sale of other securities of the Company, together comprising one integrated transaction, (x) the Options will be deemed to have been issued for the Option Value of the Options and (y) the other securities issued or sold in such integrated transaction shall be deemed to have been issued or sold for the difference of (I) the aggregate consideration received by the Company less any consideration paid or payable by the Company pursuant to the terms of such other securities of the Company, less (II) the Option Value of such Options. If any Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration other than cash received therefore will be deemed to be the net amount received by the Company therefor. If any Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company will be the Closing Sale Price of such publicly traded securities on the date of receipt of such publicly traded securities. If any Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such Common Stock, Options or Convertible Securities, as the case may be. The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Required Holders. If such parties are unable to reach agreement within ten (10) days after the occurrence of an event requiring valuation (the "Valuation Event"), the fair value of such consideration will be determined within five (5) Business Days after the tenth (10^{th}) day following the Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Required Holders. The determination of such appraiser shall be final and binding upon all parties absent manifest error and the fees and expenses of such appraiser shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if a calculation pursuant to this Section 3(b)(iv) would result in an Exercise Price that is lower than the par value of the Common Stock, then the Exercise Price shall be deemed to equal the par value of the Common Stock.

(v) Record Date. If the Company takes a record of the holders of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in Common Stock, Options or in Convertible Securities or (B) to subscribe for or purchase Common Stock, Options or Convertible Securities, then such record date will be deemed to be the date of the issue or sale of the Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase, as the case may be.

(vi) No Readjustment. For the avoidance of doubt, in the event that following the consummation of a Dilutive Issuance and the Exercise Price has been adjusted pursuant to this Section 3(b) and the Dilutive Issuance that triggered such adjustment is unwound, cancelled or expires after the fact for any reason, the Exercise Price will not be readjusted to the Exercise Price that would have been in effect if such Dilutive Issuance had not occurred or been consummated.

Notwithstanding anything to the contrary contained herein, none of the above provisions of this Section 3(b) shall be in effect until the later of the Stockholder Approval Notice Date and the Charter Effectiveness Date.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time while this Warrant is outstanding, the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to all of the record holders of all of the shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all of the holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction but excluding a stock split) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person (other than a transaction solely for purposes of reincorporation in a different state pursuant to which the surviving company remains a public company), (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions (and its Subsidiaries, taken as a whole), (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property other than a stock split, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement but excluding a stock split) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate

Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any 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 Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable contemplated Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within five Business Days of the Holder's election (or, if later, on the date of consummation of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

f) Share Combination Event Adjustment. In addition to the adjustments set forth in this Section 3, if at any time on or after the Issuance Date there occurs any share split, reverse share split, share dividend, share combination recapitalization or other similar transaction involving the Common Stock (each, a "Share Combination Event", and such date on which the Share Combination Event is effected, the "Share Combination Event Date"), then, at the close of trading on the Principal Market (or if the Common Stock no longer trades on the Principal Market, on the primary Eligible Market on which the Common Stock then trades) on the Share Combination Event Date, the number of Warrant Shares issuable upon exercise of this Warrant hereunder shall be increased by 30% of the number of Warrant Shares underlying the Warrants immediately after the Share Combination Event Date, after the Warrant Shares are adjusted as set forth in Section 3(a). Notwithstanding anything to the contrary, for clarity, upon exercise of this Warrant after a Share Combination Event, in order to exercise this Warrant for cash the holder shall pay the exercise price for each Warrant Share issued to such Holder. For example if prior to the Share Combination Event which 30% upon issuance shall be adjusted as set forth in Section 3(a). Notwithstanding anything to the contrary, for clarity, upon exercise of this Warrant after a Share Combination Event, in order to exercise this Warrant for cash the holder shall pay the exercise price for each Warrant Share issued to such holder. For example if prior to the Share Combination Event a holder of this Warrant is entitled to receive 1,000 Warrant Shares then upon effecting a 1-for-10 reverse stock split, the holder would be issued an additional 30 Warrant Shares with an exercise price per share equal to the new exercise price taking into account the reverse stock split.

g) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

h) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment; provided, however, that the Company may satisfy this notice requirement in this Section 3(g) by filing such notice with the Commission pursuant to a Current Report on Form 8-K or Quarterly Report on Form 10-Q or Annual Report on Form 10-K or in a press release.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form other than a stock split) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (excluding any granting or issuance of rights to all of the Company's stockholders pursuant to a stockholder rights plan) (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least 10 calendar days prior to the applicable record or effective date hereinafter specified (unless such information is filed with the Commission on its EDGAR system in which case a notice shall not be required), a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend,

distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

i) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws and the conditions set forth in Section 4(d) hereof and to the provisions of Section 4.1 of the Purchase Agreement, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Transfer Restrictions. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be either (i) registered pursuant to an effective registration statement under the Securities Act and under applicable state securities or blue sky laws or (ii) eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, comply with the provisions of Section 5.7 of the Purchase Agreement.

e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Securities Purchase Agreement.

All Non-executing Holders shall be third party beneficiaries to the Purchase Agreement and shall have the right to enforce the provisions thereunder as if such Holder was a Purchaser under the Purchase Agreement; provided that no Non-executing Holder shall be entitled to have any of its Registrable Securities included in the Secondary Registration Statement unless within 25 calendar days of the Closing Date, the Non-executing Holder provides the Company with (i) a copy of such Holder's broker's confirmation of investment; (ii) the name and address of the Holder and (iii) a statement signed and notarized by the Holder that it agrees for its name and address to be identified in the Secondary Registration Statement that is publicly filed with the Commission (the "Registration Materials") and (iv) the Holder has not sold or transferred the Registrable Securities before the effective date of the Secondary Registration Statement. The information described above shall be sent to the Company in accordance with Section 6(h) hereof. If the Company has not received the Registration Material with respect to any Non-executing Holder within the time frame specified above, then such Non-executing Holder's Registrable Securities may not be included in the Secondary Registration Statement and if such Registrable Securities are not included in the Secondary Registration Statement, such securities when issued will be restricted securities unless the requirements under Rule 144 for restrictive legend removal are met.

Section 6 . Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient

number of shares to provide for the issuance of all Warrant Shares then issuable upon a cash exercise of this Warrant, provided however, that following the Charter Effectiveness Date, the Company will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the maximum number of Warrant Shares issuable pursuant to this Warrant assuming a cash exercise and assuming that the Exercise Price is adjusted to the Floor Price and the number of Warrant Shares is adjusted to the maximum allowable amount pursuant to Section 3(b) and Section 3(f). The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto 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. Each party hereby irrevocably submits 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 hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is 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. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 22211 West Interstate 10, Suite 1206, San Antonio, TX, 78257, Attention: Ms. Maria Zannes, Chief Executive Officer, email address: mz@bioaffinitytech.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holders of a majority of the Warrant Shares into which the outstanding Warrants issued on the Issue Date are exercisable that are outstanding as of such date.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if

any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Maria Zannes
Chief Executive Officer

NOTICE OF EXERCISE

TO: BIOAFFINITY TECHNOLOGIES, INC.

