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

**Amendment No. 5
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

(State or other jurisdiction of
incorporation or organization)

8731

(Primary Standard Industrial
Classification Code Number)

46-5211056

(I.R.S. Employer
Identification Number)

**22211 W Interstate 10
Suite 1206
San Antonio, Texas 78257
210-698-5334**

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

**Maria Zannes
Chief Executive Officer
22211 W Interstate 10
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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 ☐
Non-accelerated filer ☒

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 which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities 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.

Subject to Completion, dated August 5, 2022.

PRELIMINARY PROSPECTUS

1,285,325 Units
Each Unit Consisting of
One Share of Common Stock,
One Tradeable Warrant to Purchase One Share of Common Stock, and
One Non-tradeable Warrant to Purchase One Share of Common Stock
(and the shares of Common Stock underlying such Warrants)



bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc., a Delaware corporation headquartered in Texas (the “Company”), develops noninvasive, early-stage diagnostics to detect, and is researching targeted therapies to treat, cancer at the cellular level.

This is the initial public offering (the “Offering”) of 1,285,325 units (each, a “Unit,” collectively, the “Units”). We currently expect the initial public offering price to be between \$6.00 and \$6.25 (the “Price Range”). The assumed initial public offering price of the Units for purposes of this prospectus is \$6.125 per Unit (the “Offering Price”), which is the midpoint of the Price Range. The actual Offering Price of the Units will be determined between the underwriters and us at the time of pricing, considering our historical performance and capital structure, prevailing market conditions, and overall assessment of our business. Each Unit consists of one share of our common stock, \$0.007 par value per share (the “Common Stock”), one tradeable warrant (each, a “Tradeable Warrant,” collectively, the “Tradeable Warrants”) to purchase one share of Common Stock at an anticipated exercise price of \$7.35 per share (120% of the assumed \$6.125 per-Unit Offering Price), and one non-tradeable warrant (each, a “Non-tradeable Warrant,” collectively, the “Non-tradeable Warrants”; together with the Tradeable Warrants, each, a “Warrant,” collectively, the “Warrants”) to purchase one share of Common Stock at an anticipated exercise price of \$7.656 per share (125% of the anticipated \$6.125 per-Unit Offering Price). The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock and the Warrants underlying the Units are immediately separable and will be issued separately in this Offering. Each Warrant offered as part of this Offering is immediately exercisable on the date of issuance and will expire five years from the date of issuance.

In connection with this Offering, our Board of Directors and stockholders approved a 1-for-7 reverse stock split of our Common Stock, which became effective with the State of Delaware on June 23, 2022. All share and per-share information in this prospectus reflects the 1-for-7 reverse stock split.

Prior to this Offering, there has been no public market for our Common Stock or our Warrants. We have applied to list our Common Stock and our Tradeable Warrants on the Nasdaq Capital Market (“Nasdaq”) under the symbols “BIAF” and “BIAFW,” respectively.

We are an “emerging growth company” and a “smaller reporting company” under applicable federal securities laws and will be subject to reduced public company reporting requirements.

We are aware that 14 of our current stockholders have indicated an interest in purchasing Units in this Offering and we currently anticipate they may purchase approximately 10.66% of the Units in this Offering, assuming that the underwriters will not exercise the Over-Allotment Option (as defined below). Immediately after this Offering, our officers and directors will control approximately 50.18% of the voting power of our Common Stock, as determined in accordance with the beneficial-ownership provisions of Rule 13d-3 and Item 403 of Regulation S-K under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). See the “Principal Stockholders” section beginning on page 96 of this prospectus for a description of how beneficial ownership is calculated and related matters.

For so long as 30% of the shares of our “Series A Convertible Preferred Stock,” par value \$0.001 per share (our “Series A Preferred Stock”), remain outstanding, the holders of our Series A Preferred Stock, voting as a separate class, are entitled to elect one director of the Company (such right, the “Series A Director Designation Right”; such director, the “Series A Representative”). Immediately prior to the closing of this Offering, all of the issued and outstanding shares of Series A Preferred Stock will be automatically converted into fully paid and nonassessable shares of Common Stock at the then-effective conversion rate of the Series A Preferred Stock. Following such automatic conversion, the Company will never again issue the shares so converted, all such converted shares will cease to be part of the Company’s authorized stock, and the Series A Director Designation Right will cease to exist because fewer than 30% of the Series A Preferred Stock shares will be outstanding. The director who currently serves as the Series A Representative, however, 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 by the holders of the Common Stock following the conversion of the Series A Preferred Stock into Common Stock in connection with this Offering. See the “Management—Board of Directors Composition” section of this prospectus.

Investing in our securities involves a high degree of risk. See the “Risk Factors” section beginning on page 14 of this prospectus for a discussion of the factors that you should consider before investing in our Common Stock.

Neither the Securities and Exchange Commission (the “SEC”) nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Total Assuming No Exercise of Over- Allotment Option	Total With Full Exercise of Over- Allotment Option
Public Offering Price	\$	\$	\$

Underwriting discount ⁽¹⁾	\$	\$	\$
Proceeds, before expenses, to us ⁽²⁾	\$	\$	\$

- (1) We have agreed to issue, on the closing date of this Offering, a warrant to WallachBeth Capital, LLC, the representative of the underwriters (the “**Representative**”; such warrant, the “**Representative’s Warrant**”), to purchase an amount equal to two percent (2.0%) of the aggregate number of shares of Common Stock underlying the Units sold by us in this Offering. The Representative’s Warrant is exercisable for a period of five years from the closing date of this Offering, commencing on the date that is 180 days after the commencement date of sales of the Units. Please read the section titled “Underwriting” for a description of all underwriting compensation payable by us in connection with this Offering.
- (2) The amount of Offering proceeds to us presented in this table does not give effect to any exercise of the Over-Allotment Option (if any) we have granted to the underwriters or upon the exercise of the Warrant we will issue to the Representative, as described herein.

We have granted the underwriters a 45-day option from the date of this prospectus to purchase up to a total of an additional 192,799 shares of Common Stock at the initial Offering Price per Unit less \$0.02, and/or 192,799 Tradeable Warrants at \$0.01 per Tradeable Warrant, and/or 192,799 Non-tradeable Warrants at \$0.01 per Non-tradeable Warrant, or any combination of additional shares of Common Stock and Warrants representing, in the aggregate, up to 15% of the number of Units sold in this Offering (the “**Over-Allotment Option**”), in all cases less the underwriting discount.

The underwriters expect to deliver the Units to purchasers on or about _____, 2022 through the book-entry facilities of The Depository Trust Company.

WallachBeth Capital, LLC
Craft Capital Management LLC
WestPark Capital, Inc.

The date of this prospectus is August 5, 2022.

bioAffinity Technologies, Inc.

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MARKET, INDUSTRY, AND OTHER DATA

About this Prospectus

You should rely only on the information contained in this prospectus prepared by us or on our behalf or to which we have referred you. We have not, and the underwriters have not, authorized any other person to provide you with information different from that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell the securities described herein in any jurisdiction where an offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our Common Stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. Please read “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements.”

Unless the context otherwise requires, the information in this prospectus (other than in the historical financial statements) assumes that the underwriters will not exercise their option to purchase additional shares of Common Stock or additional Warrants.

Through and including _____, 2022 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this Offering, may be required to deliver a prospectus. This is in addition to a dealer’s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this Offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this Offering in any jurisdiction where action for that purpose is required, other than in the

United States. Persons outside of the United States who come into possession of this prospectus and any free writing prospectus must inform themselves about and observe any restrictions relating to this Offering and the distribution of this prospectus outside of the United States. See “Underwriting—Selling Restrictions” on page 114.

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 Common Stock. You should read this entire prospectus carefully, including the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes appearing at the end of this prospectus, before making any investment decision. Our fiscal year ends on December 31. Unless the context otherwise requires, references to “bioAffinity,” the “Company,” “we,” “us,” and “our” in this prospectus refer to bioAffinity Technologies, Inc. and our consolidated subsidiaries.

Overview

bioAffinity Technologies, Inc. is a privately held company incorporated in Delaware addressing the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer treatment. Our Company develops proprietary noninvasive diagnostic tests and cancer therapeutics using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Research and optimization of our platform technologies are conducted in our laboratories at The University of Texas at San Antonio. We are developing our platform technologies so that, in the future, they will be able to detect and monitor diseases of the lung and other cancers and treat many cancers.

More than 100 different types of cancers have been identified, all marked by the abnormal and unrestricted proliferation of cells that can eventually kill a patient stricken with the disease. Lung, breast, prostate, and colorectal cancers are the most common, representing more than half of all cancer diagnoses. Lung cancer alone, by far the deadliest, is responsible for an estimated 1.8 million deaths worldwide annually.¹

A patient’s overall cancer survivability depends on the type of cancer and the stage at which cancer is treated. The early diagnosis of cancer, before it spreads, is a significant contributor to survival. This is true for lung cancer that is most often detected in later stage when the cancer has spread to other parts of the body. However, if lung cancer is detected and treated early (Stage I), the current overall five-year survival rate of 20.5%² for Stages II-IV can leap to a 10-year survival rate of 92%.³

Current diagnostic protocols include lab tests, various imaging techniques, and biopsy followed by microscopic examination of tissue samples. None of these methods perfectly detects cancer cells, especially in the early stages of the disease. Low-dose computed tomography (LDCT) is recommended for screening patients at high risk for lung cancer. Results of a large clinical trial of more than 53,000 patients showed that screening for lung cancer by LDCT lowered the mortality rate by 20% as compared to x-ray imaging.^{4,5} However, the study found that of every 100 people screened for lung cancer who received a positive LDCT result, fewer than four of those individuals truly had the disease. Consequently, there is a great and urgent need for better targeted diagnostic methods that are safe, accurate, rapid, noninvasive, and cost effective for the detection of early-stage lung cancer.

Our first diagnostic test, CyPath® Lung, addresses the need for early detection of lung cancer, the leading cause of cancer-related deaths. In order to identify patients more confidently who need to undergo more invasive follow-up procedures, physicians will be able to order CyPath® Lung to assist in the assessment of the potential for the disease. CyPath® Lung thus serves as another tool in the physician’s decision-making process to distinguish between patients who are likely to have lung cancer and will benefit from timely intervention and those who are likely without disease and should continue their annual screening for lung cancer.

¹ The Cancer Atlas, Third Edition, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <https://canceratlas.cancer.org/the-burden/lung-cancer/>.

² SEER Cancer Statistics Review, 1975–2018; <https://seer.cancer.gov/statfacts/html/lungb.htm>.

³ The International Early Lung Cancer Action Program Investigators, Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med.* 2006;355:1763-71.

⁴ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med.* 2011;365:395-409.

⁵ Church TR, Black WC, Aberle DR, et al. Results of initial low-dose computed tomographic screening for lung cancer. *N Engl J Med.* 2013;368:1980-1991.

CyPath® Lung is a noninvasive test for the early detection of lung cancer. Our test uses flow cytometry to analyze the different type of cells in a person’s sputum, or phlegm from the lungs, to find characteristics indicative of lung cancer, including cancer and cancer-related cells that have shed from a lung tumor. Flow cytometry is a technology to group cells into populations of cells that look similar, based on their size, internal structures, and the presence of certain molecules on the outside or inside of the cell. Flow cytometry does this one cell at a time, scanning a large number of cells in a relatively short time period. For example, an average sputum sample containing about 20 million cells can be profiled cell-by-cell by flow cytometry in less than 20 minutes using the CyPath® Lung protocol. To collect a sputum sample, a patient blows into a hand-held, noninvasive assist device that acts to break up mucus in the lungs and help a person cough up the sputum from the lung into a collection cup. The sputum sample is shipped overnight to the laboratory and processed in accordance with CyPath® Lung protocol. Sample processing includes labeling cells with a synthetic porphyrin that attaches to cancer and cancer-associated cells (specifically, the porphyrin called *meso*-tetra (4-carboxyphenyl) porphine or “TCPP”). Sample processing also includes the use of antibodies that attach to specific types of cells. The processed sputum sample is run through a flow cytometer that can identify cancer and cancer-related cells labeled by TCPP and other cell populations. The resulting data is automatically analyzed immediately after data acquisition by proprietary automated analysis software that is fully integrated into the test

and generates both quantitative and qualitative diagnostic results in the form of a patient report that is provided to the ordering physician.

CyPath® Lung has the potential to increase overall diagnostic accuracy of lung cancer leading to increased survival, lower the number of unnecessary invasive procedures, reduce patient anxiety, and lower medical costs.⁶ bioAffinity Technologies intends to develop the CyPath® platform technology for use in the detection of other lung diseases, such as chronic obstructive pulmonary disease (“*COPD*”) and asthma. The Company further intends to develop tests to detect other cancers, including prostate cancer at an early stage, and to monitor for recurrence of bladder cancer.

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, our Company is focused on expanding its broad platform technologies to create targeted therapeutics to fight cancer. In researching how TCPP, the porphyrin used in CyPath® Lung, enters cancer cells, we discovered a novel potential therapy that kills cancer cells that have been grown in petri dishes without apparent harm to normal cells. This approach uses RNA interference (“*RNAi*”), a natural mechanism for selectively silencing (eliminating or “knocking down”) a gene. Genes provide cells with instructions for making proteins, and silencing a gene by RNAi refers to stopping or reducing production of the protein specified by that gene. We discovered that treating cells in the laboratory with certain small interfering RNAs (“*siRNAs*,” which are short, chemically synthesized nucleic acid molecules), we can silence the two genes and thereby the production of two cell-surface proteins, causing potent and selective cancer cell death while leaving normal cells virtually unharmed. Our potential therapies will be achieved, in part, by advancing studies of the siRNA-driven silencing of two genes encoding for the cell surface proteins CD320 and LRP2. We found that silencing these two genes resulted in cell death in multiple human cancer cell lines, including lung, breast, prostate, melanoma, and brain cancer cell lines, but left normal human fibroblast and breast epithelial cells virtually unaffected.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of the CyPath® Lung test. As a result, since our inception in 2014, we have generated no revenue from sales of the CyPath® Lung test and have funded our operations principally through private sales of our equity or debt securities. We have never been profitable and, as of March 31, 2022, we had an accumulated deficit of approximately \$30.0 million. We currently have a total negative working capital of \$12.8 million, including \$11.7 million of convertible notes. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests or therapeutic products and advance them through clinical trials.

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 22211 West Interstate 10, Suite 1206, San Antonio, Texas 78257, and our telephone number at that address is (210) 698-5334. Our laboratory diagnostic and therapeutic research is conducted at The Harvey Sandler Cancer Research Laboratories, which is located at Science Research Laboratories, Suite 1.424, University of Texas at San Antonio, San Antonio, Texas 78249. 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.

⁶ Analysis of the Potential Diagnostic, Patient And Economic Impact of CyPath® Lung When Used After LDCT Screening to Detect Lung Cancer, bioAffinity Technologies Internal Analysis with citations, 2022; attached as Appendix I of this prospectus.

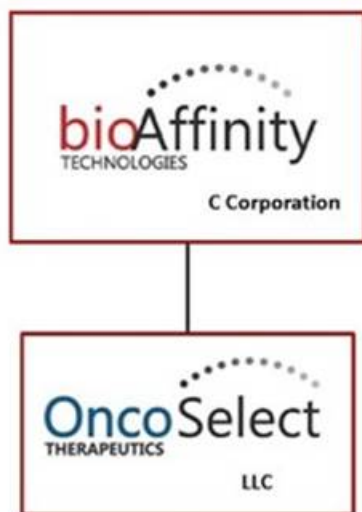
Reverse Stock Split

Our Board of Directors and stockholders approved an amendment to our Certificate of Incorporation to effect a 1-for-7 reverse stock split of our Common Stock in connection with this Offering, which became effective with the State of Delaware on June 23, 2022. As a result of the reverse stock split every seven shares of our outstanding Common Stock was combined and reclassified into one share of our Common Stock. No fractional shares were issued in connection with the reverse stock split, and any of our stockholders that were entitled to receive a fractional share as a result of the reverse stock split instead received cash in lieu of the fractional share valued at the per-Unit price of this Offering. The purpose of the reverse stock split was to allow us to meet the minimum share price requirement of the Nasdaq Capital Market.

Organizational Structure

The following organizational chart depicts our principal operating subsidiaries:

bioAffinity Technologies, Inc. Corporate Structure



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

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

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

We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of this Offering or until we are no longer an EGC, which would be the case if (i) our total annual gross revenues are \$1.07 billion or more; (ii) we issue more than \$1 billion in non-convertible debt during a consecutive three-year period; or (iii) we become a “large accelerated filer,” as defined in the Exchange Act. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting obligations in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. For more information, see “Risk Factors—General Risk Factors—*We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.*”

Our Business

bioAffinity Technologies, Inc. focuses on the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer therapeutics. The Company has developed a proprietary platform for *in vitro* diagnostics of which the first is a noninvasive test for early detection of lung cancer. The Company’s diagnostic tests are based on platform technologies that may be applicable to detecting other lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma, and diagnosing other types of cancer such as prostate and bladder cancers.