(1) The undersigned hereby elects to purchase _____Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____
_____
_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____,_____

Holder's Signature: _____

Holder's Address: _____

Exhibit 4.20

PRE-FUNDED COMMON STOCK PURCHASE WARRANT

BIOAFFINITY TECHNOLOGIES, INC.

Warrant Shares: **Issue Date**:

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, [__] or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from **bioAffinity Technologies, Inc.,** a Delaware corporation (the "Company"), up to **[*] shares** (as subject to adjustment hereunder, the "Warrant Shares") of the common stock, par value $0.007 per share, of the Company ("Common Stock"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Purchase Agreement"), dated [*], among the Company and the purchasers signatory thereto.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the terms and conditions hereof, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise substantially in the form attached hereto as Exhibit A (the "Notice of Exercise"). Within the earlier of (i) one (1) Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the attached Notice of Exercise. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

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b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of $0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of $0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever, including in the event this Warrant shall not have been exercised prior to the Termination Date. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be $0.0001, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the highest Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") within two (2) hours of the time of Holder's delivery of the Notice of Exercise pursuant to Section 2(a) hereof if such Notice of Exercise is delivered during "regular trading hours" or within two (2) hours thereafter the close of "regular trading hours" on a Trading Day or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is delivered pursuant to Section 2(a) hereof within two (2) hours after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

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

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted on a Trading Market and if prices for the Common Stock are then reported on OTCQB or OTCQX, as applicable, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX, as applicable, (c) if the Common Stock is not then listed or quoted for trading on a Trading Market or on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted on a Trading Market and if prices for the Common Stock are then reported on OTCQB or OTCQX, as applicable, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on a Trading Market or on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the transfer agent to the Holder (the "Transfer Agent") by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (A) the earlier of (i) two (2) Trading Days and (ii) the number of days comprising the Standard Settlement Period, in each case after the delivery to the Company of the Notice of Exercise and (B) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company (such date, the "Warrant Share Delivery Date") provided that payment of the aggregate Exercise Price (other than in the instance of a cashless exercise) is received by the Company by such date. Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Warrant Share Delivery Date. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, provided that payment of the aggregate Exercise Price (other than in the instance of a cashless exercise) is received by the Company by such date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Purchase Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of Warrants with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto as Exhibit B duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, " Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on a number of outstanding shares of Common Stock that was provided by the Company. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on the number of outstanding shares of Common Stock that was provided by the Company. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within two (2) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon written notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant. If the Warrant is unexercisable as a result of the Holder's Beneficial Ownership Limitation, no alternate consideration is owing to the Holder.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time while this Warrant is outstanding the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to all of the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of the Company's assets in one or a series of related transactions, (iii) any, direct or indirect,

purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of greater than 50% of the voting power of the outstanding common and preferred stock of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (other than a stock split), or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement (other than a stock split)) with another Person or group of Persons whereby such other Person or group acquires greater than 50% of the voting power of the outstanding common and preferred stock of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any 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 Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity, or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto, and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment; provided, however, that the Company may satisfy this notice requirement in this Section 3(f) by filing such notice with the Commission pursuant to a Current Report on Form 8-K, Quarterly Report on Form 10-Q or Annual Report on Form 10-K.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form other than a stock split) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights (excluding any granting or issuance of rights to all of the Company's shareholders pursuant to a shareholder rights plan), (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least four (4) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Company's subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

iii. Voluntary Adjustment by the Company . Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Initial Exercise Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise" only as permitted in Section 2(c), and to receive the cash payments contemplated pursuant to Sections 2(d)(i) and 2(d)(iv), in no event will the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares. The Company covenants that, at all times during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment (it being understood that this Warrant shall not in any case prevent the Company from effecting any such amendment, reorganization, transfer, consolidation, merger, dissolution, issuance or sale). Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action, which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the right to exercise this Warrant terminates on the Termination Date. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: Chief Executive Officer

[SIGNATURE PAGE TO PRE-FUNDED COMMON STOCK PURCHASE WARRANT,
BIOAFFINITY TECHNOLOGIES, INC.]

EXHIBIT A

NOTICE OF EXERCISE

TO: **BIOAFFINITY TECHNOLOGIES, INC.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder’s Signature:

Holder’s Address:

Exhibit 5.1

BLANKROME

1271 Avenue of the Americas | New York, NY 10020
blankrome.com

May 5, 2025

The Board of Directors
bioAffinity Technologies, Inc.
3300 Nacogdoches Road
Suite 216
San Antonio, Texas 78217

Ladies and Gentlemen:

This opinion is furnished to you in connection with a Registration Statement on Form S-1 (the "***Registration Statement***") filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Securities Act***"), for the registration by bioAffinity Technologies, Inc., a Delaware corporation (the "***Company***"), of the Company's securities consisting of: (a) shares (the "***Shares***") of the Company's common stock, par value $0.007 per share (the "***Common Stock***") or Pre-Funded Warrants (the "***Pre-Funded Warrants***") to purchase shares of Common Stock (the "***Pre-Funded Warrant Shares***") in lieu of the Shares, with each Share or Pre-Funded Warrant to be accompanied by a warrant (each, a "***Common Warrant***" and collectively, the "***Common Warrants***") to purchase one and one-half share of Common Stock; (b) the shares of Common Stock underlying the Common Warrants (the "***Common Warrant Shares***"); (c) warrants (the "***Placement Agent Warrants***" and, together with the Pre-Funded Warrants and Common Warrants, the "***Warrants***") to purchase shares of Common Stock to be issued to WallachBeth Capital, LLC ("***WallachBeth***"), as partial compensation for WallachBeth acting as the placement agent for the offering; and (d) the shares of Common Stock issuable upon exercise of the Placement Agent Warrants (the "***Placement Agent Warrant Shares***" and, together with the Pre-Funded Warrant Shares and the Common Warrant Shares, the "***Warrant Shares***"). The proposed maximum aggregate offering price of the Shares and the Warrant Shares is $11,123,000. This opinion is being delivered at the request of the Company and in accordance with the requirements of Item 601(b)(5) of Regulation S-K promulgated by the Commission.

In rendering the opinions set forth herein, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Registration Statement, (ii) resolutions adopted by the Board of Directors of the Company, (iii) the certificate of incorporation of the Company, as amended, (the "***Certificate of Incorporation***"), (iv) the amended and restated bylaws of the Company, as amended (v) the form of the Warrants filed as exhibits to the Registration Statement, and (vi) such other corporate records, agreements, certificates, including, but not limited to, certificates or comparable documents of public officials and of officers and representatives of the Company, statutes and other instruments and documents as we considered relevant and necessary as a basis for the opinions hereinafter expressed.

In rendering this opinion, we have assumed, without inquiry, (i) the authenticity of all documents submitted to us as originals; (ii) the conformity to the original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies; (iii) the legal capacity of all natural persons and the genuineness of all signatures on the Registration Statement and all documents submitted to us; and (iv) that the books and records of the Company are maintained in accordance with proper corporate procedures. As to various questions of fact material to such opinions, we have relied upon statements or certificates of officials and representatives of the Company and others.

With respect to the Warrant Shares, we express no opinion with respect to shares of Common Stock issuable upon the reset of the Common Warrants pursuant to anti-dilution provisions included therein (the "Anti-Dilution Adjustment") which shares were not registered pursuant to the Registration Statement because such Anti-Dilution Adjustment is subject to obtaining stockholder approval.

BLANKROME

Based on the foregoing, and subject to the qualifications, exceptions and assumptions stated herein, we are of the opinion that:

1. The Shares have been duly authorized for issuance and, when issued, delivered and paid for, as contemplated in the Registration Statement and prospectus, will be validly issued, fully paid and non-assessable.

2. The Warrants have been duly authorized by the Company, and when issued, delivered and paid for, as contemplated in the Registration Statement and prospectus, the Warrants will constitute valid and binding obligations of the Company.

3. The Warrant Shares have been duly authorized for issuance and, when issued and delivered against payment therefor upon the exercise thereof in accordance with the terms therein, the Warrant Shares will be validly issued, fully paid and non-assessable.

We are opining solely on (i) all applicable statutory provisions of Delaware corporate law, including the rules and regulations underlying those provisions, all applicable provisions of the Delaware Constitution and all applicable judicial and regulatory determinations, all as in effect on the date hereof, and (ii) as to the Warrants constituting valid and legally binding obligations of the Company, the applicable laws of the State of New York in effect on the date hereof that, in our experience, are normally applicable to transactions of the type contemplated by the Warrants. We express no opinion with respect to the laws of any other jurisdiction.

With regard to our opinion concerning the Warrants constituting valid and binding obligations of the Company:

1. Our opinion is subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, conservatorship, moratorium, fraudulent conveyance, fraudulent transfer, and similar laws and court decisions affecting the rights and remedies of creditors and secured parties generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, impossibility of performance, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.

2. Our opinion is subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.

3. We express no opinion as to any provision of the Warrants that: (a) provides for liquidated damages, buy-in damages, monetary penalties, prepayment or make-whole payments or other economic remedies to the extent such provisions may constitute unlawful penalties, (b) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights, (c) restricts non-written modifications and waivers, (d) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy, (e) relates to exclusivity, election or accumulation of rights or remedies, (f) authorizes or validates conclusive or discretionary determinations, (g) provides that provisions of the Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable, (h) purporting to indemnify a party from its own conduct; (i) purporting to waive or release any rights or agree not to assert set-offs or claims of any kind; (j) purporting to prohibit oral amendments or oral waivers of provisions; (k) purporting to confer jurisdiction on a court to adjudicate any controversy relating to such agreements; (l) purporting to waive any objection to the laying of venue or any claim that an action or proceeding has been brought in an inconvenient forum; (m) purporting to waive trial by jury; (n) relating to indemnification and contribution provisions; (o) relating to releases of claims; (p) relating to liability limitations; (q) as to choice of law provisions; or (r) pursuant to which the parties agree to agree to any matter in the future.

4. We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law or jurisdiction provided for in the Warrants.

We hereby consent to the filing of this opinion as an Exhibit to the Registration Statement. We also hereby consent to the use of our name as your counsel under "Legal Matters" in the prospectus constituting part of the Registration Statement. In giving this consent, we do not thereby concede that we come within the categories of persons whose consent is required by the Securities Act or the General Rules and Regulations promulgated thereunder. This opinion is strictly limited to the matters stated herein and no other or more extensive opinion is intended, implied or to be inferred beyond the matters expressly stated herein. This opinion letter is not a guaranty nor may one be inferred or implied.

Very truly yours,

/s/ Blank Rome LLP

BLANK ROME LLP

Exhibit 10.42

SECURITIES PURCHASE AGREEMENT

THIS SECURITIES PURCHASE AGREEMENT (this "Agreement") is entered into and made effective as of [*], 2025, by and between BIOAFFINITY TECHNOLOGIES, INC., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

RECITALS

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an effective registration statement under the Securities Act (as defined below), the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. Capitalized but undefined terms used herein have the meanings set forth in the Warrants. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the respective meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Agreement" shall have the meaning ascribed to such term in the Preamble.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day other than Saturday, Sunday, or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; *provided*, *however*, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home," "shelter-in-place," "non-essential employee," or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York are generally open for use by customers on such day.

"Charter Effectiveness Date" means the effective date of the filing of an amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to increase the Company's authorized number of shares of Common Stock to 350,000,000 shares.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived, but in no event later than the first (1st) Trading Day following the date hereof (or the second (2nd) Trading Day following the date hereof. if this Agreement is signed on a day that is not a Trading Day or after 4:00 p.m. (New York City time) and before midnight (New York City time) on a Trading Day).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.007 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Warrant Shares" means the shares of Common Stock issuable upon exercise of the Common Warrants.

"Common Warrants" means, collectively, the Common Stock purchase warrants delivered to each Purchaser at the Closing in accordance with Section 2.2(a) hereof, which warrants shall be, in the form of Exhibit A attached hereto.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant, or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company" shall have the meaning ascribed to such term in the Preamble.

"Company Counsel" means Blank Rome LLP, with offices located at 1271 6th Ave, New York, NY 10020.

"Disclosure Schedules" means the Disclosure Schedules of the Company delivered concurrently herewith.

"Dilutive Issuance" has the meaning set forth in Section 3(b) of the Common Warrants.

"Disclosure Time" means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent, and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent.

"DWAC" means the Deposit or Withdrawal at Custodian system of The Depository Trust Company.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Exempt Issuance" means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities;, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibition period in Section 4.12(a) herein, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"FCPA" means the United States Foreign Corrupt Practices Act of 1977, as amended.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(b).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right, or other restriction.

"Lock-Up Agreement" means the Lock-Up Agreement, by and among the Company and the directors and officers of the Company, substantially in the form of Exhibit C attached hereto.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"OFAC" means the Office of Foreign Assets Control of the United States Department of the Treasury.

"Per Share Purchase Price" equals $[*], except that in the case of Pre-Funded Warrants, the purchase price equals $[*] minus $0.007, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations, and other similar transactions of the Common Stock that occur after the date of this Agreement, and up to and including the Closing Date.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof), or other entity of any kind.

"Placement Agent" means WallachBeth Capital, LLC.

"Pre-Funded Warrant Shares" means the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants.

"Pre-Funded Warrants" means, collectively, the pre-funded Common Stock purchase warrants delivered to the Purchasers at the Closing in accordance with Section 2.2(a) hereof, in substantially the form of Exhibit B attached hereto.

"Proceeding" means an action, claim, suit, investigation, or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or, to the knowledge of the Company, threatened.