Once cancer has been diagnosed, a variety of treatment options are available, depending on the cancer type and stage. Surgery and radiation treatments are typically site-specific, while chemotherapy is usually systemically administered. Chemotherapy presents a particular challenge because of a relative lack of selectivity for cancer cells and inability to differentiate between normal, healthy cells and cancer cells. Ideally, site-specific delivery of cancer-killing drugs would treat the disease and spare healthy cells. Our research to discover how the porphyrin used in CyPath® Lung enters cancer cells has led to discoveries that could lead to novel cancer therapeutics that selectively kill cancer cells of the lung, breast, brain, skin and prostate without apparent harm to normal (non-cancerous) cells.

Our First Diagnostic Test - CyPath® Lung

Lung cancer remains the most commonly diagnosed cancer and the leading cause of cancer-related deaths worldwide. Globally, there were an estimated 2.1 million lung cancer cases and 1.8 million lung cancer deaths in 2018.⁷ If detected and treated early (Stage I), the overall five-year survival rate of 21.5% leaps to a 10-year survival rate of 92%.⁸ Unfortunately, most lung cancer is detected in late stages. A large national clinical trial showed that screening for lung cancer using low-dose computed tomography (“*LDCT*”) can lower the mortality rate by 20% as compared to screening by x-ray if LDCT screening is used by patients at high risk for lung cancer on an annual basis.⁹ LDCT is therefore recommended for screening of an estimated 18 million Americans who are at high risk for lung cancer. However, LDCT was shown to have a low positive predictive rate 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 of those patients truly 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. (False positive means a person who does not have lung cancer but receives a positive result, in this case from LDCT screening.)

CyPath® Lung is a test for early-stage lung cancer that is designed to meet the need for greater diagnostic certainty. 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.¹⁰ 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.¹¹

⁷ The Cancer Atlas, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <https://canceratlas.cancer.org/the-burden/lung-cancer/>.

⁸ The International Early Lung Cancer Action Program Investigators, Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med.* 2006;355:1763-71.

⁹ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med.* 2011;365:395-409.

¹⁰ Analysis of the Potential Diagnostic, Patient And Economic Impact of CyPath® Lung When Used After LDCT Screening to Detect Lung Cancer, bioAffinity Technologies Internal Analysis with citations, 2022; attached as Appendix I of this prospectus.

¹¹ Ibid.

The CyPath® Lung diagnostic process uses sputum, or phlegm, that is obtained noninvasively in the privacy of a patient’s home. Physicians can order the test for patients they suspect have lung cancer or patients with a positive LDCT screening result. CyPath® Lung uses flow cytometry to analyze cell populations in a person’s sputum to find characteristics indicative of lung cancer, including cancer or cancer-related cells that have shed from a lung tumor. A patient collects his or her sample using a hand-held, noninvasive assist device that acts to break up mucus in the lungs and help a person cough up their sputum from the lung into a collection cup. The sputum sample is shipped overnight to a clinical pathology laboratory that is accredited by the College of American Pathologists (“*CAP*”) and certified by the Clinical Laboratory Improvement Amendments of 1988 (“*CLIA*”) program, and processed with CyPath® that includes antibodies that distinguish different cell types and the synthetic porphyrin TCPP that identifies cancer cells and/or cancer-associated cells. The sputum sample is analyzed using flow cytometry, a well-established technology that analyzes the properties of single cells in minutes. An average sputum sample containing about 20 million cells can be profiled by flow cytometry in less than 20 minutes. Proprietary automated analysis software developed by the Company analyzes sample data in minutes, resulting in a patient report provided to the physician who orders the test. CyPath® Lung can be used by physicians to find early-stage lung cancer in their patients who have undergone lung cancer screening.

The Company conducted a 150-patient test validation trial of people at high risk for lung cancer including patients with the disease (N=28) and those 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 smaller than 20 millimeters ("*mm*") or no nodules at all, this trial resulted in 92% sensitivity and 87% specificity. 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.¹²

This 19-month test validation trial required participants to provide a sputum sample and CT imaging of the lungs. 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. Data acquired by flow cytometry and patient data was analyzed to produce results. The data 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 patient age.

The CyPath® technology is based on research originating at Los Alamos National Laboratory in collaboration with St. Mary's Hospital (Colorado) in which cancer samples were differentiated from non-cancer samples with 100% accuracy.¹³ This early research was conducted with sputum from 12 uranium miners. Microscope slides were made and the sputum samples labeled with the active ingredient of CyPath®, the synthetic and fluorescent porphyrin TCPP. Porphyrins are pigments that can be taken up by cells and can result in the cell fluorescing a red or purplish color that can be detected under a microscope or by flow cytometry. 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.¹⁴ 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 and the presence of lung cancer. The length of the study and specific follow-up was not reported, but researchers did report that one patient entering the study as a healthy subject was correctly diagnosed with cancer by the test.

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

The CyPath® Lung laboratory test will be ordered by a physician for use by people at high risk for lung cancer who are recommended for annual screening by LDCT. While LDCT is shown to lower the mortality rate of lung cancer by at least 20% as compared to x-ray screening,¹⁵ the LDCT screening method has a low positive predictive value that can result in many people undergoing unnecessary invasive diagnostic procedures to confirm or rule out the presence of lung cancer. A physician who orders a CyPath® Lung test can have greater confidence in determining the next steps in patient care.¹⁶ Noninvasive sample collection and the test's three-day turnaround in providing patient results after sample receipt make CyPath® Lung well suited for both sophisticated and less developed markets. Existing Current Procedural Terminology ("*CPT*") codes associated with flow cytometry have been identified for use in reimbursement of CyPath® Lung as a laboratory-developed test (an "*LDT*") based on the test's use of flow cytometry to detect lung cancer.

¹² Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365:395-409.

¹³ Cole, et. al. US Patent 5,162,231, supplemental material.

¹⁴ El-Far MA, Pimstone N. A comparative study of 28 porphyrins and their abilities to localize in mouse mammary carcinoma: uroporphyrin I superior to hematoporphyrin derivative. *Prog Clin Biol Res*. 1984;170:661-672.

¹⁵ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365:395-409.

¹⁶ Ibid, Internal Analysis, 2022, attached as Appendix I of this prospectus.

Patients will use the Smiths Medical's acapella® Choice Blue device with CyPath® Lung to assist patients in opening lung passageways and expelling sputum into a collection cup noninvasively. The acapella® Choice Blue has been 510(k) cleared by the U.S. Food and Drug Administration (the "*FDA*") as a positive expiratory pressure device to help mobilize lung secretions in people with certain lung conditions. bioAffinity Technologies has an agreement with GO2 Partners to produce patient collection kits and to provide warehousing and distributions 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.

The Company's business-development plan (our "*Business Plan*") envisions four phases of expanding market entry that are timed to maximize Company resources and minimize market risk. Each of the four phases are discussed in detail in the "Business—CyPath® Lung Business Development Plan" section of this prospectus beginning on page 62.

OncoSelect® Therapeutics Research

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

Unlike many of our industry competitors, OncoSelect® does not pursue therapies that depend on specific mutations, biomarkers, or other genetic or epigenetic abnormalities for their effect. We pursue research based on our own scientific discoveries demonstrating that inhibition of the expression of two specific cell membrane proteins result in the selective killing of various cancer cell types grown in the laboratory with little or no effect on normal (non-cancerous) cells.

Our scientific discoveries stemmed from research we conducted to better understand the mechanism by which TCPP, the synthetic porphyrin used in CyPath® Lung, selectively enters cancer cells. We have established several specific areas of therapeutic research that have evolved from our TCPP experiments.

OncoSelect® therapies offer the possibility of broad applications in cancer treatment. OncoSelect® will use a licensing business model for selective chemotherapeutic compounds to be developed by the Company.

The Company will pursue its therapeutics business through OncoSelect®. Initial therapeutic compositions to be developed will be based on market and cost factors. Composition synthesis is being outsourced to one of several select vendors. bioAffinity will conduct initial testing of promising compounds with assistance from select vendors who have contractually relinquished any claim to discoveries, data, or intellectual property. Additional patents will be filed based on testing, and results will be publicized to evaluate the interest in individual compounds and pursue licensing opportunities. The Company will continue to develop, test, publish its findings, and partner to maximize

revenues and contain expenses.

Intellectual Property Portfolio

As of August 3, 2022, the Company and its subsidiary OncoSelect have a patent estate that includes 14 issued U.S. and foreign counterpart patents, including three U.S. patents and eleven foreign counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, Italy, Mexico, Spain, Sweden, and the United Kingdom. Two awarded patents directed at diagnostic applications expire in 2022, and one U.S. patent and nine counterpart foreign patents directed at diagnostic applications expire in 2030. Therapeutic patents registered in Australia and Mexico expire in 2037. One therapeutic patent application that has been granted in China expires in 2037 once registered.

With regard to our diagnostic test CyPath[®] Lung and other diagnostic candidates, we have three issued U.S. patents and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom. With regard to our diagnostic patent applications, one of two families is directed at diagnosing lung health using flow cytometry, and the other is directed at proprietary compensation beads used to calibrate the flow cytometry instrument and used in CyPath[®] Lung data acquisition. Pending applications directed at diagnosing lung health include one pending U.S. non-provisional patent application and eight foreign counterpart patent applications in Australia, Canada, China, European Patent Office, Hong Kong, Japan, Mexico, and Singapore filed in 2019, one provisional patent application filed in 2021 and two provisional patent applications filed in 2022. The patent application directed at the composition of compensation beads was filed as a provisional application in 2021.

With regard to our therapeutic product candidates, we have three pending U.S. patent applications, two issued foreign patents, three pending Patent Cooperation Treaty International patent applications, and ten foreign applications pending in Canada, China, European Patent Office, Hong Kong, India, and Japan. The therapeutic intellectual property is made up of four families directed at our therapeutic product candidates, including two families directed at siRNA product candidates, one family directed at soluble CD320 used in the treatment of cancer, and one family directed at porphyrin conjugates for treating cancer.

INDUSTRY, BUSINESS DEVELOPMENT, AND COMPETITION

Industry Opportunity

The global market for cancer diagnostic tests is expected to grow dramatically in coming years. Cancer diagnostic tests, including devices, grew from \$156.27 billion in 2020 to \$170.21 billion in 2021, with a compound annual growth rate of 8.9%, and is projected to reach \$239.23 billion in 2025.¹⁷ Lung cancer is the most common cancer globally and its incidence continues to increase in some large nations including China.¹⁸ The global market for lung cancer diagnostic tests was estimated at \$2.5 billion in 2020 and is projected to reach a value of \$4.3 billion by 2027, with a compounded annual growth rate of 8.1% over 2020-2027.¹⁹ Clinical diagnostics play an important role in disease prevention, detection, and management. bioAffinity's first test, CyPath[®] Lung, focuses on the leading cause of cancer death among both men and women. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined, making up almost 18% of all cancer deaths worldwide. Lung cancer typically may not be symptomatic in its early stages when it is most treatable. An estimated 18 million patients at high risk for lung cancer in the U.S. are recommended for annual screening. Initially, physicians would order CyPath[®] Lung for those high-risk patients as an adjunct to LDCT screening to aid in the decision whether or not to pursue more aggressive follow-up procedures. A more accurate and reliable lung diagnostic pathway using LDCT and noninvasive methods could result in fewer patients being subjected to the stresses of unnecessary, invasive diagnostic procedures such as biopsies. CyPath[®] Lung is well suited for use in both sophisticated and less-developed markets because sample collection is noninvasive and conducted at home, the sample can be shipped overnight by commercial carriers and sample processing and automated analysis can be completed by laboratory technicians skilled in general laboratory techniques. Patient reports are provided to the ordering physician within three days of sample receipt at the laboratory.

¹⁷ Global Cancer Diagnostics Market Research Report 2021 - ResearchAndMarkets.com., 2021.

¹⁸ Zhang Y, Luo G, Etcheberria J, Hao Y. Global patterns and trends in lung cancer incidence: a population-based study. *J Thorac Oncol.* 2021;16:933-944.

¹⁹ Reportlinker: Global Lung Cancer Diagnostics Industry. <https://www.reportlinker.com/p05834219/Global-Lung-Cancer-Diagnostics-Industry.html>.

Competitive Strengths

bioAffinity Technologies conducts an ongoing competitive analysis of companies in the lung cancer diagnostic sector of the clinical diagnostics market. In 2022, the Company evaluated companies that reported an interest in diagnosing lung cancer, focusing on 67 companies and academic institutions it identified as active in the early lung cancer diagnostic sector. A thorough evaluation of the early lung cancer diagnostic landscape reveals multiple reasons why CyPath[®] Lung is positioned to be a market leader. CyPath[®] Lung performance shown in the Company's test validation trial resulted in 92% sensitivity and 87% specificity in high-risk patients who had lung nodules 20 mm or smaller. Eight out of ten (80%) Stage I tumors were correctly identified, indicating that CyPath[®] Lung can find lung cancer at its earliest stage. Overall, when diagnosing lung cancer in all stages, the clinical trial resulted in CyPath[®] Lung specificity of 88% and sensitivity of 82%, similar to far more invasive procedures and surgery currently used to diagnose lung cancer. (See the "Comparison of CyPath[®] Lung to Current Standards of Care" chart in the "Business" section of this prospectus.) The test validation trial of 150 patients was conducted over 19 months. 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. Test data used to produce results included: (1) the proportion of cells with a high ratio of high TCPF 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 patient age.

The majority of competitors' tests either incorrectly classify a high proportion of people without cancer as having the disease (known as false negatives) more than 50% of the time or misdiagnose people as cancer-free (known as false positives) more than 50% of the time. It is important to note that most competitors who have conducted clinical trials also have not designed their trials to evaluate the test's measure of accuracy – such as sensitivity and specificity – in the high-risk population for whom the test is intended. CyPath[®] Lung has identified existing CPT codes for use with CyPath[®] Lung that have a reimbursable track record. A patient collects his or her sample at home, which is a particular benefit during a pandemic. Sample processing for CyPath[®] Lung can be done by laboratory technicians, and reagents used by the test are widely available. Data acquisition and analysis and test results are fully automated.

Business Strategies

The Company is moving forward with commercialization of CyPath[®] Lung in a systematic, four-phased Business Plan that is expected to maximize resources and minimize market risk. Briefly, Phase 1 of the Business Plan begins with a market launch in Texas of CyPath[®] Lung as an LDT under the CLIA program administered by the Centers for Medicare and Medicaid Services ("CMS"), in partnership with the states, and standards issued by CAP. An LDT is a type of *in vitro* diagnostic ("IVD") test that is developed, validated and performed within a single laboratory. CyPath[®] Lung has been validated and is being performed by Precision Pathology Services ("Precision Pathology"), a CAP-accredited, CLIA-certified clinical pathology laboratory in San Antonio, Texas, pursuant to a joint development agreement with the Company. Precision Pathology has completed the required analytical validation in accordance with CLIA, which looks at the performance characteristics of a test used to describe the quality of patient test results and includes an analysis of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference interval, and other performance characteristics that the test system must be evaluated by in the laboratory that intends to offer the test system for sale. This analytical validation is limited to the specific conditions, staff, equipment

and patient population of the particular laboratory. Having completed the CLIA analytical validation, Precision Pathology is offering the CyPath® Lung test for sale with a controlled rollout beginning in Texas, which we anticipate will require six months, before expanding throughout the Southwest region of the U.S. through the first half of 2023. After establishing CyPath® Lung in the Southwest market, the laboratory will expand sales in 2023 to additional states with plans to market the test nationwide.

In Phase 2, the Company will launch CyPath® Lung as a CE-marked IVD test in the European Union (the “EU”). We intend to execute an agreement in Phase 2 with one or more commercial laboratories to sell CyPath® Lung in the EU market. In Phase 3, we will submit a request for *de novo* classification to the FDA to classify CyPath® Lung as a Class II IVD medical device for the detection of lung cancer. In order to seek *de novo* classification and marketing authorization of CyPath® Lung by the FDA, we must conduct a “pivotal clinical trial” to demonstrate the safety and efficacy of CyPath® Lung. We are currently working with a contract research organization (a “CRO”) to finalize the design of the pivotal clinical trial and plan to submit a pre-submission package to the FDA in the third quarter of 2022 to obtain the FDA’s feedback on the study design. A pivotal clinical trial is scheduled to begin in early 2023. Final design of the pivotal clinical trial has not been determined at this time, including the number of participants and patient follow-up. We expect to conduct a pivotal clinical trial that requires between two to three years depending on the clinical trial’s size, objectives and endpoints. Assuming the study is successful, we intend to submit a *de novo* classification request to the FDA within six months of study completion. If the *de novo* request is granted by the FDA, we expect such marketing authorization to result in a larger market and greater market share for CyPath® Lung. FDA marketing authorization also can lead to higher reimbursement, expanded claims and additional indications for use of CyPath® Lung for the early detection of lung cancer. Phase 4 will accelerate the diagnostic’s market presence to expand into other global markets, including China, Southeast Asia, and Australia. The timeline for commercialization is discussed in the “Business—CyPath® Lung Business Development Plan” section on page 62.

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 14 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:

- our limited operating history and history of net losses since our inception;
 - our need to obtain substantial additional funding to complete the development and commercialization of our diagnostic tests and therapeutic product candidates;
 - potential dilution to our stockholders, including purchasers of Common Stock in this Offering, resulting from the conversion of our preferred stock, par value \$0.001 per share (our “Preferred Stock”) and convertible debt outstanding, and potential restrictions, due to raising additional capital;
 - the impact of a material weakness identified in our internal control over financial reporting;
 - the early stage of our development efforts;
-
- the unpredictability of future trial results;
 - the difficulty in predicting the results, timing, and cost of our development of our diagnostic tests and therapeutic product candidates and the likelihood of obtaining regulatory approval;
 - the risk of experiencing delays or difficulties in the enrollment and/or retention of patients in clinical trials;
 - potential changes to interim, “top-line” or preliminary results from our clinical trials as more patient data becomes available and are subject to audit and verification procedures;
 - the risk that the FDA may not agree with our LDT regulatory strategy or that Congress may enact legislation giving the FDA new authorities to regulate LDTs;
 - the lengthy, time consuming, and unpredictable nature of regulatory approval processes;
 - the risk that our preclinical studies and clinical trials fail to demonstrate the safety and efficacy of our diagnostic tests or therapeutic product candidates;
 - the risk that data from clinical trials conducted outside of the United States may not be accepted by regulatory authorities;
 - the impact of ongoing regulatory obligations and continued regulatory review, even if we receive regulatory approval for any of our diagnostic tests or therapeutic product candidates;
 - our lack of control over the supply, regulatory status, or regulatory approval of third-party drugs or biologics with which our diagnostic tests or therapeutic product candidates are used in combination;
 - our lack of control over the conduct of investigator-initiated clinical trials or other clinical trials sponsored by organizations or agencies other than us;
 - the risk that we fail to develop additional diagnostic tests or therapeutic product candidates;
 - the risk that we are unable to penetrate multiple markets;
 - the risk that our diagnostic tests and therapeutic product candidates may fail to achieve market acceptance, even they receive marketing authorization;
 - if we are unable to obtain and maintain sufficient intellectual property protection for our platform and our diagnostic tests or therapeutic product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitive position may be adversely affected;
 - the price of our stock may be volatile, and you could lose all or part of your investment. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price;
 - our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees;
 - we face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively; and

- our business is affected by the ongoing COVID-19 pandemic and may be significantly adversely affected as the pandemic continues or if other events out of our control disrupt our business or that of our third-party providers.

THE OFFERING

Issuer.	bioAffinity Technologies, Inc.
Securities Offered.	1,285,325 Units, each Unit consisting of (i) one share of our Common Stock, (ii) one five-year Tradeable Warrant to purchase one share of our Common Stock for an assumed exercise price of \$7.35 per share (120% of the assumed \$6.125 Offering Price of one Unit, which is the midpoint of the Price Range set forth on the cover of this prospectus), and one five-year Non-tradeable Warrant to purchase one share of our Common Stock for an assumed exercise price of \$7.656 per share (125% of the assumed \$6.125 per-Unit Offering Price), as adjusted to reflect a 1-for-7 reverse stock split of our Common Stock that became effective on June 23, 2022. The Warrants are exercisable from the date of issuance until the fifth anniversary of such date. The actual number of Units we will offer will be determined based on the actual Offering Price. The Units will not be certificated or issued in stand-alone form. The shares of our Common Stock and the Warrants underlying the Units are immediately separable upon issuance and will be issued separately in this Offering.
Description of the Warrants.	Each Unit consists of one share of Common Stock and two Warrants: one Tradeable Warrant and one Non-tradeable Warrant. Each Tradeable Warrant is exercisable for one share of Common Stock for an assumed \$7.35 per share (120% of the assumed \$6.125 Offering Price of one Unit). Each Non-tradeable Warrant is exercisable for one share of Common Stock for an assumed \$7.656 per share (125% of the assumed per-Unit Offering Price). Upon the exercise of a Warrant, the assumed exercise price of the underlying share of Common Stock is subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations, or similar events affecting our Common Stock as described herein. A holder may not exercise any portion of a Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would beneficially own more than 9.99% of our outstanding Common Stock after exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. Each Warrant will be exercisable immediately upon issuance and will expire five (5) years after the initial issuance date. The terms of the 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 “ <i>Warrant Agent</i> ”). This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants. For more information regarding the Warrants, you should carefully read the section titled “Description of Securities—Warrants” on page 100 of this prospectus.
Over-Allotment Option.	We have granted the underwriters a 45-day Over-Allotment Option to purchase up to an additional 192,799 shares of Common Stock at the Offering Price per Unit less \$0.02, and/or up to 192,799 Tradeable Warrants at \$0.01 per Tradeable Warrant, and/or up to 192,799 Non-tradeable Warrants at \$0.01 per Non-tradeable Warrant, or any combination of additional shares of Common Stock and Warrants representing, in the aggregate, up to 15% of the number of Units sold in this Offering solely to cover over-allotments, if any, in all cases less the underwriting discounts payable by us.
Voting Rights.	Each share of Common Stock entitles its holder to one vote on all matters to be voted on by stockholders generally. Holders of our “Series A Convertible Preferred Stock,” par value \$0.001 per share (our “<i>Series A Preferred Stock</i>”), have the same voting rights and powers as holders of the Common Stock. Each holder of our Series A Preferred Stock is entitled to the number of votes such holder would be entitled to upon the conversion of their Series A Preferred Stock shares into shares of Common Stock. Shares of our Series A Preferred Stock have voting rights and powers equal to the voting rights and powers of our Common Stock and vote together with the shares of our Common Stock as a single class for all matters except for the election of a designated director as described below and as required by law. For so long as 30% of the Series A Preferred Stock shares remain outstanding, the holders of our Series A Preferred Stock, voting as a separate class, are entitled to elect one director of the Company (such right, the “<i>Series A Director Designation Right</i>”; such director, the “<i>Series A Representative</i>”). In accordance with Section 3(B)(i) of the Certificate of Designation of the Series A Preferred Stock, all of the issued and outstanding shares of Series A Preferred Stock will be automatically converted into fully paid and nonassessable shares of Common Stock at the then-effective conversion rate of the Series A Preferred Stock immediately prior to the closing of this Offering. 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 in connection with and immediately prior to this Offering, the Company will never again issue the shares so converted, and all such converted shares will cease to be part of the Company’s authorized stock. Furthermore, the Series A Director Designation Right will cease to exist because fewer than 30% of the Series A Preferred Stock shares will be outstanding. The director who currently serves as the Series A Representative, however, 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 by the holders of the Common Stock following the conversion of the Series A Preferred Stock into Common Stock in connection with this Offering. See “Description of Securities.” As determined in accordance with the beneficial-ownership provisions of Rule 13d-3 and Item 403 of Regulation S-K under the Exchange Act, immediately after this Offering, our officers and directors will control approximately 50.18% of the voting power of our Common Stock. See “Principal Stockholders.”

Use of Proceeds.

We estimate that the net proceeds to us from the sale of our Units in this Offering will be approximately \$6.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This assumes an Offering Price of \$6.125 per Unit. If the underwriters exercise their Over-Allotment Option in shares of Common Stock in full, the net proceeds to us will be approximately \$7.3 million.

We intend to use the net proceeds from this Offering for working capital and for general corporate purposes, which may include laboratory test and therapeutic product development, general and administrative matters, and capital expenditures. We may also use a portion of the net proceeds for the acquisition of, or investment in, technologies, solutions or businesses that complement our business, although we have no present commitments or agreements to enter into any acquisitions or investments.

We cannot specify with certainty all of the uses of the net proceeds that we will receive from this Offering. Accordingly, we will have broad discretion in the application of these proceeds and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this Offering.

Dividend Policy.

We do not anticipate paying dividends on our Common Stock for the foreseeable future.

Underwriters' Compensation.

In connection with this Offering, the underwriters will receive an underwriting discount equal to 9.0% (subject to reduction) of the Offering Price of the Units in this Offering and of the shares or Warrants sold in the exercise of its Over-Allotment Option. If more than 25.0% of the Units offered hereby are sold to existing investors in the Company, then the cash fee to the underwriters will be reduced to 4.0% of the aggregate gross proceeds from the existing investors. We are aware that certain of our current stockholders have indicated an interest in purchasing Units in this Offering and we currently anticipate they may purchase approximately 10.66% of the Units in this Offering, assuming that the underwriters will not exercise the Over-Allotment Option. In addition, we have agreed to reimburse certain accountable expenses of the Representative, indemnify the underwriters for certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof, in connection with this Offering, and provide to the Representative a right of first refusal to participate in future offerings. See "Underwriting" starting on page 109 of this prospectus.

Representative's Warrant.

The registration statement of which this prospectus is a part also registers for sale the Representative's Warrant, which gives the Representative the right to purchase up to 2.0% (subject to reduction) of the shares of Common Stock underlying the Units sold in this Offering, as a portion of the underwriting compensation in connection with this Offering. The Representative's Warrant will be exercisable at any time, and from time to time, in whole or in part, during the period commencing 180 days after the commencement of sales of the Units in this Offering and expires five years from the effective date of this Offering at an exercise price of \$7.044 (115% of the assumed Offering Price per Unit). We are registering the Representative's Warrant and the shares of Common Stock underlying the Representative's Warrant in the registration statement of which this prospectus is a part. See "Underwriting—Representative's Warrant" on page 110 of this prospectus for a description of the Representative's Warrant.

Placement Agent's Warrant.

In connection with the sale of our convertible bridge notes in the fourth quarter of 2021 and the first quarter of 2022, our placement agent, WallachBeth Capital, LLC (the "**Placement Agent**"), will receive a commission of 9.0% of the gross proceeds received from introduced parties and will be issued a warrant to purchase 29,464 shares of our Common Stock (the "**Placement Agent's Warrant**"). The Placement Agent's Warrant will have substantially the same terms as those issued to our noteholders. That warrant is considered as compensation to the Placement Agent pursuant to the rules of FINRA and will not be exercisable until 180 days after the commencement of the sale of the Units in this Offering. The exercise price of one share of our Common Stock pursuant to the Placement Agent's Warrant will be equal to 120% of the initial Offering Price of one Unit in this Offering. We are registering the shares of Common Stock underlying the Placement Agent's Warrant in the registration statement of which this prospectus is a part.

Lock-Up Agreements.

We have agreed with the underwriters not to sell additional equity securities for a period of 180 days after the effective date of this Offering. Our directors and officers have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our Common Stock or securities convertible into Common Stock, subject to certain exceptions, for a period of 180 days after the date of this prospectus, which restriction may be waived in the discretion of the Representative. See "Underwriting—Lock-Up Agreements" on page 111 of this prospectus.

Risk Factors.

You should read the "Risk Factors" section beginning on page 14 of this prospectus and the other information included herein for a discussion of factors to consider prior to deciding to invest in our Units.

Reverse Stock Split.

In connection with this Offering, we completed a 1-for-7 reverse stock split of our Common Stock on June 23, 2022. The purpose of the reverse stock split was to meet the minimum stock price requirement of the Nasdaq Capital Market. All share numbers in this prospectus have been adjusted to give effect to the reverse stock split.

Proposed Nasdaq Capital Market Listing.

We have applied to have our Common Stock listed on the Nasdaq Capital Market under the symbol "**BIAF**." We have applied to have our Warrants listed on the Nasdaq Capital Market under the symbol "**BIAFW**." No assurance can be given that our Nasdaq listing applications will be approved, or that a trading market will develop for our Common Stock or Warrants. **We will not proceed with this Offering if our applications to list our Common Stock or our Warrants on Nasdaq are not approved.**

Transfer Agent and Warrant Agent.

The transfer agent and registrar for our Common Stock and the Warrant Agent for our Warrants is VStock Transfer, LLC.

- (1) The number of shares of Common Stock outstanding immediately before this Offering excludes: (i) any shares of Common Stock issuable upon the mandatory conversion of convertible promissory notes issued by us to a number of investors in private placement transactions occurring between December 2018 and January 2022 at a conversion price of \$4.20 per share; (ii) 756,558 shares issuable upon the mandatory conversion of our Series A Preferred Stock issued by us to a number of investors in a private placement in July 2017; (iii) 2,815,967 shares issuable upon the exercise of Common Stock purchase warrants that were issued by us to a number of investors in private placement transactions occurring between March 2017 and July 2022 with a weighted average exercise price equal to the initial Offering Price in this Offering; and (iv) 876,952 shares issuable upon the exercise of stock options issued under our 2014 Equity Incentive Plan to certain of our employees, directors, and consultants between April 2014 and March 2022.
- (2) The number of shares of Common Stock to be outstanding immediately following this Offering excludes:
- 2,570,650 shares of Common Stock issuable upon the exercise of the Warrants underlying the Units sold in this Offering;
 - 192,799 shares of Common Stock issuable upon the exercise of the Over-Allotment Option;
 - 25,507 shares of Common Stock issuable upon the exercise of the Representative's Warrant and 29,464 shares of Common Stock issuable upon the exercise of the Placement Agent's Warrant;
 - 2,815,967 shares of Common Stock issuable upon the exercise of Common Stock purchase warrants with a term of five years issued to the holders of our convertible notes with a weighted average exercise price equal to \$5.25 per share; and
 - 876,952 shares of Common Stock issuable upon the exercise of stock options granted under our 2014 Equity Incentive Plan with a weighted average exercise price equal to \$4.11 per share.

Except as otherwise indicated, all information in this prospectus assumes:

- the issuance of 756,558 shares of Common Stock issuable upon the conversion of Series A Preferred Stock at the completion of this Offering;
- an assumed initial Offering Price of \$6.125 per Unit, which is the midpoint of the Price Range set forth on the cover page of this prospectus;
- no exercise of the Warrants underlying the Units in this Offering;
- no exercise of any options under the Company's 2014 Equity Incentive Plan;
- no exercise of the Representative's Warrant or the Placement Agent's Warrant; and
- no exercise of the Over-Allotment Option.

SUMMARY FINANCIAL DATA

We have derived the following summary of our consolidated statement of operations data for the years ended December 31, 2021 and 2020, and the consolidated balance sheet data as of December 31, 2021 and 2020, from our audited consolidated financial statements appearing elsewhere in this prospectus. We have derived the following summary of our condensed consolidated statement of operations data for the three months ended March 31, 2022 and 2021, and the balance sheet data as of March 31, 2022, from our unaudited interim condensed consolidated financial statements appearing elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in our opinion, all adjustments, consisting only of normal recurring adjustments, necessary for the fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

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You should read the following summary financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the MD&A section of this prospectus.

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 and the three months ended March 31, 2022 and 2021 (amounts in thousands, except share and per share data). Share amounts have been adjusted for the 1-for-7 reverse stock split that became effective on June 23, 2022.

	Year Ended December 31,		Three Months Ended March 31,	
	2021	2020	2022	2021
	(Unaudited)			
Operating expenses				
Research and development	\$ 1,196	\$ 1,415	\$ 322	\$ 295
Clinical development	130	195	52	9
General and administrative	881	994	353	187
Total operating expense	2,207	2,604	727	491
Loss from operations	(2,207)	(2,604)	(727)	(491)
Other income (expense), including tax	(4,119)	(4,665)	(745)	(225)
Net loss	\$ (6,326)	\$ (7,269)	\$ (1,472)	\$ (716)
Net loss per common share, basic and diluted	\$ (2.36)	\$ (2.72)	\$ (0.55)	\$ (0.27)
Weighted average common shares outstanding, basic and diluted	2,675,270	2,674,859	2,681,221	2,674,859

The following table summarizes our consolidated balance sheets at March 31, 2022 and December 31, 2021 (amounts in thousands):

	As of December 31, 2021	As of March 31, 2022
		(Unaudited)

	Actual	Actual	As Adjusted ⁽¹⁾⁽²⁾
Cash and cash equivalents	\$ 1,361	\$ 1,028	\$ 6,571
Working capital (deficit)	\$ (11,593)	\$ (12,778)	\$ 5,666
Total assets	\$ 1,453	\$ 1,353	\$ 6,896
Total liabilities	\$ 13,200	\$ 14,033	\$ 1,132
Total convertible preferred stock	\$ (4,044)	\$ (4,044)	—
Accumulated deficit	\$ (28,513)	\$ (29,985)	\$ (29,985)
Total stockholders' deficit	\$ (15,791)	\$ (16,725)	\$ 6,486

- (1) The as adjusted balance sheet data gives effect to the issuance and sale of Units in this Offering at an assumed Offering Price of \$6.125 per Unit, which is the midpoint of the Price Range set forth on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted balance sheet data also gives effect to the conversion of our preferred stock, and convertible notes and related accrued interest.
- (2) Each \$1.00 increase (decrease) in the assumed Offering Price of \$6.125 per Unit would increase (decrease) as adjusted cash and cash equivalents, working capital, total assets, and total equity by approximately \$1.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual Offering Price and other terms of our Offering determined at pricing.