"Preliminary Prospectus" means the preliminary prospectus filed for the Registration Statement at the time the Registration Statement is declared effective by the Commission.

"Prospectus" means the final prospectus complying with Rule 424(b) of the Securities Act, that is filed with the Commission in connection with the offer and sale of the Securities.

"Purchaser" shall have the meaning ascribed to such term in the Preamble.

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.9.

"Registration Statement" means the effective registration statement with Commission File No. 333- [*], including all information, documents, and exhibits filed with or incorporated by reference into such registration statement, which registers the sale of the Securities to the Purchasers.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Registrable Securities" means any Warrant Shares that could become issuable under the Common Warrants on and after the later of the Charter Effectiveness Date and the Stockholder Approval Date pursuant to Section 3(b) of the Common Warrants.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Secondary Registration Statement" shall mean the registration statement on Form S-1 (or other appropriate form) covering all the additional shares that could be underlying the Common Warrants as a result of a Dilutive Issuance by the Company.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(h).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Securities" means the Shares, the Warrants and the Warrant Shares.

"Secondary Registration Statement" shall mean the registration statement registration statement on Form S-1 (or other appropriate form) covering all the additional shares that could be underlying the Common Warrants as a result of a Dilutive Issuance by the Company.

"Shares" means the shares of Common Stock issued or issuable to each Purchaser pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

"Stockholder Approval Date" means the date of the approval by the Company's stockholders of Section 3(b) of the Common Warrants.

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for the Shares (or Pre-Funded Warrants in lieu of Shares) and accompanying Common Warrants purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds (minus, if applicable, a Purchaser's aggregate exercise price of the Pre-Funded Warrants, which amounts shall be paid as and when such Pre-Funded Warrants are exercised for cash).

"Subsidiary" means any subsidiary of the Company as set forth in the SEC Reports, where applicable, also including any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Support Agreement" means the Support Agreement, by and among the Company and each of the stockholders party thereto, substantially in the form of Exhibit C attached hereto

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, The Nasdaq Capital Market, The Nasdaq Global Market, The Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, the Warrants, all exhibits and schedules thereto and hereto, the Lock-Up Agreements, the Support Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means Vstock Transfer, LLC., the current transfer agent of the Company, with a mailing address of 18 Lafayette Place, Woodmere, NY 11598, and any successor transfer agent of the Company.

"Variable Rate Transaction" shall have the meaning ascribed to such term in Section 4.12(b)

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the OTCQB Venture Market ("OTCQB") or the OTCQX Best Market ("OTCQX") is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the Pink Open Market ("Pink Market") operated by OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants.

"Warrants" means, collectively, the Common Warrants and the Pre-Funded Warrants.

ARTICLE II. PURCHASE AND SALE

2.1 Closing.

On the Closing Date, upon the terms and subject to the conditions set forth herein, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of $[*] of Shares (or Pre-Funded Warrants) and accompanying Common Warrants. Each Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser shall be made available for "Delivery Versus Payment" settlement with the Company or its designee. The Company shall deliver to each Purchaser its respective Shares (or Pre-Funded Warrants) and Common Warrants as determined pursuant to Section 2.2(a), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall take place remotely by electronic transfer of the Closing documentation. Notwithstanding anything herein to the contrary, if at any time on or after the time of execution of this Agreement by the Company and an applicable Purchaser, through, and including the time immediately prior to the Closing (the "Pre-Settlement Period"), such Purchaser sells to any Person all, or any portion, of the Shares to be issued hereunder to such Purchaser at the Closing (collectively, the "Pre-Settlement Shares"), such Purchaser shall, automatically hereunder (without any additional required actions by such Purchaser or the Company), be deemed to be unconditionally bound to purchase, such Pre-Settlement Shares at the Closing; provided, that the Company shall not be required to deliver any Pre-Settlement Shares to such Purchaser prior to the Company's receipt of the purchase price of such Pre-Settlement Shares hereunder; and provided further that the Company hereby acknowledges and agrees that the forgoing shall not constitute a representation or covenant by such Purchaser as to whether or not during the Pre-Settlement Period such Purchaser shall sell any shares of Common Stock to any Person and that any such decision to sell any shares of Common Stock by such Purchaser shall solely be made at the time such Purchaser elects to effect any such sale, if any. Unless otherwise directed by the Placement Agent, settlement of the Shares shall occur via "Delivery Versus Payment" ("DVP") (i.e., on the Closing Date, the Company shall issue the Shares registered in the Purchasers' names and addresses and released by the Transfer Agent directly to the account(s) at the Placement Agent identified by each Purchaser; upon receipt of such Shares, the Placement Agent shall promptly electronically deliver such Shares to the applicable Purchaser, and payment therefor shall be made by the Placement Agent (or its clearing firm) by wire transfer to the Company). Notwithstanding anything to the contrary herein and a Purchaser's Subscription Amount set forth on the signature pages attached hereto, the number of Shares purchased by a Purchaser (and its Affiliates) hereunder shall not, when aggregated with all other shares of Common Stock owned by such Purchaser (and its Affiliates) at such time, result in such Purchaser beneficially owning (as determined in accordance with Section 13(d) of the Exchange Act) in excess of 9.9% of the then issued and outstanding Common Stock outstanding at the Closing (the "Beneficial Ownership Maximum"), and such Purchaser's Subscription Amount, to the extent it would otherwise exceed the Beneficial Ownership Maximum immediately prior to the Closing, shall be conditioned upon the issuance of Shares at the Closing to the other Purchasers signatory hereto. To the extent that a Purchaser's beneficial ownership of the Shares would otherwise be deemed to exceed the Beneficial Ownership Maximum, such Purchaser's Subscription Amount shall automatically be reduced as necessary in order to comply with this paragraph.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) a legal opinion of Company Counsel, addressed to the Placement Agent and the Purchasers, in a form reasonably acceptable to the Placement Agent and Purchasers;

(vi) a signed letter from the Chief Financial Officer of the Company addressed to the Placement Agent and the Purchasers, in form and substance reasonably satisfactory to the Placement Agent and its counsel, containing statements and information of the type ordinarily included in chief financial officer certificates to placement agents with respect to the financial statements and certain financial information contained in or incorporated by reference into the Registration Statement, the Preliminary Prospectus, and the Prospectus.

(iii) subject to Section 2.1, the Company shall have provided each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer;

(iv) subject to Section 2.1, a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver, on an expedited basis via DWAC, the number of Shares equal to such Purchaser's Subscription Amount divided by the Per Share Purchase Price, registered in accordance with the instructions of such Purchaser; and

(v) a Warrant registered in the name of such Purchaser to purchase up to a number of shares of Common Stock equal to 150% of such Purchaser's Shares and Pre-Funded Warrants, with an exercise price equal to $[*], subject to adjustment therein;

(vi) the duly executed Lock-Up Agreements;

(vii) if applicable, for each Purchaser of Pre-Funded Warrants pursuant to Section 2.1, a signed Pre-Funded Warrant registered in the name of such Purchaser to purchase up to a number of shares of Common Stock equal to the portion of such Purchaser's Subscription Amount applicable to Pre-Funded Warrants divided by the Per Share Purchase Price minus $0.007, with an exercise price equal to $0.007, subject to adjustment therein;

(viii) the duly executed Support Agreements, signed by stockholders of the Company representing not less than 16% of the shares of Common Stock outstanding; and

(ix) the Preliminary Prospectus and Prospectus (which may be delivered in accordance with Rule 172 under the Securities Act).

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount, which shall be made available for "Delivery Versus Payment" settlement with the Company or its designee.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants, and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed in all material respects; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(iv) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met: the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(v) all obligations, covenants, and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed in all material respects;

(vi) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(vii) there shall have been no Material Adverse Effect with respect to the Company since the date of this Agreement; and

(viii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Shares at the Closing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the SEC Reports (as defined below) and the Disclosure Schedules, which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of

the Disclosure Schedules or as set forth in the SEC Reports, the Company hereby makes the following representations and warranties to each Purchaser:

(a) *Subsidiaries*. All of the direct and indirect significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission) of the Company are set forth in the Company's SEC Reports. Except as set forth in Schedule 3.1(a), the Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable, and free of preemptive and similar rights to subscribe for or purchase securities.

(b) *Organization and Qualification.* The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing, and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws, or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not reasonably be expected to result in a Material Adverse Effect and no material Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit, or curtail such power and authority or qualification. For the purposes of this Agreement, a "Material Adverse Effect" means (i) a material adverse effect on the legality, validity, or enforceability of any Transaction Document, (ii) a material adverse effect on the business, assets, condition (financial or otherwise), prospects or results of operations of the Company and its Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document, *provided*, *however*, that, in the case of clause (i), the following shall be deemed to constitute, alone or in combination, or be taken into account in the determination of whether, there has been or will be a Material Adverse Effect: any actions taken or not taken by the Company as required by this Agreement.

(c) *Authorization; Enforcement.* The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors, or the Company's shareholders (other than Stockholder Approval and the filing of the certificate of amendment contemplated thereby) in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) *No Conflicts*. The execution, delivery, and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities, and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws, or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution, or similar adjustments, acceleration, or cancellation (with or without notice, lapse of time, or both) of, any agreement, credit facility, debt, or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree, or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as would not reasonably be expected to result in a Material Adverse Effect.

(e) *Filings, Consents and Approvals*. The Company is not required to obtain any consent, waiver, authorization, or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local, or other governmental authority or other Person in connection with the execution, delivery, and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.3 of this Agreement, (ii) the filing with the Commission of the Prospectus, (iii) if required, application(s) to each applicable Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (iv) such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) *Issuance of the Securities; Registration.*

(i) The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid, and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company will reserve on or prior to the Closing Date from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants (other than Registrable Securities), provided however, that following the Charter Effectiveness Date, in addition to reserving the number of shares issuable pursuant to this Agreement, the Company will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the maximum number of Warrant Shares issuable pursuant to the Warrants assuming a cash exercise and assuming that the Exercise Price is adjusted to the Floor Price and the number of Warrant Shares is adjusted to the maximum allowable amount pursuant to Section 3(b) and Section 3(f) of the Warrants.

(ii) The Company has prepared and filed the Registration Statement in conformity with the requirements of the Securities Act, which became effective on May [*], 2025, including the Preliminary Prospectus, and such amendments and supplements thereto as may have been required to the date of this Agreement. The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of the Preliminary Prospectus or the Prospectus has been issued by the Commission and no proceedings for that purpose have been instituted or, to the knowledge of the Company, are threatened by the Commission. The Company shall file the Preliminary Prospectus or the Prospectus with the Commission pursuant to Rule 424(b). At the time the Registration Statement and any amendments thereto became effective as determined under the Securities Act, at the date of this Agreement and at the Closing Date, the Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Prospectus and any amendments or supplements thereto, at the time the Preliminary Prospectus, the Prospectus or any amendment or supplement thereto was issued and at the Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

Any "issuer free writing prospectus" (as defined in Rule 433 under the Securities Act) relating to the Securities is hereafter referred to as an "Issuer Free Writing Prospectus." Any reference herein to the Preliminary Prospectus and the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein as of the date of filing thereof; and any reference herein to any "amendment" or "supplement" with respect to any of the Preliminary Prospectus and the Prospectus shall be deemed to refer to and include (i) the filing of any document with the Commission incorporated or deemed to be incorporated therein by reference

after the date of filing of such Preliminary Prospectus or Prospectus and (ii) any such document so filed.

All references in this Agreement to the Registration Statement, the Preliminary Prospectus, the Prospectus, or any Issuer Free Writing Prospectus, or any amendments or supplements to any of the foregoing, shall be deemed to include any copy thereof filed with the Commission on EDGAR.

(iii) The Registration Statement complies, and the Prospectus and any further amendments or supplements to the Registration Statement or the Prospectus will comply, in all material respects, with the applicable provisions of the Securities Act, and do not, and will not, as of the applicable effective date as to each part of the Registration Statement and as of the applicable filing date as to the Prospectus and any amendment thereof or supplement thereto, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(iv) No order preventing or suspending the use of the Prospectus has been issued by the Commission.

(g) *Capitalization.* The capitalization of the Company as of the date hereof is substantially as set forth on Schedule 3.1(g), which Schedule 3.1(g) shall also include the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof. Except as set forth on Schedule 3.1(g), the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options or vesting of restricted share units under the Company's stock option and incentive plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans, and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. Except as set forth on Schedule 3.1(g), no Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as a result of the purchase and sale of the Securities and as set forth on Schedule 3.1(g), there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchasers). There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. Except for the stock appreciation rights and restricted stock units issued pursuant to the Company's equity incentive plan, the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) *SEC Reports; Financial Statements.* The Company has filed all reports, schedules, forms, statements, and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Preliminary Prospectus and the Prospectus, being collectively referred to herein as the "SEC Reports") and, during the past twelve (12) calendar months, such SEC Reports have been filed on a timely basis or the Company has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with GAAP, except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) *Material Changes; Undisclosed Events, Liabilities or Developments.* Since the date of the latest audited financial statements included within the SEC Reports, except as set forth on Schedule 3.1(i), (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement or as set forth on Schedule 3.1(i), no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(ii) *Litigation*. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency, or regulatory authority (federal, state, county, local, or foreign) (collectively, an "Action"), which (i) adversely affects or challenges the legality, validity, or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Except as set forth in the SEC Reports, neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty, which could result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or threatened, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(j) *Labor Relations*. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and

the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non- competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters that would reasonably be expected to have a Material Adverse Effect. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(k) *Compliance*. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(l) *Environmental Laws.* The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(m) *Regulatory Permits.* The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(n) *Title to Assets.* The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance in all material respects.