Cautionary Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. Statements that are predictive in nature, that depend upon or refer to future events or conditions, or that include the words “may,” “could,” “plan,” “project,” “budget,” “predict,” “pursue,” “target,” “seek,” “objective,” “believe,” “expect,” “anticipate,” “intend,” “estimate,” and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters identify forward-looking statements. Our forward-looking statements include statements about our business strategy, our industry, our future profitability, our expected capital expenditures and the impact of such expenditures on our performance, the costs of being a publicly traded corporation, and our capital programs.

A forward-looking statement may include a statement of the assumptions or bases underlying the forward-looking statement. We believe that we have chosen these assumptions or bases in good faith and that they are reasonable. You are cautioned not to place undue reliance on any forward-looking statements. You should also understand that it is not possible to predict or identify all such factors and should not consider the following list to be a complete statement of all potential risks and uncertainties. Factors that could cause our actual results to differ materially from the results contemplated by such forward-looking statements include, but are not limited to, statements about:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operation;
- the success, cost and timing of our clinical trials;
- 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 ultimate impact of the ongoing COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of 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 current diagnostic tests or future diagnostic and therapeutic product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- 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 our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our 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; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

In addition, statements such as “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus and, although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

You should not place undue reliance on our forward-looking statements. Although forward-looking statements reflect our good-faith beliefs at the time they are made, forward-looking statements involve known and unknown risks, uncertainties, and other factors, including the factors described under “Risk Factors,” which may cause our actual results, performance or achievements to differ materially from anticipated future results, performance, or achievements expressed or implied by such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances, or otherwise, unless required by law. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

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 Business

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.

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

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

- Develop, enhance and protect our diagnostic tests and therapeutic products;
- Raise sufficient funding to support our diagnostic tests and therapeutic product development program(s);
- Complete pre-clinical testing;
- Work with our partners to commercialize our first diagnostic test, CyPath[®] Lung, as an LDT under the CAP/CLIA guidelines and regulations administered by CMS and CAP;

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- Work with our partners to develop and commercialize our first diagnostic test, CyPath[®] Lung, as a CE -marked test in accordance with the In Vitro Diagnostic Device Regulation (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 that will be initially funded by the proceeds of this Offering, 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.

WithumSmith+Brown, PC, our independent registered public accounting firm for the fiscal year ended December 31, 2021, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2021, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern. As of December 31, 2021, we had total negative working capital of \$11.6 million, including \$11.2 million of convertible notes, and a stockholders’ deficit of \$15.8 million. As of March 31, 2022, we had total negative working capital of \$12.8 million, including \$11.7 million of convertible notes, and a stockholders’ deficit of \$16.7 million. 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 this Offering, management anticipates that our cash resources are sufficient to continue operations through July 2022. The future of the Company is dependent upon its ability to obtain financing and upon future profitable operations from the development of its 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.

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. 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.

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

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

Until such time, if ever, as we can generate substantial income from sale of our diagnostic test(s) and therapeutic product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our Common Stock (the “*Common Stockholders*”). In addition, the terms of any future financings 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, or 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.

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 United States, 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 postmarketing 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.

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

We must demonstrate that 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 payers and others in the medical community necessary for commercial success.

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

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

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

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

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of our diagnostic tests or 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.

If we are unable to convince physicians as to 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 the 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 face competition and will 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. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

A substantial number of the companies against which we are competing have or, against which we may compete 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 than we do. 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, and Vivienne Rebel, M.D., Ph.D., our Chief Science and Medical Officer and Executive Vice President.

The loss of the services of any of our executive officers 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 the selling of diagnostic tests and pharmaceutical products. Any growth will require us to expand our management and our operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our operational, managerial, and financial resources.

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

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

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Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other diagnostic tests or therapeutic product candidates, which could have a material adverse effect on our operating results and overall financial condition.

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

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

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

We will depend on third parties to manufacture and market 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, 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.

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

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

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

liability claim, or series of claims, brought against us could have a material adverse effect on our business, financial condition, and results of operations.

While we have obtained product liability insurance covering CyPath® Lung as a commercialized LDT to be sold by Precision Pathology, a CAP-accredited, CLIA-certified clinical pathology laboratory, 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 United States and abroad. Numerous federal and state laws and regulations govern the collection, dissemination, use and confidentiality of personal information, including genetic, biometric and health information, 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and the Genetic Information Nondiscrimination Act of 2008. 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 users of our proposed diagnostic tests or therapeutic products are unable to obtain adequate reimbursement from third-party payers or governmental agencies or if new restrictive legislation is adopted, market acceptance of our proposed tests or products may be limited, and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations (“HMOs”) and other payers 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 proposed 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 payers 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: comply with the regulations of the FDA or foreign health authorities; provide true, complete and accurate information to the FDA or foreign health authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or 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 and ordering of prescription of any diagnostic tests or therapeutic products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations and current and future arrangements with investigators, healthcare professionals, customers and third-party payors, may be subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the 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 is found to not 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 pre-revenue company engaged in the development of diagnostic technology, 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 payers 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, and 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 test or product development. In addition, legislation and regulations affecting the pricing of diagnostic tests, pharmaceuticals, or healthcare services may change in ways adverse to us before or after any of our proposed tests and products are approved for marketing.

Our competitive position depends on protection of our intellectual property.

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

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

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

Although we have executed assignment of invention agreements with current scientific and technical employees and in the future will require our scientific and technical employees and consultants to enter into broad assignment of invention agreements, and 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.

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 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 United States or in other 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 United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing diagnostic tests and product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; and
- if enforced, a court may not hold that our patents are valid, enforceable and infringed.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States 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 United States and other countries, including the Leahy-Smith America Invents Act (the “*Leahy-Smith Act*”), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the United States Patent and Trademark Office (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 United States 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 United States 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 entitled 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 United States 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 (i) file any patent application related to our diagnostic tests and therapeutic product candidates and other proprietary technologies we may develop or (ii) 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, the U.S. 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, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, 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 United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our diagnostic tests and therapeutic product candidates, when the terms of all patents covering a diagnostic test or therapeutic product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new diagnostic test or therapeutic product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests and therapeutic products similar or identical to ours.

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

If we or a licensee initiate legal proceedings against a third party to enforce a patent covering one of our diagnostic tests or therapeutic product candidates, the defendant could counterclaim that the patent covering our diagnostic tests or therapeutic product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, 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 United States 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 (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our diagnostic tests or therapeutic product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or therapeutic product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

In the United States, 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 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 those in the United States. 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 United States. 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 United States 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 United States 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.

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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, then 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 or 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 United States 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.

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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 cyber-attacks 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.

Our business is affected by the ongoing COVID-19 pandemic and may be significantly adversely affected as the pandemic continues or if other events out of our control disrupt our business or that of our third-party providers.

While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results. We have experienced and may in the future experience disruptions from COVID-19 to our business in a number of ways, including:

- delays in supply chain and manufacturing, including the shutdown of manufacturing facilities and delays in delivery of supplies and reagents;
- delays in discovery and preclinical efforts;
- changes to procedures or shut down, or reduction in capacity, of clinical trial sites due to limited availability of clinical trial staff and diversion of healthcare resources away from clinical trials and other business considerations;
- limited patient access, enrollment, and participation due to travel restrictions and safety concerns; and
- changes in regulatory and other requirements for conducting preclinical studies and clinical trials during the pandemic.

The most significant impact of the COVID-19 pandemic has been closure of clinical collection sites during the test validation trial. Should the pandemic continue and result in closure of clinical collection sites during the pivotal clinical trial, the trial may be delayed due to a lack of collecting sputum samples necessary to conduct the trial. Further delays could result if we are required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance on conducting clinical trials during the pandemic, which was updated in July 2020, January 2021, and August 2021. The guidance describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report (or as a separate document): contingency measures implemented to manage the trial and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic-related trial disruptions by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational diagnostic test and therapeutic product and/or trial; alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial. In its most recent update to this guidance, the FDA addressed questions from clinical practitioners aiming to adapt their operations in a pandemic environment. The questions focused on when to suspend, continue, or initiate a trial, how to handle remote-site monitoring visits, and related matters. There is no assurance that the FDA's guidance governing clinical trials during the pandemic will remain in effect or, even if it does, help address the risks and challenges enumerated above.

Other potential impacts of the COVID-19 pandemic on our future planned clinical trials could relate to the prioritization of healthcare resources toward pandemic efforts, potentially resulting in the diminished attention of physicians serving as our clinical trial investigators and the reduced availability of site staff supporting the conduct of our clinical trials, and interruptions or delays in the operations of the FDA.

If the COVID-19 pandemic continues, other aspects of our future planned clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, clinical trial site data monitoring and efficacy, safety and translational data collection, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our trials or we may have to pause enrollment or we may choose to or be required to pause enrollment and/or patient dosing in our ongoing or planned clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue. Patients may need to withdraw due to COVID-19 infections or experience increased adverse events and deaths in our clinical trials due to COVID-19-related infections.

In addition, we currently rely on third parties to, among other things, manufacture materials used in our patient collection kit, ship clinical trial samples, perform quality testing, and supply other goods and services to run our business. If the operations of any third party in our supply chain for materials is adversely impacted by the COVID-19 pandemic, including due to staffing shortages, production slowdowns, and disruptions in delivery systems, our supply chain may be disrupted and our costs could be increased for future clinical trials and for our research and development operations as planned.

We previously closed our offices and requested that most of our personnel work remotely, excepting researchers, laboratory personnel and contractors who must perform essential activities that must be completed on-site. bioAffinity Technologies' research laboratories are located on The University of Texas at San Antonio campus and have followed safety procedures as instructed by the university. Our increased reliance on personnel working from home could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, research or clinical trial sites, and other important agencies and contractors. Further, we and our third-party

service providers, including the clinical trial sites, our manufacturers and suppliers, may experience staffing shortages.

Our employees and contractors conducting research and development activities may not be able to access our laboratory for an extended period of time as a result of the possibility that governmental authorities further modify current restrictions. In addition, when our facilities are open, we could encounter delays in connection with implementing precautionary measures to mitigate the risk of exposing our facilities and employees to COVID-19 or otherwise in connection with addressing an actual or potential exposure to COVID-19. As a result, this may delay research and development initiatives.

The trading prices for shares of other biotechnology companies have been highly volatile as a result of the COVID-19 pandemic and following this Offering the trading prices for our Common Stock and/or Warrants could also experience high volatility. As a result, we may face difficulties raising capital through sales of our Common Stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the COVID-19 could materially and adversely affect our business and the value of our Common Stock.

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

In addition, our business could be significantly adversely affected by other business disruptions to us or our third-party providers that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations and contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to Government Regulations

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

The FDA considers an LDT to be a test that is developed, validated, and performed within a single laboratory. The FDA has historically asserted its authority to regulate LDTs as medical devices under the 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.

There have been numerous legislative proposals to clarify the FDA's regulatory authority over medical devices. These include two bills reintroduced in 2021: the VALID Act, which would expressly grant the FDA authority to regulate LDTs under a risk-based framework; and the VITAL Act, which would assign LDTs to regulation solely under CLIA and would direct CMS to update its CLIA regulations. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business. In the meantime, the regulation by the FDA of LDTs remains uncertain.

If FDA premarket review, classification or approval is required for CyPath® Lung before we obtain *de novo* classification, our phased strategy for market entry would be adversely affected. Our laboratory licensee could be forced to stop performing CyPath® Lung while we worked to obtain *de novo* classification. Our business, results of operations and financial condition would be negatively affected unless and until such review were completed and our request for *de novo* classification were granted.

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

Additionally, obtaining FDA marketing authorization, approval or *de novo* classification for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices can take several years and requires 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 us or our laboratory licensee 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 United States. Our laboratory licensee, Precision Pathology Services, is accredited by CAP and holds a CLIA certificate of accreditation. Any failure by our laboratory licensee to comply with CLIA/CAP requirements could result in adverse findings on inspection that, if not timely corrected, could result in loss of accreditation and the inability to perform laboratory testing.

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

Smiths Medicals 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, which has been licensed to Precision Pathology Services and used by the laboratory to develop and validate software integrated into the test procedure that generates the quantitative and qualitative diagnostic results that are included in their 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 or our laboratory licensee is 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 United States, 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 United States 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 the 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 eventually clinical testing approval of any regulatory filing for our product candidates is completed, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than the third party originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If the FDA requires the licensors to narrow the indications to smaller patient subsets, the market opportunities for our product candidates, if approved, and the ability to generate revenues and royalties may be materially limited. To the extent the licensors seek regulatory approval in foreign countries, they may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

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

In addition to regulations in the United States, to market and sell our diagnostic tests and therapeutic products in the EU, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States 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 United States, 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 United States, 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 United States 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 United States have requirements for approval of diagnostic tests or therapeutic product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our diagnostic tests or therapeutic products in certain countries. We do not have any diagnostic tests or therapeutic product candidates approved for sale in any foreign jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our diagnostic tests or therapeutic product candidates by regulatory or payor authorities in the EU, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that diagnostic test or therapeutic product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our diagnostic tests or therapeutic product candidates will be harmed.

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

In order to market any diagnostic test or therapeutic product outside of the United States, we must establish and comply with numerous and varying regulatory requirements of

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

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us 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 United States and abroad. We operate in a highly regulated industry and new laws, regulations or 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 of healthcare services 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

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- 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

There has been no prior public market for our Common Stock or Warrants, the stock price of our Common Stock or Warrants may be volatile or may decline regardless of our operating performance, and you may not be able to resell your Common Stock or Warrants at or above the Offering Price.

There has been no public market for our Common Stock or Warrants prior to this Offering. The Offering Price for our Units will be determined through negotiations between the underwriter and us and may vary from the market price of our Units following this Offering. If you purchase Units in this Offering, you may not be able to resell the Common Stock or Warrants at or above the Offering Price. An active or liquid market in our Common Stock or Warrants may not develop upon the completion of this Offering or, if it does develop, it may not be sustainable. Further, an inactive market may also impair our ability to raise capital by selling our Common Stock in the future and may impair our ability to enter into strategic partnerships or acquire companies or products by using our Common Stock as consideration.

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.

The Warrants may not have any value.

Each Tradeable Warrant will have an assumed exercise price equal to \$7.35 (120% of the assumed \$6.125 Offering Price per Unit, which is the midpoint of the Price Range set forth on the cover of this Prospectus). Each Non-tradeable Warrant will have an assumed exercise price equal to \$7.656 (125% of the assumed \$6.125 Offering Price per Unit). The Warrants will be exercisable from the date of issuance until the fifth anniversary of the issue date. In the event our Common Stock price does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value.

Holders of Warrants have no rights as stockholders 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. Upon exercise of the Warrants, the holders will be entitled 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 Tradeable Warrants and our Non-tradeable Warrants provide that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by the warrant certificate (whether brought against a party to the warrant certificate or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. 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.

We will have broad discretion in the use of the net proceeds of this Offering and may not use them effectively or in ways that increase the value of our share price.

While we believe that our use of the net proceeds that we will receive from this Offering will be accomplished, we cannot assure you that circumstances could result in a change of such use. As a result, we will have discretion in the application of the net proceeds, including working capital and other general corporate purposes, and you and other stockholders may disagree with how we spend or invest these proceeds. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest the net proceeds from our Offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

Future sales of substantial amounts of shares of our Common Stock by existing shareholders could adversely affect the trading price of our Common Stock and Warrants.

If our existing shareholders sell substantial amounts of shares of our Common Stock following the Offering, the market price of our Common Stock and Warrants could fall. Such sales by our existing shareholders might make it more difficult for us to issue new equity or equity-related securities in the future at a time and place we deem appropriate. At this time, the overhang from existing shares is 10-12%. The shares of Common Stock and the Warrants offered in this Offering will be eligible for immediate resale in the public market without restrictions. All remaining shares of Common Stock, which are currently held by our existing shareholders, may be sold in the public market in the future subject to the lock-up agreements and the restrictions contained in Rule 144 under the Securities Act of 1933, as amended (the “*Securities Act*”). If any existing shareholders sell a substantial amount of shares, the prevailing market price for our Common Stock could be adversely affected.

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If you invest in securities in this Offering, you will incur immediate and substantial dilution in the book value of your Common Stock.

The Offering Price per share of our Common Stock that is part of a Unit will be substantially higher than the net tangible book value per share of our Common Stock immediately after this Offering. Investors purchasing Units in this Offering will pay a price per Unit that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Units in this Offering will incur immediate dilution of \$5.26 per share of our Common Stock, based on the assumed Offering Price of \$6.125 per Unit. Further, investors purchasing Units in this Offering will contribute approximately 30% of the total amount invested by stockholders since our inception, but will own only approximately 18% of the total number of shares of our Common Stock outstanding after this Offering.

This dilution is due to our investors who purchased shares of our Common Stock prior to this Offering having paid substantially less when they purchased their shares than the price offered to the public in this Offering and the exercise of stock options granted to our employees. To the extent that our convertible notes, bridge notes, or Preferred Stock shares are converted into Common Stock or outstanding warrants or stock options are exercised, we issue restricted stock to our employees under our equity incentive plan, or if we otherwise issue additional shares of our Common Stock in each case at per share prices below the price to the public in this Offering, there will be further dilution to new investors. As a result of the dilution to investors purchasing Units in this Offering, investors may receive significantly less than the purchase price paid in this Offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this Offering, see “Dilution.”

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

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

The market price of our Common Stock may be subject to fluctuation and you could lose all or part of your investment.

Our assumed Offering Price has been arbitrarily determined by us and may not be indicative of prices that will prevail in the trading market. The price of our Common Stock may decline following our public offering. The stock market in general has been, and the market price of our Common Stock or 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 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 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.

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, referred to as the Internal Revenue Code, 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 carry-forwards 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 our 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 carry-forwards 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 us, 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 amended and restated certificate of incorporation (our “**A&R Charter**”) and amended and restated bylaws (our “**A&R Bylaws**”) that will become effective upon the closing of this Offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

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

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

willing to pay for our stock.

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

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

- establish a classified structure for our Board so that not all members of our Board are elected at one time;
- permit the Board to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of our capital stock;
- require super-majority voting to amend some provisions in our A&R Charter and A&R Bylaws;
- authorize the issuance of “blank check” preferred stock that our Board could use to implement a stockholder rights plan;
- prohibit stockholders from calling special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the Board is expressly authorized to adopt, amend, alter or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision in our A&R 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 us, prevent changes in our Board or management, and make certain transactions more challenging that stockholders might otherwise believe to be in their best interests.

Upon completion of this Offering, we will be subject to the provisions of Section 203 of the DGCL, which will generally prohibit 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 A&R 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 A&R 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, stockholder or employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL, our A&R 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 A&R Charter and our A&R Bylaws contain a federal forum provision which provides that unless the Company consents 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. 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 A&R 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 A&R 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 A&R Charter will contain 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 A&R Charter and our A&R Bylaws will 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 A&R Charter will 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 A&R 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 majority 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 50.18% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

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

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

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

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

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

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 (the “*Sarbanes-Oxley Act*”) 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.

General Risks

We are an “emerging growth company” and a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our Units less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (the “*JOBS Act*”), and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced MD&A disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended

transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (1) following the fifth anniversary of the completion of this Offering, (2) in which we have total annual gross revenue of at least \$1.07 billion, or (3) in which we are deemed to be a large accelerated filer, which means the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th; and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this Offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements in our Annual Report on Form 10-K, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common shares held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds \$700 million as of the end of that year’s second fiscal quarter.

Investors may find our Common Stock less attractive to the extent we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “*Dodd-Frank Act*”) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits smaller “emerging growth companies” to implement many of these requirements over a longer period and up to five years from the pricing of this Offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this Offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the “MD&A—Recent Accounting Pronouncements” section of this prospectus.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our A&R Charter and A&R Bylaws that will become effective upon the closing of this Offering will provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director’s duty of loyalty to the corporation or its 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; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our A&R Bylaws that will become effective upon the closing of this Offering will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our A&R Bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We believe that these A&R Charter and A&R Bylaws provisions are necessary to attract and retain qualified persons as directors and officers.

While we maintain directors’ and officers’ liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of Units in this Offering will be approximately \$6.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This assumes an Offering Price of \$6.125 per Unit, which is the midpoint of the Price Range set forth on the cover of this prospectus. If the underwriters exercise their option to purchase additional shares of our Common Stock in full, the net proceeds to us will be approximately \$7.3 million.

We intend to use the net proceeds from this Offering for working capital and for general corporate purposes, which may include product and test development, general and administrative matters, and capital expenditures. We may also use a portion of the net proceeds for the acquisition of, or investment in, technologies, solutions or businesses that complement our business, although we have no present commitments or agreements to enter into any acquisitions or investments. We expect the proceeds from this Offering together with anticipated sales of our diagnostic LDT test should be sufficient for the Company to complete the *de novo* pivotal clinical trial and, if results are positive, to submit and obtain FDA marketing authorization of CyPath® Lung for sale and enter the EU market for sale of CyPath® Lung as a CE-marked IVD test.

We cannot specify with certainty all of the uses of the net proceeds that we will receive from this Offering. Accordingly, we will have broad discretion in the application of these proceeds and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this Offering.

Each \$1.00 increase or decrease in the assumed Offering Price of \$6.125 per Unit would increase or decrease the net proceeds to us from this Offering by approximately \$1.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of Units we are offering. Each 100,000 Unit increase or decrease in the number of Units offered by us would increase or decrease the net proceeds to us from this Offering by approximately \$0.6 million, assuming that the assumed Offering Price of \$6.125 per Unit remains the same, and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us.

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2022:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to a 1-for-7 reverse stock split and the issuance and sale of 1,285,325 Units in this Offering at an assumed Offering Price of \$6.125 per Unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 Units 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 Securities” sections of this prospectus.

	As of March 31, 2022	
	Actual	Pro Forma As Adjusted ⁽¹⁾
Cash and cash equivalents	\$ 1,028	\$ 7,292
Total indebtedness	11,926	312
Convertible preferred stock	4,044	—
Stockholders' deficit:		
Common stock	19	51
Additional paid-in capital	13,242	36,420
Accumulated deficit	(29,985)	(29,985)
Total stockholders' equity (deficit)	\$ (16,724)	6,486
Total capitalization	\$ (754)	6,798

(1) The as adjusted balance sheet data also gives effect to the conversion of our preferred stock, and convertible notes and related accrued interest.

A \$1.00 increase (decrease) in the assumed Offering Price of \$6.125 per share of Common Stock, 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 \$1.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses. Similarly, each increase (decrease) of 100,000 Units in the number of Units 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 \$0.6 million, assuming the assumed Offering Price of \$6.125 per Unit remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

DILUTION

If you invest in our securities in this Offering, your ownership interest will be immediately diluted to the extent of the difference between the Offering Price per share of our Common Stock that is a part of the Unit and the pro forma as adjusted net tangible book value per share of our Common Stock immediately after this Offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of Units in this Offering and the pro forma as adjusted net tangible book value per share of Common Stock immediately after completion of this Offering.

Our historical net tangible book value (deficit) as of March 31, 2022 was approximately \$(17.0 million), or \$(6.22) per share of our Common Stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets, adjusted to remove capitalized deferred offering costs we expect to recognize as an offset to the proceeds from this Offering, less our total liabilities and convertible Preferred Stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by 2,727,583, the number of shares of our Common Stock outstanding as of March 31, 2022, which includes

34,670 shares of unvested restricted stock units (as adjusted to give effect to the 1-for-7 reverse stock split).

After giving effect to the (i) sale and issuance by us of Units in this Offering, based on an assumed Offering Price of \$6.125 per Unit and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the underwriter's option is not exercised, our pro forma as adjusted net tangible book value as of March 31, 2022 would have been \$6.2 million, or \$0.86 per share. This represents an immediate increase in pro forma net tangible book value of \$7.08 per share to our existing stockholders and immediate dilution of \$5.26 per share to investors purchasing Units in this Offering at the assumed Offering Price. The following table illustrates this dilution:

Assumed initial Offering Price per Unit	\$ 6.125
Net tangible book value per share as of March 31, 2022	\$ (6.22)
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this Offering	\$ 7.08
Pro forma as adjusted net tangible book value per share immediately after this Offering	\$ 0.86
Dilution per share to new investors in this Offering	\$ 5.26

- (1) The number of shares of Common Stock to be outstanding immediately before this Offering excludes: (i) any shares of Common Stock issuable upon the mandatory conversion of the approximately \$10.8 million in convertible notes and related interest issued by us to a number of investors in private placements between December 2018 and March 2022 at a conversion price equal to \$4.20 per share; and (ii) 756,558 shares of Common stock issuable upon the conversion of Series A Preferred Stock.

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- (2) The number of shares of Common Stock as of March 31, 2022, to be outstanding immediately following this Offering excludes:

- 2,570,650 shares of Common Stock issuable upon the exercise of the Warrants underlying the Units sold in this Offering;
- 192,799 shares of Common Stock issuable upon the exercise of the Over-Allotment Option;
- 192,799 shares of Common Stock issuable upon the exercise of 192,799 Tradeable Warrants issuable upon the exercise of the Over-Allotment Option;
- 192,799 shares of Common Stock issuable upon the exercise of 192,799 Non-tradeable Warrants issuable upon the exercise of the Over-Allotment Option;
- 25,507 shares of Common Stock issuable upon the exercise of the Representative's Warrant and 29,464 shares of Common Stock issuable upon the exercise of the Placement Agent's Warrant;
- 756,558 shares of Common stock issuable upon the conversion of Series A Preferred Stock;
- 876,952 shares of Common Stock issuable on the exercise of stock options; and
- 2,815,967 shares of Common Stock issuable on the exercise of outstanding warrants issued to the holders of our convertible notes with a weighted average exercise price equal to \$5.25 per share.

Each \$1.00 increase or decrease in the assumed Offering Price of \$6.125 per Unit would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to new investors by approximately \$0.16, and would increase or decrease, as applicable, dilution per share to new investors in this Offering by approximately \$0.84, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares of Common Stock from us in full, the pro forma as adjusted net tangible book value per share of our Common Stock immediately after this Offering would be increased by \$0.12 per share, and the dilution in pro forma net tangible book value per share to new investors in this Offering would be \$5.14 per share.

We may also increase or decrease the number of Units we are offering. A 100,000 Unit increase in the number of Units offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share by \$0.06 and decrease the dilution per share to investors participating in this Offering by \$0.07, assuming the assumed Offering Price of \$6.125 per Unit remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 100,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this Offering by \$0.06 and increase the dilution per share to new investors participating in this Offering by \$0.06, assuming the assumed Offering Price of \$6.125 per Unit remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table presents, on a pro forma as adjusted basis as of March 31, 2022, after giving effect to the new investors purchasing Units in this Offering with respect to the number of shares purchased from us, the total consideration paid or to be paid to us, which includes net proceeds received from the issuance of Common Stock, and the average price per share paid or to be paid to us at an assumed Offering Price of \$6.125 per Unit before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
			(in thousands)		
Existing stockholders	5,995,206	82%	\$ 17,946,457	70%	\$ 2.99
New investors	1,285,325	18%	\$ 7,872,616	30%	\$ 6.125
Totals	7,280,531	100%	\$ 25,819,073	100%	\$ 3.55

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Each \$1.00 increase or decrease in the assumed Offering Price of \$6.125 per Unit would increase or decrease, as applicable, the total consideration paid by new investors and total consideration paid by all stockholders by approximately \$1.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares of Common Stock in this Offering. If the underwriters exercise their option to purchase additional shares of Common Stock in full from us, our existing stockholders would own 82% and our new investors would own 18% of the total number of shares of our Common Stock outstanding upon the completion of this Offering.

The number of shares of Common Stock that will be outstanding after this Offering is based on 2,727,583 shares of our Common Stock outstanding as of August 3, 2022, and excludes 1,108,399 shares of Common Stock reserved for issuance under our 2014 Equity Incentive Plan and 2,815,967 shares of Common Stock issuable on the exercise of outstanding warrants issued to the holders of our convertible notes with a weighted average exercise price equal to \$5.25 per share.

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."

Our Management's Discussion and Analysis disclosure has been adjusted for the 1-for-7 reverse stock split that became effective on June 23, 2022 prior to the completion of this Offering.

Overview

This section presents management's perspective on our financial condition and results of operations. The following discussion and analysis is intended to highlight and supplement data and information presented elsewhere in this prospectus, and should be read in conjunction with the sections "Prospectus Summary—Summary Historical Consolidated Financial and Other Data" and our consolidated financial statements and notes thereto appearing at the end of this prospectus. It 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 results to differ materially from management's expectations. Factors that could cause such differences are discussed in the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Data as of and for the years ended December 31, 2021 and 2020 has been derived from our audited consolidated financial statements appearing at the end of this prospectus. Data as of and for the three months ended March 31, 2022 and 2021 has been derived from our unaudited condensed consolidated financial statements appearing at the end of this prospectus. Results for any interim period should not be construed as an inference of what our results would be for any full fiscal year or future period.

Our MD&A is organized as follows:

- *Company Overview* – Discussion of our Business Plan and strategy in order to provide context for the remainder of the MD&A.
- *Critical Accounting Policies and Use of Estimates* – Accounting policies that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.
- *Results of Operations* – Analysis of our financial results comparing: (i) three months ended March 31, 2022, to the comparable period in 2021, and (ii) the year ended December 31, 2021 to the year ended December 31, 2020.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows, and discussion of our financial condition and potential sources of liquidity.

Company Overview

Business

bioAffinity Technologies, Inc. is a privately held biotech company incorporated in Delaware with laboratories at The University of Texas at San Antonio.

Recent Developments

- Precision Pathology, a CAP -accredited, CLIA -certified clinical pathology laboratory and our licensee in San Antonio, Texas, fully validated and certified our first test, CyPath® Lung, a noninvasive test for the detection of early lung cancer, as an LDT, thereby allowing for the sale of the test to physicians.
- We anticipate recognizing revenue in the second quarter of 2022 as Precision Pathology sells the CyPath® Lung test to physicians.
- In the fourth quarter of 2021 and the first quarter of 2022, the Company raised an additional \$2.4 million through the sale of convertible bridge notes.
- We are working with a CRO to finalize the design of our pivotal clinical trial in CyPath® Lung for pre-submission to the FDA for review.

Financial

To date, we have devoted a substantial portion of our efforts and financial resources to the development of our first diagnostic test, CyPath® Lung. As a result, since our inception in 2014, we have generated no revenue from sales of the CyPath® Lung test and have funded our operations principally through private sales of our equity or debt securities. We have never been profitable and, as of March 31, 2022, we had total negative working capital of \$12.8 million, including \$11.7 million of convertible notes, and an accumulated deficit of approximately \$30.0 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests or therapeutic products and advance them through clinical trials.

In the fourth quarter of 2021 and the first quarter of 2022, the Company raised an additional \$2.4 million through the sale of bridge notes that are convertible into the Company's Common Stock at the time of an initial public offering (an "*IPO*"), or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bear interest at six percent (6%). Additionally, each noteholder received a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to \$5.25 per share. With one exception, the convertible bridge notes were amended in May 2022 to have a maturity date of August 31, 2022. The maturity date of one convertible bridge note with a principal amount of \$100,000 was not extended and has been repaid in full. In July 2022, all but six of the bridge notes with an aggregate principal amount of \$325,000 were further amended to have a maturity date of October 31, 2022. As consideration for the maturity-date extension, each noteholder received a warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing the principal amount of such holder's note by 10.5 at an exercise price equal to \$5.25 per share of Common Stock, representing 50% warrant coverage on the principal amount of the note. In connection with the sale of our convertible bridge notes, our Placement Agent will be paid commissions of nine percent (9.0%) and will be issued the Placement Agent's Warrant to purchase 29,464 shares of Common Stock. The Placement Agent's Warrant will have

substantially the same terms as the warrants issued to our noteholders but will have an exercise price per share equal to 120% of the initial Offering Price of one Unit in this Offering.

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

Development of Our Diagnostic Tests

Our first diagnostic test, CyPath[®] Lung, is a noninvasive test to detect early-stage lung cancer in people at high risk for the disease.