(o) *Intellectual Property.* The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement except where such expiration, termination or abandonment would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(p) *Insurance*. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage of $2 million. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(q) *Transactions With Affiliates and Employees* . Except as set forth onSchedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers, consultants and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(r) *Sarbanes-Oxley; Internal Accounting Controls.* Except as set forth in the SEC Reports, the Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes- Oxley Act of 2002, as amended, that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. Except as set forth in the SEC Reports, the Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a- 15(e) and 15d- 15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the

Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(s) *Certain Fees*. Except for fees payable by the Company to the Placement Agent, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor, or consultant, finder, placement agent, investment banker, bank, or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(t) *Investment Company*. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(u) *Registration Rights.* Except as set forth on Schedule 3.1(v), no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(v) *Listing and Maintenance Requirements*. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as set forth on Schedule 3.1(w), the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(w) *Application of Takeover Protections*. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(x) *Disclosure.* Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information which is not otherwise disclosed in the Prospectus. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement and the SEC Reports, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(y) *No Integrated Offering.* Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) *Solvency*. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. Schedule 3.1(aa) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of $100,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $100,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(bb) *Tax Status.* Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, subject to permanent extensions (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(cc) *Foreign Corrupt Practices*. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(dd) *Accountants*. The Company's independent registered public accounting firm is WithumSmith+Brown, PC. To the knowledge and belief of the Company, the Auditor is expected to express an opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending

(ee) *Acknowledgment Regarding Purchasers' Purchase of Securities.* The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(ff) *Acknowledgment Regarding Purchaser's Trading Activity.* Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(f) and 4.14 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Securities for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly- traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Common Stock, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter- party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the Securities are outstanding, including, without limitation, during the periods that the value of the Warrant Shares deliverable with respect to Securities are being determined, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(gg) *Regulation M Compliance*. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Placement Agent in connection with the placement of the Securities.

(hh) *Stock Option Plans*. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(ii) *Cybersecurity*. (i)(x) To the knowledge of the Company, there has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance in all material respects with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards designed to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery procedure consistent with commercially reasonable industry standards and practices.

(jj) *Office of Foreign Assets Control.* Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(kk) *U.S. Real Property Holding Corporation.* The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) *Bank Holding Company Act*. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) *Money Laundering*. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(nn) *Other Covered Persons.* Other than the Placement Agent, the Company is not aware of any person (other than any Issuer Covered Person) that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with the sale of any Securities.

(oo) *Clinical and Preclinical Studies*. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with the applicable protocols, procedures and controls pursuant to accepted professional scientific standards and all authorizations and applicable laws and the rules and regulations promulgated thereunder and any applicable laws, rules, and regulations of the jurisdiction in which such trials and studies are being conducted; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Preliminary Prospectus or the Prospectus are, to the Company's knowledge, accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement, the Preliminary Prospectus or the Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or

referred to in the Registration Statement, the Preliminary Prospectus or the Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement, the Preliminary Prospectus or the Prospectus, the Company has not received any written notices or correspondence from the US Food and Drug Administration or any governmental entity requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) *Organization; Authority*. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing, and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company, or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company, or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies, and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) *Understandings or Arrangements*. Such Purchaser is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities (this representation and warranty not limiting such Purchaser's right to sell the Securities pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) *Purchaser Status*. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is, an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) *Experience of Such Purchaser.* Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication, and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) *Access to Information.* Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities, (ii) access to information about the Company and its financial condition, results of operations, business, properties, management, and prospects sufficient to enable it to evaluate its investment, and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that neither the Placement Agent nor any Affiliate of the Placement Agent has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Placement Agent nor any Affiliate has made or makes any representation as to the Company or the quality of the Securities and the Placement Agent and any Affiliate may have acquired non-public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(f) *Certain Transactions and Confidentiality*. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal, and other advisors, employees, agents, and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

(g) *Information Regarding Purchaser.* The Purchaser has provided the Company with true, complete, and correct information regarding all applicable items set forth on the Purchaser's signature page to this Agreement.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend, or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby. Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 [Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance or resale of the Warrant Shares or if the Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale or resale of the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale or resale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any Purchaser to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws and that the issuance of any Warrant Shares that are issuable as a result of the operation of Section 3(b) of the Warrants are subject to Stockholder Approval). The Company shall use best efforts to keep a registration statement (including the Registration Statement) registering the issuance or resale of the Warrant Shares effective during the term of the Warrants.

4.2 Furnishing of Information. Until the earlier of the time that (i) no Purchaser owns Securities or (ii) the Warrants have expired, the Company covenants to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act except in the case of a sale of all or substantially all of the assets of the Company, a merger or reorganization of the Company with one or more other entities in which the Company is not the surviving entity or any transaction or series of related transactions as a result of which any Person (together with its Affiliates) acquires then outstanding securities of the Company representing more than fifty percent (50%) of the voting control of the Company .

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall (a) by the Disclosure Time, issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees, or agents in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees, or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate and be no further force and effect. The Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (i) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission and (ii) to the extent such disclosure is required by law or Trading Market or Financial Industry Regulatory Authority, Inc. regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (ii).

4.5 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented in writing to the receipt of such information and agreed in writing with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates or agents, including, without limitation, the Placement Agent, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, employees, Affiliates or agents, including, without limitation, the Placement Agent, not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously with the delivery of such notice file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.6 Reservation of Common Stock. As of the date hereof, the Company will reserve on or prior to the Closing Date and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement and Warrant Shares pursuant to any exercise of the Warrants (other than Registrable Securities), provided however, that following the Charter Effectiveness Date, in addition to reserving the number of shares of Common Stock to be issued pursuant to this Agreement, the Company will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the maximum number of Warrant Shares issuable pursuant to the Warrants assuming a cash exercise and assuming that the Exercise Price is adjusted to the Floor Price and the number of Warrant Shares is adjusted to the maximum allowable amount pursuant to Section 3(b) and Section 3(f) of the Warrants.

4.7 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.3. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.3, such Purchaser will maintain the confidentiality of the existence and terms of this transaction (other than as disclosed to its legal and other representatives).

4.8 Use of Proceeds. Except as set forth in the Prospectus, the Company shall use the net proceeds from the sale of the Securities hereunder for working capital purposes and shall not use such proceeds: (a) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), or the debt of any officer, director, or executive management of the Company, or any sponsor, general partner, manager, or advisor or any of the Company's affiliates, (b) for the redemption of any Common Stock or Common Stock Equivalents, (c) for the settlement of any outstanding litigation or (d) in violation of FCPA or OFAC regulation.