Our current five-year Business Plan for the commercial development of CyPath[®] Lung contemplates the following major initiatives:

- Initial market launch of CyPath[®] Lung as an LDT in Texas, expanding sales to the Southwest U.S. to be followed by an expanding sale of the test to U.S. physicians;
- Launch CyPath[®] Lung as a CE-marked IVD test in the EU;
- Initiate and complete a pivotal clinical trial proving the efficacy of CyPath[®] Lung;
- Submit to the FDA for clearance for the Company to directly sell CyPath[®] Lung as an FDA-cleared test to U.S. physicians for detection of early-stage lung cancer in people at high risk for the disease; and
- Expand the EU market and sale of CyPath[®] Lung in Asia, Eastern Europe and Australia.

Notwithstanding that initial and interim data appear promising, the outcomes of our future clinical trials are uncertain and future clinical trials may ultimately be unsuccessful.

Results of Operations

Three Months Ended March 31, 2022 Compared to Three Months Ended March 31, 2021

We did not have revenue during the three months ended March 31, 2022 and 2021. Net loss for the three months ending March 31, 2022 and 2021 were approximately \$1.5 million and \$0.7 million, respectively, resulting from the operational activities described below.

Operating Expenses

	Three months Ended March 31, ⁽¹⁾		Change in 2022 Versus 2021	
	2022	2021	\$	%
Operating Expenses	(amount in thousands)			
Research and development	\$ 322	\$ 295	\$ 27	9%
Clinical development	52	9	43	478%
General and administrative	353	187	166	89%
Total operating expenses	<u>\$ 727</u>	<u>\$ 491</u>	<u>\$ 236</u>	<u>48%</u>

- (1) Represents operating expenses from our unaudited condensed consolidated financial statements for the three-month period ended March 31, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Operating expenses totaled approximately \$0.7 million and \$0.5 million during the three months ended March 31, 2022 and 2021, respectively. The increase in operating expenses is the result of the following factors.

Research and Development Expenses

Our research and development expenses consist primarily of expenditures for lab operations, preclinical studies, compensation and consulting costs.

Research and development expenses totaled approximately \$322,000 and \$295,000 for the three months ended March 31, 2022, and 2021, respectively. The increase of approximately \$27,000, or 9%, for the three months ended March 31, 2022, compared to the same period in 2021, was primarily attributable to an increase of \$20,000 related to legal costs related to patents and annuities in the current year as we maintain our patent portfolio, as well as expand our portfolio to include protecting the use of TCPP for the diagnosis, monitoring, and treatment of cancer.

Clinical development

Clinical development expenses totaled approximately \$52,000 and \$9,000 for the three months ended March 31, 2022 and 2021, respectively. The increase of approximately \$43,000, or 478%, for the three months ended March 31, 2022, compared to the same period in 2021 was primarily attributable to an increase of approximately \$37,000 in professional fees including consulting fees, as well as increases in clinical study activities related to site costs, compared to 2021 as operations were still being affected by the global pandemic.

General and Administrative

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

General and administrative expenses totaled approximately \$353,000 and \$187,000 for the three months ended March 31, 2022 and 2021, respectively. The increase of approximately \$166,000, or 89%, for the three months ended March 31, 2022, compared to the same period in 2021, was primarily attributable to an increase of approximately \$100,000 related to consulting and legal fees incurred in 2022 compared to 2021 as we prepare for a potential IPO, as well as an increase of approximately \$43,000 for stock-

based compensation.

Other Income (Expense)

	Three Months Ended March 31, ⁽¹⁾		Change in 2022 Versus 2021	
	2022	2021	\$	%
	(amount in thousands)			
Interest income (expense), net	\$ (1,147)	\$ (112)	\$ (1,035)	924%
Gain (loss) on change in fair value of convertible notes	404	(111)	515	-464%
Total other income (expense)	<u>\$ (743)</u>	<u>\$ (223)</u>	<u>\$ (520)</u>	<u>233%</u>

(1) Represents other income (expense) from our unaudited condensed consolidated financial statements for the three-month period ended March 31, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Other income (expense) totaled approximately (\$0.7) million and (\$223,000) for the three months ended March 31, 2022 and 2021, respectively.

Interest Income (Expense), net

Interest expense increased \$1.0 million, or 924%, to approximately \$1.1 million for the three months ended March 31, 2022, compared to \$112,000 for the three months ended March 31, 2021. The increase was due to an additional \$3.5 million in convertible notes of outstanding during the quarter compared to the same period in the prior year. Additionally, in 2022 the Company recorded interest expense of approximately \$0.5 million for the amortization of debt discount related to the issuance of bridge notes.

Gain (loss) on change in fair value of convertible notes

There was a gain of approximately \$0.4 million on the change in fair value of convertible notes during the three months ended March 31, 2022 compared to a loss of approximately \$0.1 million during the three months ended March 31, 2021. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term and other assumptions during the reported periods. Refer to our notes to unaudited condensed consolidated financial statements for further discussion on our convertible notes.

Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future. We did not have revenue during the years ending December 31, 2021 and 2020. We do anticipate generating revenues during 2022. Net loss for 2021 and 2020 were \$6.3 million and \$7.3 million, respectively, resulting from the operational activities described below.

Operating Expenses

	Year Ended December 31,		Change in 2021 Versus 2020	
	2021	2020	\$	%
	(amount in thousands)		(amount in thousands)	
Operating Expenses:				
Research and development	\$ 1,196	\$ 1,415	\$ (219)	-16%
Clinical development	130	195	(65)	-33%
General and administrative	881	994	(113)	-11%
Total operating expense	<u>\$ 2,207</u>	<u>\$ 2,604</u>	<u>\$ (397)</u>	<u>-15%</u>

Operating expenses totaled \$2.2 million and \$2.6 million during 2021 and 2020, respectively. The decrease in operating expenses is the result of the following factors.

Research and Development

Our research and development expenses consist primarily of expenditures for lab operations, preclinical studies, compensation and consulting costs.

Research and development expenses totaled \$1.2 million and \$1.4 million during 2021 and 2020, respectively. The decrease of approximately \$219,000, or 16%, for 2021 compared to 2020 was primarily attributable to a decrease of almost \$115,000 related to compensation and benefits as a result of a decrease in personnel, as well as decreases in lab operations of \$80,000 as we minimized personnel in our labs to assist in maintaining recommended social distancing requirements due to the COVID-19 pandemic. Additionally, this decrease was due to a decrease in stock compensation expense of approximately \$44,000 related to option grants to employees and consultants in 2021 compared to 2020. These decreases were partially offset by an increase of approximately \$35,000 in legal costs for patents and annuities in 2021.

Clinical development

Clinical development expenses totaled approximately \$130,000 and \$195,000 during 2021 and 2020, respectively. The decrease of approximately \$65,000, or 33%, for 2021, compared to 2020 was primarily attributable to a decrease of approximately \$75,000 in professional fees including consulting and legal fees incurred in the prior year related to finalizing the evaluation and output for our CyPath[®] Lung test.

General and Administrative

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

General and administrative expenses totaled approximately \$0.9 million and \$1.0 million during 2021 and 2020, respectively. The decrease of \$113,000, or 11%, for 2021 compared to 2020 was primarily attributable to a decrease of approximately \$55,000 in compensation due to a change in the number of personnel as well as decreases of approximately \$190,000 for stock-based compensation related to forfeitures of stock options previously granted. These decreases were partially offset by an increase of more than \$100,000 in consulting and legal fees in 2021, largely related to the costs of filing new patents, responding to examiner comments on applications, and utilizing consulting services for purposes of the 2019–2020 and 2020–2021 audits.

Other Income (Expense)

	December 31,		Versus 2020	
	2021	2020	\$	%
	(amount in thousands)		(amount in thousands)	
Interest income (expense), net	\$ (1,002)	\$ (381)	\$ (621)	163%
Gain on extinguishment of debt	239	—	239	100%
Fair value of warrants	(4,080)	—	(4,080)	100%
Loss on change in fair value of convertible notes	725	(4,281)	5,006	-117%
Total other income (expense)	<u>\$ (4,118)</u>	<u>\$ (4,662)</u>	<u>\$ 544</u>	-12%

Other income (expense) totaled approximately (\$4.1) million and (\$4.7) million for 2021 and 2020, respectively.

Interest income (expense)

We had net interest expense of approximately \$1.0 million and \$381,000 for the year ended December 31, 2021 and 2020, respectively. The increase of approximately \$620,000, or 163%, was attributable to an increase of \$3.3 million in convertible notes and bridge notes outstanding compared to prior year, partially offset by interest earned on average outstanding cash balances. Additionally, in 2022 the Company recorded interest expense of approximately \$0.5 million for the amortization of debt discount related to the issuance of bridge notes.

Gain on Extinguishment of Debt

In April 2020, the Company received an initial U.S. Small Business Administration (the “SBA”) Paycheck Protection Program Loan (the “PPP Loan”). In June 2021, the Company received forgiveness from the SBA and recorded a gain of \$239,000 on the extinguishment of the PPP Loan.

Fair value of warrants

During the fourth quarter 2021, in connection with the issuance of the bridge notes, the Company amended the terms of certain convertible notes. As an inducement to amending the notes, the Company issued Common Stock warrants with the same terms and conditions as the warrants issued to the bridge note holders. The estimated fair value of the warrants was \$4.1 million and immediately expensed within the accompanying statement of operations.

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

The gain on the change in fair value of convertible notes totaled approximately \$0.7 million during 2021 compared to a loss of \$4.3 million during 2020, respectively. The change in the fair value of convertible notes resulted primarily from changes in the calculation of the fair value of our stock, the reduction in the expected term and other assumptions during the reported periods. Refer to our notes to audited financial statements for further discussion on our convertible notes.

Liquidity and Capital Resources

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. We have an accumulated deficit of approximately \$28.5 million as of December 31, 2021. We anticipate that we will continue to incur additional losses for the foreseeable future. To date, we have funded our operations primarily through the sale of our equity and debt securities, resulting in gross proceeds of approximately \$17.9 million. Cash and cash equivalents were approximately \$1.0 million as of March 31, 2022.

In the fourth quarter of 2021 and the first quarter of 2022, the Company issued a total of \$2.4 million in bridge notes convertible into the Company’s Common Stock, at the time of an IPO, or at the noteholder’s option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The convertible bridge notes bear interest at six percent (6%). Additionally, each noteholder received a warrant to purchase one share of Common Stock based on the investor’s bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to \$5.25 per share. With one exception, the convertible bridge notes were amended in May 2022 to have a maturity date of August 31, 2022. The maturity date of one convertible bridge note with a principal amount of \$100,000 was not extended and has been repaid in full. In July 2022, all but six of the bridge notes with an aggregate principal amount of \$325,000 were further amended to have a maturity date of October 31, 2022. As consideration for the maturity-date extension, each noteholder received a warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing the principal amount of such holder’s note by 10.5 at an exercise price equal to \$5.25 per share of Common Stock, representing 50% warrant coverage on the principal amount of the note. In connection with the sale of our convertible bridge notes, we will pay our Placement Agent commissions of nine percent (9.0%) and will issue the Placement Agent’s Warrant to our Placement Agent to purchase 29,464 shares of Common Stock. The Placement Agent’s Warrant will have substantially the same terms as the warrants issued to our noteholders but will have an exercise price per share equal to 120% of the initial Offering Price of one Unit in this Offering.

Based on our current level of expected operating expenditures, we expect to be able to fund our operations until September of 2022. This assumes that we spend minimally on general operations, and that we do not encounter any unexpected events or other circumstances that could shorten this time period.

We are actively seeking sources of financing, including to fund our continued operations and research and development programs. To raise additional capital, we may sell additional equity or debt securities, or enter into collaborative, strategic and/or licensing transactions. There can be no assurance that we will be able to complete any financing transaction in a timely manner or on acceptable terms or otherwise or enter into a collaborative or strategic transaction. If we are not able to raise additional cash, we may be forced to delay, curtail, or cease development of our diagnostic tests or therapeutic products, or cease operations altogether.

Our financial statements include explanatory disclosures regarding substantial doubt about our ability to continue as a going concern. Future reports on our financial statements may also include explanatory disclosures with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue our operations.

Cash Flows

The following information reflects cash flows for the periods presented:

	Three months ended		Year Ended	
	March 31, ⁽¹⁾		December 31,	
	2022	2021	2021	2020
	(amounts in thousands)		(amounts in thousands)	
Cash and cash equivalents at beginning of period	\$ 1,361	\$ 83	\$ 83	\$ 578
Net cash used in operating activities	(633)	(392)	(2,049)	(2,207)
Net cash used in investing activities	—	—	—	(3)

Net cash provided by financing activities	301	537	3,327	1,715
Cash and cash equivalents at end of period	\$ 1,028	\$ 228	\$ 1,361	\$ 83

(1) Represents cash flows for continuing operations from our unaudited condensed consolidated financial statements for the three-month period ended March 31, 2022 and 2021, respectively. Refer to our notes to unaudited condensed consolidated financial statements for further discussion.

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$0.6 million and \$0.4 million for the three months ended March 31, 2022 and 2021, respectively. The increase of approximately \$240,000 in cash used by operations during the three months ended March 31, 2022, compared to the same period in 2021, was primarily attributable to an increase of \$0.8 million in our loss from operations as compared to prior year as described above. These increases were partially offset by adjustments for the amortization of debt discount related to the issuance of bridge notes.

Net cash used in operating activities was \$2.0 million and \$2.2 million during the years ended December 31, 2021 and 2020, respectively. The decrease of approximately \$130,000 in cash used during 2021 compared to 2020 was primarily attributable to a decrease of almost \$400,000 in our loss from operations, partially offset by a decrease of approximately \$230,000 in non-cash charges related to stock-based compensation.

Net Cash Used in Investing Activities

The Company did not use any cash in investing activities for the three months ended March 31, 2022, and 2021, respectively.

The Company did not use any cash in investing activities in 2021, compared to \$3,000 for the year ended December 31, 2020. The decrease in cash used in investing activities in 2021, compared to 2020, is attributable to the purchase of lab and office equipment in 2020.

Net Cash Provided by Financing Activities

Cash provided by financing activities was approximately \$0.4 million and \$0.5 million for the three months ended March 31, 2022, and 2021, respectively. The decrease in cash provided by financing activities for the three months ended March 31, 2022, compared to 2021, is attributable to the issuance of \$0.5 million of our bridge notes during the period partially offset by debt issuance costs, compared to the issuance of \$0.3 million of our convertible notes the same period in the prior year, as well as receiving a second draw on our PPP Loan of a \$212,000 in March 2021. Additionally, the Company had an increase in deferred offering costs related to the anticipated IPO.

During the year ended December 31, 2021, net cash provided by financing activities was \$3.3 million consisting of \$3.3 million from the issuance of convertible notes, as well as receiving a second draw on our PPP Loan of \$212,000 in March 2021, partially offset by the payment of approximately \$180,000 in debt issuance costs. In April 2022, the Company submitted an application for forgiveness for the second draw on our PPP Loan and received notice of forgiveness from the SBA. During the year ended December 31, 2020, net cash provided by financing activities was \$1.5 million from the issuance of convertible notes during the year, and an initial draw on our PPP Loan of \$239,000 in April 2020. In June 2021, the Company received notice of forgiveness from the SBA for the first draw on our PPP Loan.

Critical Accounting Policies and Use of Estimates

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

Share-Based Compensation

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

Accounting for Income Taxes

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

Fair Value of Convertible Notes Payable

We adopted FASB ASU No. 2016-01 “*Financial Instruments—Overall (Subtopic 825-10)*.” In applying ASC 825, it is necessary to determine whether to bifurcate the Beneficial Conversion Feature from the convertible note. Under ASC 825, provided the fixed conversion price stipulated in the convertible note is greater than the fair market value at the date of issuance (“out of the money”), the beneficial conversion feature guidance is not applicable, and the convertible notes are eligible to be valued at fair value and any adjustments recorded in the statement of operations.

The Company has elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the statements of operations until the convertible notes are settled. The fair value of the convertible notes is determined with the assistance of a third-party valuation firm. Given the conversion terms that exist, there were two scenarios considered: i) conversion into a preferred share class, ii) conversion into the common share class. Given the recent issuance dates, a negotiation discount was calibrated and applied such that the probability weighted valuation of the recently issued notes is equal to par value as of the respective issuance dates. The probabilities of each conversion scenario were discussed and assigned based on the expectations regarding the future of the Company.

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.

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 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.

Quantitative and Qualitative Disclosures About Market Risk

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

Change in Auditors

On October 18, 2021, the finance committee of the Board approved the engagement of WithumSmith+Brown, PC (“*Withum*”) as the Company’s independent registered public accounting firm to audit the Company’s consolidated financial statements for the fiscal year ending December 31, 2021, replacing Ernst & Young LLP (“*EY*”), subject to completion of services related to the year ended December 31, 2020.

The report of EY on bioAffinity Technologies’ balance sheet as of December 31, 2020 and the statements of operations, changes in stockholders’ deficit and cash flows for the year then ended, did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainties, audit scope or accounting principles, other than an explanatory paragraph that states the Company has suffered recurring losses from operations and negative cash flows from operations and has a net capital deficiency that raise substantial doubt about the Company’s ability to continue as a going concern.

During the period from January 1, 2020 to December 31, 2020 there were no disagreements between the Company and EY on any matter of accounting principles or practices, financial disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of EY, would have caused it to make reference to the subject matter of the disagreements in its reports on bioAffinity Technologies’ financial statements for such period.

During the period from January 1, 2020 to December 31, 2020, there were no “reportable events” (as defined in Item 304(a)(1)(v) of Regulation S-K under the Exchange Act).

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For the period through October 17, 2021, neither the Company nor anyone on the Company’s behalf consulted with Withum with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on the Company financial statements, and neither a written report nor oral advice was provided to the Company that Withum concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any other matter that was the subject of a disagreement.

Emerging Growth Company Status

As an EGC under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of this Offering, although if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time, or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

BUSINESS

bioAffinity Technologies, Inc. focuses on the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer treatment. The Company has developed a proprietary platform, called CyPath®, for *in vitro* diagnostics, the first of which is a noninvasive test for early detection of lung cancer called CyPath® Lung. CyPath® Lung detects lung cancer and the platform will be further developed to detect other forms of cancer and lung diseases. bioAffinity Technologies’ OncoSelect® therapies are being developed based on novel discoveries shown *in vitro* to kill cancer lung, breast, brain, skin, and prostate cells without apparent harm to normal cells.

More than 100 different types of cancers have been identified, all marked by the abnormal and unrestricted proliferation of cells that can eventually kill a patient stricken with the disease. Breast, prostate, lung, and colorectal cancers are the most common, representing more than half of all cancer diagnoses. Lung cancer alone, by far the deadliest, is responsible for 18% of all cancer deaths.²⁰ Worldwide, 10 million cancer-related deaths were reported in 2020²¹ Nearly 33 million people have been living with cancer for at least five years. The number of cancer survivors is expected to increase with time.²²

A patient’s overall cancer survivability often depends on the type of cancer and the stage at which cancer is diagnosed and treated. The early diagnosis of cancer, before it spreads, is a significant contributor to survival. Current diagnostic protocols include lab tests, various imaging techniques, and biopsy followed by microscopic examination of tissue samples. None of these methods perfectly detects cancer cells, especially in the early stages of the disease. Consequently, there is a great need for better targeted diagnostic methods that are safe, accurate, rapid, noninvasive, and cost-effective for the detection of early-stage cancers.

²⁰ Sung, et al., Global Cancer Statistics 2020. *CA Cancer J Clin.* 2021;71(3):209-249.

²¹ World Health Organization (WHO). Cancer Fact Sheet. February 3, 2022. <https://www.who.int/news-room/fact-sheets/detail/cancer>.

²² Weir, et al., Preventing Chronic Disease, 2021;18:210006. https://www.cdc.gov/pcd/issues/2021/21_0006.htm.

Once cancer has been diagnosed, a variety of treatment options are available, depending on the cancer type and stage. Surgery and radiation treatments are typically site-specific, while chemotherapy is usually systemically administered. Chemotherapy presents a particular challenge because of a relative lack of selectivity for cancer cells, i.e., its

inability to differentiate between healthy and cancer cells. Ideally, cancer-specific delivery of cytotoxic (cell-killing) drugs would treat the disease and spare healthy cells.

Our First Diagnostic Test – CyPath® Lung

Lung cancer is the leading cause of cancer-related death worldwide, claiming nearly 1.8 million lives annually.²³ If detected and treated early (Stage I), the dismal overall five-year survival rate of 20.5%²⁴ can leap to a 10-year survival rate of 92%.²⁵ Individuals at high risk for lung cancer are recommended for annual screening by low-dose computed tomography (“LDCT”). High-risk individuals are defined as those who are 50-80 years of age and have smoked at least 20 pack-years, or an equivalent of one pack of cigarettes a day for 20 years, and who are currently smoking or have not quit smoking in the past 15 years.²⁶ The National Lung Cancer Screening Trial (the “NLCST”) of more than 53,000 patients showed that screening for lung cancer by LDCT lowered the mortality rate by 20% as compared to screening using x-ray, but had a low positive predictive value of less than 4%.^{27,28} More simply stated, the NLCST found that of every 100 people screened for lung cancer that resulted in a positive LDCT result, fewer than four of those individuals had the disease. Apart from LDCT, there is currently no reliable noninvasive method that can detect lung cancer at an early stage. CyPath® Lung is designed to be a cost-effective,²⁹ noninvasive, early-stage lung cancer diagnostic. Its use in conjunction with LDCT, CyPath® Lung is predicted to improve the positive predictive value (the proportion of true positive results) by a factor of five.²⁹ Improving the positive predictive value of LDCT with the use of CyPath® Lung can result in fewer patients unnecessarily subjected to invasive diagnostic procedures, earlier detection of lung cancer, and a reduction in healthcare costs.³⁰

CyPath® Lung uses well-established 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. In particular, CyPath® uses a fluorescent bio-label, the synthetic porphyrin TCPP, that has an unusually high affinity for cancer and cancer-related cells.³¹ 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. bioAffinity holds multiple patents protecting its use of TCPP for the diagnosis, monitoring, and treatment of cancer. In addition, the Company has multiple domestic and foreign patent applications to protect the use of flow cytometry and its automated analysis in the detection of lung diseases using sputum as a sample.

²³ The Cancer Atlas, Third Edition, American Cancer Society (ACS), World Health Organization (WHO) and The Union for International Cancer Control (UICC); <https://canceratlas.cancer.org/the-burden/lung-cancer/>.

²⁴ SEER Cancer Statistics Review, 1975–2018; <https://seer.cancer.gov/statfacts/html/lungb.htm>.

²⁵ The International Early Lung Cancer Action Program Investigators, Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med.* 2006;355:1763-71.

²⁶ U . S . Preventive Services Task Force Recommendations for lung-cancer screening. Accessed December 10, 2021. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>.

²⁷ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med.* 2011;365:395-409.

²⁸ Church TR, Black WC, Aberle DR, et al. Results of initial low-dose computed tomographic screening for lung cancer. *N Engl J Med.* 2013;368:1980-1991.

²⁹ Analysis of the Potential Diagnostic, Patient And Economic Impact of CyPath® Lung When Used After LDCT Screening to Detect Lung Cancer, bioAffinity Technologies Internal Analysis, 2022; attached as Appendix I of this prospectus.

³⁰ Ibid.

³¹ El-Far MA, Pimstone N. A comparative study of 28 porphyrins and their abilities to localize in mouse mammary carcinoma: uroporphyrin I superior to hematoporphyrin derivative. *Prog Clin Biol Res.* 1984;170:661–672.

A 19-month test validation clinical trial of CyPath® Lung³² collected sputum noninvasively from people at high risk for lung cancer, including patients with the disease (N=28) and those cancer-free (N=122). Patients collected their sputum sample over three days at home before bringing their sample to the clinical collection site. Samples were shipped overnight to the laboratory for analysis. Study participants in the high-risk cohort had a CT to confirm they did not have lung cancer. Those in the cancer cohort had imaging and a biopsy that confirmed lung cancer. After providing a sputum sample, participants 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 analysis to produce the results 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 patient age.

More than half of those in the cancer cohort had lung cancer in the earlier Stages I-II. The analysis, performed on an LSRII flow cytometer, resulted in 92% sensitivity and 87% specificity in the subgroup of these patients (N=132) who had no nodules or lung nodules smaller than 20 mm on their LDCT scan, while 8 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 the 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.

Following completion of the test validation trial, CyPath® Lung was evaluated independently by Precision Pathology, which has developed the test for sale as an LDT in accordance with CAP and CMS regulations and guidance. As part of CAP/CLIA certification, Precision Pathology evaluated the performance of CyPath® Lung employing its own laboratory technicians and a different flow cytometer, the Navios EX. A total of 32 samples obtained over 14 months were analyzed by Precision Pathology from high-risk individuals, of which 25 samples were from individuals at high risk without lung cancer and seven samples were from cancer patients. Participants provided a sputum sample and CT scan of the lungs, with a physician confirming that participants were cancer free or diagnosed with lung cancer. Participants were not followed-up after providing the sputum sample and CT scan or biopsy. Results of Precision Pathology’s certification were comparable to those from test validation trial with sensitivity of 83%, specificity of 77%, and a negative predictive value greater than 95%.³³ These studies demonstrate that CyPath® Lung remains robust to differences in sample handling, processing, and the type of flow cytometer.

Regulations governing the sale and use of CyPath® Lung in the U.S. and foreign markets are multifold. In the U.S., CyPath® Lung initially will be sold as an LDT governed by CMS regulations in accordance with CLIA regulations and guidance. CAP has been granted authority to promulgate guidance to accompany CLIA regulations and often is more stringent and expansive. Thus, the regulations often are referred to as CAP/CLIA rules. bioAffinity Technologies licensed its intellectual property to Precision Pathology under the terms of a joint development agreement to develop the test as an LDT and complete the required analytical validation of the test. Validation under CAP/CLIA looks at the performance characteristics of a test used to describe the quality of patient test results, and includes an analysis of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference interval, and other performance characteristics required for the test system in the laboratory that intends to offer the test for sale. This analytical validation is limited to the specific conditions, staff, equipment and patient population of the particular laboratory. In this case, sale of CyPath® Lung is limited to Precision Pathology.

bioAffinity Technologies intends to voluntarily seek FDA clearance of the CyPath® Lung as a Class II IVD medical device for the detection of lung cancer. The Company expects to submit *de novo* classification request to the FDA following completion of a pivotal clinical trial. We are currently working with a CRO to finalize the design of the pivotal clinical trial. The size, duration of the pivotal trial, and patient follow-up will be determined with the CRO as part of study design. Similar to the test validation trial, the planned pivotal trial will analyze flow cytometry and patient data including (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and patient age.

We plan to submit a pre-submission package to the FDA in the third quarter of 2022 to obtain the FDA’s feedback on the study design. A pivotal clinical trial is scheduled to begin in early 2023. Final design of the pivotal clinical trial has not been determined at this time, including the number of participants and patient follow-up. We expect to conduct a pivotal clinical trial that requires between two to three years depending on the clinical trial’s size, objectives and endpoints. Assuming the study is successful, we intend to submit a *de novo* classification request to the FDA within six months of study completion.

CyPath® Lung is designed to be patient-friendly. The diagnostic process uses sputum that is obtained noninvasively in the privacy of a patient’s home. Physicians order the test for their patients after lung cancer screening reveals a lung nodule considered to be indeterminant because of the nodule size and lack of suspicious characteristics. Lung nodules are considered indeterminate if their size is between 6–20 mm in diameter. Lung nodules of that size are associated with a lung cancer risk as low as 0.5% and up to 16%.³⁴

The Patient- and Physician-Friendly CyPath® Lung Process



³² M.E. Lemieux, et al., Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning, 2022, submitted for publication.
³³ Ibid.
³⁴ Gierada et al; <https://pubmed.ncbi.nlm.nih.gov/25326638/>.

For the CyPath® Lung test, patients are given a small sample collection kit during an office visit with their physician. (See Figure above.) A patient collects his or her sample at home using a hand-held assist device called an acapella® Choice Blue (Smiths Medical), which acts to break up mucus in the lung by breathing through it. The hand-held acapella® Choice Blue is provided with the kit. The use of the acapella® Choice Blue helps the patient cough up the sputum from the lung into a collection cup that is also supplied with the kit. In addition to the kit’s step-by-step instructions, an instructional video and a live patient coach is available by calling 855-MYLUNGS to help patients with sample collection. With the patient’s permission, the patient coach will proactively call or text patients to offer assistance. After a sample is collected, the patient puts the collection cup containing the sample in the kit and uses a pre-addressed envelope contained in the kit to overnight the sample to the laboratory.

At the laboratory, the sputum is processed by technicians into a single-cell suspension and labeled with the fluorescent porphyrin TCPP that preferentially binds to cancer cells and/or cancer-related cells. Cells are also stained with fluorescently labeled antibodies that identify hematopoietic and epithelial cells within the sputum sample. A viability dye is used to eliminate dead cells. A laboratory technician skilled in general laboratory techniques can accomplish sample processing, labeling, and data collection.

CyPath® Lung uses flow cytometry to analyze cell populations in a person’s sputum to find characteristics indicative of lung cancer, including cancer and cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories that records properties of labeled and unlabeled single cells. Physicians receive test results within three days after the laboratory receives the patient’s sputum sample. CyPath® Lung testing helps identify patients who should undergo more aggressive follow-up procedures to confirm a suspected lung cancer. When CyPath® Lung sample analysis determines a patient is unlikely or very unlikely to have lung cancer, the result can serve to support a physicians’ decision to monitor this patient by following a recommended LDCT screening routine.

Sputum is an excellent sample for analysis. The lungs bathe in sputum. Therefore, if a malignancy is present in the lung, sputum is in direct contact with it. Sputum can thus provide a snapshot of the tumor itself, its microenvironment, and its area of field cancerization. Studies have shown that expert cytological analysis of sputum can detect cancerous and pre-malignant cells,³⁵ but the process of looking at microscopy slides is an extremely laborious approach and demands years of expertise. Without automation, this approach does not lend itself well to examining the entire sample for cost-effective, large-scale screening or diagnosis.

Flow cytometry solves the problem of throughput, but manual data analysis still requires people with extensive expertise. To address these issues, we developed an algorithm as part of the test validation trial that used machine learning to distinguish samples from high-risk patients who had lung cancer from those who are cancer-free. As part of LDT development by Precision Pathology, software was developed and integrated into the test protocol leading to high-throughput and user-friendly analysis of flow cytometric sample data. An average sputum sample containing about 20 million cells can be profiled by flow cytometry in less than 20 minutes. A physician’s report is generated within minutes after data acquisition. The test can be put into routine lab use without requiring expert evaluation of samples or being subject to operator bias. Our approach allows the entire sputum sample to be rapidly analyzed. The numerical analysis developed with machine learning and used in the test’s automated platform captures complex interactions between lung cancer, the microenvironment and areas of field cancerization which would be difficult if not impossible for individuals to predict or detect reliably by eye. For example, during test development, we discovered that viability staining density suggests a link with apoptosis, or cell death, that is linked to many cancers, including lung cancer. Our model also suggests that specific markers of immune cell populations may be informative as to the presence of cancer in the lung. These findings are a product of automated analysis and machine learning. To our knowledge, CyPath® Lung is the first cancer diagnostic that combines automated flow cytometric analysis with machine learning to predict the presence of lung cancer from sputum samples.

³⁵ T. Neumann, et al., Premalignant and Malignant Cells in Sputum From Lung Cancer Patients, Cancer Cytopathology, Dec. 25, 2009, page 473-481.

Cellular uptake by cells of the synthetic porphyrin TCPP as measured by the CyPath® Lung test is an important indicator of the presence of cancer in the lung due to TCPP's high affinity to bind to cancer cells and/or cancer-related cells. Porphyrins are a class of organic compounds that are important in nature and industry. Porphyrins all share a core structure. An example of a naturally occurring porphyrin in the body is heme that gives red blood cells their color and is important for transporting oxygen in the blood. Porphyrins also are essential components of molecules in the liver to clean our blood of foreign substances.

In medicine, the selective uptake and retention of porphyrins in cancerous tissue has been known for many years. The underlying mechanism for this phenomenon is not entirely understood and varies according to the porphyrin structure. The porphyrin TCPP, used in the CyPath® Lung test, gets into cancer cells via CD320 receptors on the cell membrane, among others, which is a receptor that is very important for the uptake of vitamin B12. Porphyrins are also known to reside longer in cancerous tissue than normal tissue, a phenomenon that is mediated by proteins which control porphyrin travel into and out of the cell.