4.9 Indemnification of Purchasers. Subject to the provisions of this Section 4.9, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any material breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity (including a Purchaser Party's status as an investor), or any of them or their respective Affiliates, by the Company or any stockholder of the Company who is not an Affiliate of such Purchaser Party, arising out of or relating to any of the transactions contemplated by the Transaction Documents. For the avoidance of doubt, the indemnification provided herein is intended to, and shall also cover, direct claims brought by the Company against the Purchaser Parties; provided, however, that such indemnification shall not cover any loss, claim, damage or liability to the extent it is finally judicially determined to be attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in any Transaction Document or any conduct by a Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct. The Company will also indemnify each Purchaser Party, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable attorneys' fees) and expenses, as incurred, arising out of or relating to (i) any untrue or alleged untrue statement of a material fact contained in a registration statement, any prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any prospectus or supplement thereto, in

light of the circumstances under which they were made) not misleading, except to the extent, but only to the extent, that such untrue statements or omissions are based solely upon information regarding such Purchaser Party furnished in writing to the Company by such Purchaser Party expressly for use therein, or (ii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, or any state securities law, or any rule or regulation thereunder in connection therewith. If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and, except with respect to direct claims brought by the Company, the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel to the applicable Purchaser Party (which may be internal counsel), a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the actual and documented reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed. In addition, if any Purchaser Party takes actions to collect amounts due under any Transaction Documents or to enforce the provisions of any Transaction Documents, then the Company shall pay the costs incurred by such Purchaser Party for such collection, enforcement or action, including, but not limited to, attorneys' fees and disbursements. The indemnification and other payment obligations required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation, defense, collection, enforcement or action, as and when bills are received or are incurred; provided, that if any Purchaser Party is finally judicially determined not to be entitled to indemnification or payment under this Section 4.9, such Purchaser Party shall promptly (but in no event later than five (5) Business Days) reimburse the Company for any payments that are advanced under this sentence. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 Listing of Common Stock. The Company hereby agrees to use reasonable best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and prior to the Closing, the Company shall have applied to list or quote all of the Shares and the maximum number of Warrant Shares issuable upon exercise of the Warrants on such Trading Market and promptly secure the listing of all of the Shares and the maximum number of the Warrant Shares issuable upon exercise of the Warrants on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Shares, and will take such other action as is necessary to cause all of the Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing, and other obligations under the bylaws or rules of the Trading Market. The Company agrees to use commercially reasonable efforts to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer except in the case of a sale of all or substantially all of the assets of the Company, a merger or reorganization of the Company with one or more other entities in which the Company is not the surviving entity or any transaction or series of related transactions as a result of which any Person (together with its Affiliates) acquires then outstanding securities of the Company representing more than fifty percent (50%) of the voting control of the Company.

4.11 Equal Treatment of Purchasers. No consideration (including any modification of this any Transaction Documents) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of any Transaction Documents unless the same consideration is also offered to all of the parties to this Agreement. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition, or voting of Securities or otherwise.

4.12 Subsequent Equity Sales.

(a) From the date hereof until 60 days after the Closing Date, neither the Company nor any Subsidiary shall (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents or (ii) file any registration statement or any amendment or supplement thereto, other than the Prospectus or as contemplated pursuant to Section 4.17 herein, supplements or amendments to registration statements or supplements previously filed (so long as no new securities are being registered or issued thereby) or filing a registration statement on Form S-8 in connection with any employee benefit plan.

(b) From the date hereof until 12 months after the Closing Date, the Company shall be prohibited from entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price regardless of whether shares pursuant to such agreement have actually been issued and regardless of whether such agreement is subsequently canceled, provided, however, that, following the expiration of the restrictive period set forth in Section 4.12(a) above, the entry into and/or issuance of shares of Common Stock in an "at the market" offering shall not be deemed a Variable Rate Transaction. Any Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(c) Notwithstanding the foregoing, this Section 4.12 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.13 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.3. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.3, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in the Disclosure Schedules. Notwithstanding the foregoing and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty, or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.3, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.3, and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company, any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates or agents after the issuance of the initial press release as described in Section 4.3. Notwithstanding the foregoing, in the case of a Purchaser that is a multi- managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to

purchase the Securities covered by this Agreement.

4.14 Intentionally Omitted

4.15 Exercise Procedures. The form of Notice of Exercise included in the Warrants set forth the totality of the procedures required of the Purchasers in order to exercise the Warrants. No additional legal opinion, other information or instructions shall be required of the Purchasers to exercise their Warrants. Without limiting the preceding sentences, no ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required in order to exercise the Warrants. The Company shall honor exercises of the Warrants and shall deliver Warrant Shares in accordance with the terms, conditions and time periods set forth in the Transaction Documents.

4.16 Blue Sky Filings. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Warrant and Warrant Shares for, sale to the Purchasers at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

4.17 Registration Statement. As soon as practicable (and in any event within two Business Days after the Charter Effectiveness Date), the Company shall file the Secondary Registration Statement. The Company shall use commercially reasonable efforts to keep such registration statement effective at all times until no Purchaser owns any Registrable Securities.

4.18 Lock-Up; Support Agreements. The Company shall not amend, modify, waive, or terminate any provision of any of the Lock- Up Agreements except to extend the term of the lock-up period and shall enforce the provisions of each Lock-Up Agreement in accordance with its terms. If any officer or director of the Company that is a party to a Lock-Up Agreement breaches any provision of a Lock-Up Agreement, the Company shall promptly use its commercially reasonable best efforts to seek specific performance of the terms of such Lock-Up Agreement. The Company shall not amend, modify, waive, or terminate any provision of any of the Support Agreements except to extend the obligations of the stockholders thereunder and shall enforce the provisions of each Support Agreement in accordance with its terms. If any officer or director of the Company that is a party to a Support Agreement breaches any provision of a Support Agreement, the Company shall promptly use its commercially reasonable best efforts to seek specific performance of the terms of such Support Agreement.

4.19. *Stockholder Approval.* The Company shall hold a special meeting of stockholders at the earliest practicable date after the date hereof, but in no event later than ninety days after the Closing Date for the purpose of obtaining Stockholder Approval (as defined below), if required to effect the purpose thereof, with the recommendation of the Board that such proposal be approved, and the Company shall solicit proxies from its stockholders in connection therewith in the same manner as all other management proposals in such proxy statement and all management- appointed proxyholders shall vote their proxies in favor of such proposal. The Company shall use its reasonable best efforts to obtain such Stockholder Approval, and request that its officers and directors, cast their proxies in favor of such proposal. If the Company does not obtain Stockholder Approval at the first meeting, the Company shall call a meeting every three (3) months thereafter to seek Stockholder Approval until the earlier of the date Stockholder Approval is obtained or the Warrants are no longer outstanding. Notwithstanding the foregoing, the Company may, in lieu of holding a special meeting of stockholders as aforesaid, obtain the written consent of a majority of its stockholders covering the Stockholder Approval so long as prior to forty five (45) days after the Closing Date, such written consents are obtained and in accordance with Exchange Act Rule 14c-2 at least twenty (20) days shall have transpired from the date on which a written information statement containing the information specified in Schedule 14C detailing such Stockholder Approval shall have been filed with the SEC and delivered to stockholders of the Company. No later than one Trading Day following the Company obtaining the Stockholder Approval, the Company shall (i) file a Current Report on Form 8-K with the Securities and Exchange Commission that publicly discloses such Stockholder Approval and (ii) file an amendment to the Company's Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase the Company's authorized number of shares of Common Stock to 350,000,000 shares.

"Stockholder Approval" means approval from the stockholders of the Company: (a) to the adjustments in Section 3(b) of the Warrants thereby giving full effect to the adjustment in the Exercise Price and/or number of shares of Common Stock underlying the Warrants following any Dilutive Issuance, and (b) to consent to an increase in the number of authorized shares of Common Stock to 350,000,000 shares of Common Stock under the Company's Certificate of Incorporation, as amended.

4.20. Dilutive Issuances. The Company hereby agrees not to offer any securities which would result in a Dilutive Issuance until the earlier of (A) the latest of (x) the filing of the Secondary Registration Statement, (y) the Stockholder Approval Notice Date (as defined in the Warrant, and (z) the Charter Effectiveness Date and (B) eight months after the Closing Date. The Company agrees to use commercially reasonable efforts to cause the Secondary Registration Statement to become effective as soon as possible after it is filed with the Commission.

ARTICLE V. MISCELLANEOUS

5.1 Termination. This Agreement may be terminated: by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5th) Trading Day following the date hereof; *provided*, *however*, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants, and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery, and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same- day processing of any instruction letter delivered by the Company), stamp taxes, and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Preliminary Prospectus and the Prospectus, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits, and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented, or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the sum of the (i) Shares and (ii) the Pre-Funded Warrant Shares initially issuable upon exercise of the Pre-Funded Warrants, if any, based on the initial Subscription Amounts hereunder (or, prior to the Closing, the Company and each Purchaser) or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, *provided* that if any amendment, modification, or waiver disproportionately and adversely impacts a Purchaser (or multiple Purchasers), the consent of such disproportionately impacted Purchaser (or multiple Purchasers) shall also be required. No

waiver of any default with respect to any provision, condition, or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition, or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, *provided* that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. The Placement Agent shall be the third party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in this Section 5.8.

5.9 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the law of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement, and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its 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. Each party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of New York and of the United States of America sitting in the City and County of New York, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of this Agreement or any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation, and prosecution of such Action or Proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities until the expiration of the applicable statute of limitations.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, or by electronic signature (including DocuSign), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" or electronic signature page were an original thereof.

5.12 Severability. If any term, provision, covenant, or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void, or unenforceable, the remainder of the terms, provisions, covenants, and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired, or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant, or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants, and restrictions without including any of such that may be hereafter declared invalid, illegal, void, or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand, or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand, or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by, or are required to be refunded, repaid, or otherwise restored to the Company, a trustee, receiver, or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law, or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture, or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the

Company through the legal counsel of the Placement Agent. The legal counsel of the Placement Agent does not represent any of the Purchasers and only represents the Placement Agent. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18 Liquidated Damages. The Company's obligations to pay any amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid amounts due and owing have been paid notwithstanding the fact that the instrument or security pursuant to which such amounts are due and payable shall have been canceled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations, and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: Chief Executive Officer

Address for Notice
bioAffinity Technologies, Inc.
3300 Nacogdoches Road , Suite 216
San Antonio, Texas 78217
E-Mail: mz@bioaffinitytech.com

With a copy to (which shall not constitute notice):

Blank Rome LLP
1271 Avenue of the Americas
New York, NY 10020
Attn: Leslie Marlow
Email: Leslie.Marlow@BlankRome.com

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK SIGNATURE PAGE FOR PURCHASER FOLLOWS]

[PURCHASER SIGNATURE PAGES TO BIOAFFINITY TECHNOLOGIES, INC. SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser:

By:

Signature of Authorized Signatory of Purchaser:_____

Name of Authorized Signatory:

Title of Authorized Signatory:

Email Address of Authorized Signatory:

Address for Notice to Purchaser:

Address for Delivery of Securities to Purchaser (if not same as address for notice):

Subscription Amount:
Shares:
Warrant Shares:
Beneficial Ownership Blocker for Warrants ☐ 4.99% or ☐ 9.99%

EIN Number:

[SIGNATURE PAGES CONTINUE]

Exhibit 107

Calculation of Filing Fee Tables

FORM S-1
(Form Type)

BIOAFFINITY TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price [(1)(2)]	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees to be paid	Equity	Shares of Common Stock, par value $0.007 per share	457(o)			$3,500,000[(3)]	$ 0.00015310	$ 535.85
Fees to be paid	Equity	Warrants to purchase shares of Common Stock	457(g)			[(4)]		
Fees to be paid	Equity	Shares of Common Stock issuable upon exercise of the Warrants	457(g)			$ 7,507,500[(5)]	$ 0.00015310	$ 1,149.40
Fees to be paid	Equity	Pre-Funded Warrants to purchase Common Stock	457(o)			[(4)]		
Fees to be paid	Equity	Shares of Common Stock issuable upon exercise of the Pre-Funded Warrants	457(o)			[(3)]		
Fees to be paid	Equity	Placement Agent Warrants	457(g)			[(4)]		
Fees to be paid	Equity	Shares of Common Stock issuable upon exercise of the Placement Agent Warrants	457(g)	—	—	$ 115,500[(6)]	$ 0.00015310	$ 17.68
			Total Offering Amounts			$ 11,123,000		$ 1,702.93
			Total Fees Previously Paid					$ 1,702.93
			Total Fee Offsets					—
			Net Fee Due					$ 0

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), there are also being registered such indeterminate number of additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends, and similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.

(3) The proposed maximum aggregate offering price of the Common Stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants sold in the offering, and, as such, the proposed maximum aggregate offering price of the Common Stock and pre-funded warrants (including the Common Stock issuable upon exercise of the pre-funded warrants), if any, is $3,500,000.

(4) Pursuant to Rule 457(g) of the Securities Act, no separate registration fee is required for the warrants because the warrants are being registered in the same registration statement as the Common Stock issuable upon exercise of the warrants.

(5) The Warrants are exercisable for a price per share equal to 110% of the public offering price. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g), the proposed maximum aggregate offering price of the Warrants is $7,507,500, which is equal to 110% of $6,825,000 (150% of $3,500,000, plus an additional 30% to account for the increase in the number of shares of Common Stock issuable upon exercise of the Warrants if a reverse stock split is effected prior to the expiration thereof).

(6) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. We have agreed to issue to the placement agent warrants to purchase the number of shares of our common stock (the "Placement Agent Warrants") in the aggregate equal to three percent (3%) of the aggregate number of shares of our Common Stock and Pre-Funded Warrants to be issued and sold in this offering. The Placement Agent Warrants are exercisable for a price per share equal to 110% of the public offering price. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g), the proposed maximum aggregate offering price of the Placement Agent Warrants is $115,500, which is equal to 110% of $105,000 (3% of $3,500,000).