The uptake and retention of porphyrins in cancerous tissue has found application in medicine, both in the realm of cancer diagnosis and therapy. Most porphyrins are naturally highly fluorescent, that is, porphyrins absorb light at a given wavelength and subsequently emit light at a different wavelength, which can be recorded by an appropriate detector. This is how the flow cytometer detects TCPP in cells; by exposing cells to light with a certain wavelength and detecting the subsequently emitted light of a different wavelength. It is also how surgeons can determine the edges of, for example, brain tumors. In the case of using porphyrins to distinguish cancerous tissue, patients are given a porphyrin compound, which reaches all tissues, including the one that harbors the tumor. Several hours later in the operating room, the tumor-containing tissue is exposed to a light source. Because cancer cells take up more porphyrins than normal cells, a difference in fluorescence intensity between cancerous and normal tissue can be observed, indicating to surgeons how much tissue needs to be removed. Photodynamic therapy is a treatment approach for cancer in which a patient is administered a porphyrin which distributes to the tumor and several hours later the tumor is exposed to a laser light to be absorbed by the porphyrin. Energy given off by the “exposed” porphyrin can create chemicals which can kill cancer cells.

CyPath® Lung Research and Clinical Studies

The high affinity of TCPP for cancer and cancer-related cells and its fluorescent nature makes it an excellent bio-label for cancer. The CyPath® technology is based on this concept and scientific work originating at Los Alamos National Laboratory in collaboration with St. Mary's Hospital (Colorado). A clinical trial ³⁶ (Patriquin, et.al, 2015) of an earlier version of CyPath® Lung used a microscope to directly identify cells labelled with the porphyrin TCPP in one-third or less of the sputum sample. In this blinded trial, researchers manually scanned microscope slides labeled with TCPP for the presence of red fluorescing cells (“*RFCs*”) displaying a spectral signature indicating uptake of TCPP in the cell. In addition to measuring the spectral signature, the fluorescent intensity and cell size of RFCs were measured. Twelve slides per participant were scanned for RFCs and data recorded. The test data including fluorescent intensity over cell size was analyzed. The Patriquin trial was conducted over 24 months and resulted in 81% test accuracy, 77.9% sensitivity, and 65.7% specificity in the ability to correctly differentiate between samples from lung cancer patients and those at high risk who were cancer-free. The Patriquin trial required participants to provide a sputum sample and CT imaging of the lungs. Those in the cancer cohort underwent a biopsy to confirm lung cancer. High risk patients displaying indeterminant nodules were followed for 18 months to confirm they were cancer-free. The Patriquin study concluded that optimizing the test to provide for analysis of the entire sputum sample would improve results. The flow cytometry-based CyPath® Lung assay owned by the Company evaluates the entire sputum sample. The most recent test validation trial has shown improved results over the microscope-based assay.

³⁶ Patriquin, et.al., Early detection of lung cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum, *J Thorac Oncol.* 2015;10(9):1311-1318. doi: 10.1097/JTO.0000000000000627.

Studies performed to date are summarized in the table below.

CyPath® Lung Studies and Clinical Trials

Study Description	Results
<i>Porphyrin's localization and evaluation of cancer cell uptake of four different porphyrins</i>	TCPP porphyrin localizes more than other porphyrins in cancer cells; higher uptake of TCPP in cancer cells than in normal cells. Uptake was determined by visual assessment. Cell lines were used. Researchers did not report the length of time taken to conduct this study, nor any follow-up.
<i>Blinded study to diagnose lung cancer by labeling sputum with TCPP and identifying red fluorescing cells under a microscope</i>	Study of uranium miners (cancer N=8 / healthy N=4) labeling sputum labeled with TCPP resulted in 100% sensitivity and 100% specificity. Classification of cancer was made by subjective visual assessment of the presence and intensity of red fluorescing cells on slides. In this blinded study, one patient initially enrolled as a healthy subject was correctly diagnosed with cancer by the test. Length of study not reported. No patient follow-up was reported except for correct detection of cancer in patient initially enrolled as healthy.
<i>Internal validation study with microscopy-based assay completed to optimize TCPP labeling of sputum containing cancer and cancer-related cells in lung cancer samples</i>	In this research study lasting eight months, the florescence intensity of TCPP-labeled cells in sputum was measured by subjective visual assessment of microscope slides to distinguish samples from cancer and healthy cohorts. Researchers who were blinded to sample origin correctly identified samples from lung cancer patients (cancer N=15 / healthy N=12) resulting in 100% sensitivity and 100% specificity. Participants were not followed-up after providing the sputum sample and CT scan or biopsy.
<i>Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum³⁷</i>	A 24-month clinical trial of 128 high-risk smokers and cancer patients used microscopy-based assay to identify TCPP-labeled cells in sputum (cancer N=26 / high risk N=102) that resulted in 81% accuracy, 77.9% sensitivity, 65.7% specificity. Slides were scanned. Fluorescent intensity and cell size of RFCs were objectively measured by software. High-risk participants who were cancer-free were followed for 18 months to confirm status.
<i>Analysis of sputum by flow cytometry elucidates the lung environment (Bederka, et al., 2022, submitted for publication)</i>	Research reporting on CyPath® Lung including the test's quality controls and manual analysis of cell population data acquired by flow cytometry analysis of sputum. This study reports on research conducted over 19 months to acquire flow cytometry data from 164 participants' sputum samples analyzed manually for differences in cell characteristics, cell population size, and cell fluorescence intensity. Measures of accuracy were not reported. Participants were not followed-up after providing the sputum sample and CT scan or biopsy confirming cohort status.

Test validation trial lasting 19 months using bioAffinity's automated flow cytometry platform (cancer N=28 / high risk N=122) results in an overall 82% sensitivity and 88% specificity; CyPath[®] Lung sensitivity is 92% and specificity is 87% for patients with nodules smaller than 20 mm. Participants were not followed-up after providing the sputum sample and CT scan or biopsy. Flow cytometry and patient data used in analysis to produce the results 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 patient age.

The Cancer Diagnostics Market and CyPath[®] Lung

The global cancer diagnostic market grew from \$156.27 billion in 2020 to \$170.21 billion in 2021, with a compound annual growth rate (**CAGR**) of 8.9%, and is projected to reach \$239.23 billion in 2025.³⁸ The market worldwide for lung cancer diagnostic tests was estimated at \$2.5 billion in 2020 and is projected to reach value of \$4.3 billion by 2027, with a CAGR of 8.1% over 2020-2027.³⁹ bioAffinity Technologies has the potential to play a significant role in the cancer diagnostic market because the Company's platform is noninvasive, easy to use, cost-effective, and has a potential to lead to better patient outcomes. (See *Analysis of the Potential Diagnostic, Patient And Economic Impact of CyPath[®] Lung When Used After LDCT Screening to Detect Lung Cancer*; bioAffinity Technologies Internal Analysis with citations, 2022; attached as Appendix I of this prospectus.)

bioAffinity anticipates expanding its flow cytometric platform technology to detect and monitor lung disease and multiple cancers and diseases. The Company plans to develop its automated flow cytometry platform for diagnosis of other diseases of the lung such as COPD and asthma. The Company also expects to further develop its diagnostic technology to detect prostate and bladder cancers, which are among the 10 most prevalent cancers worldwide.⁴⁰

³⁷ Patriquin, et al. Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum. *J Thorac Oncol.* 2015;10(9):1311-1318. doi: 10.1097/JTO.0000000000000627.

³⁸ Global Cancer Diagnostics Market Research Report 2021 – ResearchAndMarkets.com., 2021.

³⁹ Reportlinker: Global Lung Cancer Diagnostics Industry.

⁴⁰ World Cancer Fund International, <http://www.wcrf.org/int/cancer-facts-figures/worldwide-data>.

The Company licensed CyPath[®] Lung to Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory in San Antonio, Texas, which recently began marketing of CyPath[®] Lung in Texas as an LDT in accordance with CAP/CLIA regulations pursuant to the terms of a joint development agreement between bioAffinity Technologies and Precision Pathology. CyPath[®] Lung is sold to physicians who order CyPath[®] Lung for patients at high risk for lung cancer after an LDCT confirms the presence of lung nodule(s). CPT cost codes used for reimbursement with flow cytometry are established and have been identified for laboratory billing with the CyPath[®] Lung test. See "Business—Reimbursement" on page 64.

As a front-end diagnostic tool used in conjunction with LDCT, bioAffinity Technologies' lung cancer test will help determine whether or not more expensive, specialized, and/or invasive tests are warranted. CyPath[®] Lung compares favorably to current standards of care for diagnosing lung cancer including invasive biopsies as seen in the table shown below.

Comparison of CyPath[®] Lung to Current Standards of Care

Diagnostic Test or Procedure	Intended Patient	Sensitivity	Specificity	Procedural Risk
CyPath [®] Lung ⁴¹	High risk	82%	88%	None
CyPath [®] Lung	High risk – nodules less than 20 mm	92%	87%	None
Low Dose CT screening ⁴²	High risk	93.80%	73.40%	Radiation exposure
FDG PET imaging ⁴³	Suspicious lung nodules	88%	75%	Radiation exposure
Bronchoscopy ⁴⁴	Suspicious lung nodules – central lesions	88%	47%	Invasive—risk of collapsed/bleeding lung infection
Fine Needle Biopsy ⁴⁵	Suspicious lung nodules	90.4%	75.4%	Invasive—risk of collapsed/bleeding lung infection
Core Needle Biopsy ¹⁸	Suspicious lung nodules	89.1%	88.6%	Invasive—risk of collapsed/bleeding lung infection

⁴¹ Rebel, VI, et al. Automated Flow Cytometry Test Distinguishes Cancer from Non-Cancer in Sputum with High Sensitivity and Specificity, poster, 2020 World Conference on Lung Cancer. January 2021.

⁴² National Lung Screening Trial Research Team, Church TR, Black WC, Aberle DR, Berg CD, Clingan KL, et al. Results of initial low dose computed tomographic screening for lung cancer. *N Engl J Med.* 2013;368(21):1980-1991. doi: 10.1056/NEJMoa1209120.

⁴³ Deppen SA, et al. Accuracy of FDG-PET to diagnose lung cancer in areas with infectious lung disease: a meta-analysis. *JAMA.* 2014;312(12):1227-1336. doi: 10.1001/jama.2014.11488.

⁴⁴ Silvestri GA, et al. A bronchial genomic classifier for the diagnostic evaluation of lung cancer. *N Engl J Med.* 2015;373:243-251. doi: 10.1056/NEJMoa1504601.

⁴⁵ Yao X, Gomes MM, Tsao MS, Allen CJ, Geddie W, Sekhon H. Fine-needle aspiration biopsy versus core-needle biopsy in diagnosing lung cancer: a systemic review. *Curr Oncol.* 2012;19(1):e16-e27. doi: 10.3747/co.19.871.

bioAffinity's business model is to immediately address the need for a quick-to-market, noninvasive, cost-effective lung cancer diagnostic that will save lives and reduce medical costs. The Company is ready to capture a growing market. The U.S. Preventive Services Task Force recommended doubling the number of Americans at high-risk for lung cancer who are recommended for annual screening from 9 million to 18 million. China has an estimated 300 million smokers.⁴⁶ The European Union is estimated to have 34 million people at high risk for lung cancer. Following its entry into the U.S. market, the Company expects to pursue CE marking of CyPath® Lung for sale in the European Union and is pursuing collaboration with a strategic partner to develop the test for the China market.

bioAffinity conducted market research with pulmonologists, oncologists, cardiothoracic surgeons, radiologists, and internists engaged in the diagnosis and treatment of lung cancer to help assess these stakeholders' reactions to the new diagnostic, CyPath® Lung. Research revealed a strong interest in CyPath® Lung, driven by the high level of unmet clinical need for noninvasive diagnostics. A survey conducted with 240 pulmonologists and internists, the primary audience for the test, showed that 96% would use CyPath® Lung if it were available today as an adjunct used for diagnosis after LDCT screening. Physicians see the value of a noninvasive diagnostic technology with the ability to confirm or rule out cancer and reduce the number of costly invasive procedures that result from LDCT's low positive predictive rate.

Joint Development Agreement with Precision Pathology Services

bioAffinity Technologies entered into a Joint Development Agreement with Precision Pathology in October 2018 to develop CyPath® Lung as an LDT under CLIA. The Joint Development Agreement contains details concerning each party's duties and responsibilities in the development project. Under the agreement, bioAffinity Technologies is solely responsible for: (i) conducting all research and clinical trials; (ii) conducting all sales and marketing activities; (iii) preparing and implementing all advertising; (iv) attending all medical and industry conferences; (v) training all personnel; and (vi) procuring, assembling, labeling and storing the product. Precision Pathology is solely responsible for: (i) all steps necessary to validate CyPath® Lung for purposes of CLIA; (ii) receiving and handling all CyPath® Lung test kits returned for processing; (iii) sending out all bills and claims in connection with the sale and processing of the CyPath® Lung test and evaluating the results; (iv) communicating test results to physicians; and (v) properly equipping, maintaining and staffing laboratories to process the CyPath® Lung tests.

The Joint Development Agreement contains a license by bioAffinity Technologies to Precision Pathology of bioAffinity Technologies' intellectual property associated with CyPath® Lung to allow Precision Pathology to manufacture, use, market and sell the CyPath® Lung LDT only in those U.S. states and territories where Precision Pathology is permitted under applicable law to offer, sell and market the CyPath® Lung LDT. The license requires Precision Pathology to pay bioAffinity Technologies a royalty of 50% of the gross revenue received by Precision Pathology from the sale and processing of the CyPath® Lung test. The Joint Development Agreement also provides that bioAffinity Technologies will be the sole owner of any intellectual property that is developed by either party during the joint development project, regardless of inventorship. bioAffinity Technologies is solely responsible for preparing, filing, prosecuting and maintaining all patent applications and patents covering any jointly developed intellectual property.

The Joint Development Agreement remains in effect until bioAffinity Technologies obtains FDA approval to directly commercialize CyPath® Lung or its functional equivalent unless terminated earlier by either party in connection with the other party's breach of the agreement or the other party's insolvency or bankruptcy. All licenses granted under the Joint Development Agreement terminate upon the termination of the Joint Development Agreement.

CyPath® Lung Business Development Plan

The CyPath® Lung test will be ordered by physicians for use by people at high risk for lung cancer who are recommended for annual screening by LDCT. While LDCT is shown to lower the mortality rate of lung cancer by approximately 20%,⁴⁷ the screening method has a low positive predictive value that can result in many people undergoing unnecessary invasive procedures. Inserting CyPath® Lung into the diagnostic pathway can provide more confidence in choosing a path forward for physicians and their patients. The speed and ease of patient use make CyPath® Lung well suited for both sophisticated and less developed markets. Existing CPT cost codes associated with flow cytometry have been identified for use to obtain reimbursement by private carriers and governmental agencies.

bioAffinity Technologies will provide the Smith Medical acapella® Choice Blue device with CyPath® Lung to assist patients in expelling sputum out of their lungs into a collection cup noninvasively. bioAffinity Technologies has an agreement with GO2 Partners, Inc. to produce patient collection kits and to provide warehousing and distributions services for sending out the kits. GO2 has produced 3,000 patient collection kits under our contract at a cost of \$9.06 per kit. GO2 charges us a nominal storage fee for warehousing the kits and charges us \$6.00 to ship out a kit once a physician has ordered it. The agreement with GO2 has an indefinite term, does not have any provision regarding termination, and can be terminated by either party at will at any time. Reagents and other laboratory equipment and supplies are commercially available, each from 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 and wholly owned by bioAffinity Technologies.

We believe in the viability of the Company's 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 Company resources and minimize market risk. Phase 1 of our Business Plan begins with a controlled market launch of the Company's LDT CyPath® Lung in Texas beginning in the second quarter of 2022, followed by expansion into the Southwest market area in the first quarter of 2023. The Company expects to begin a staged nationwide expansion of sales and marketing in the third quarter of 2023. Phase 2 of our Business Plan anticipates entering the EU market with CyPath® Lung as a CE-marked IVD test in the third quarter of 2023 with sales in the Netherlands, followed by a staged EU expansion in the fourth quarter of 2024. Phase 3 of our Business Plan focuses on the marketing of an FDA-cleared CyPath® Lung test, beginning with a pivotal clinical trial in the U.S. We expect to submit a pre-submission to the FDA in the third quarter of 2022 and to open the pivotal clinical trial in the first quarter of 2023. We anticipate that the pivotal clinical trial will require between two to three years depending on the trial's size, objectives and endpoints. Assuming the study is successful, we intend to submit a *de novo* classification request to the FDA within six months of study completion and anticipate FDA marketing authorization of the test in 2026. Phase 4 of our Business Plan accelerates the market presence of CyPath® Lung in foreign countries in Asia, Australia and Eastern Europe after obtaining such FDA marketing authorization in 2026.

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

⁴⁶ Pratt A, Pastorelli A. The Bill China Cannot Afford: health, economic and social costs of China's tobacco epidemic. World Health Organization Regional Office for the Western Pacific; 2017. Accessed February 8, 2022. <https://apps.who.int/iris/bitstream/handle/10665/255469/9789290617907-eng.pdf?sequence=1&isAllowed=y>.

⁴⁷ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365:395-409. doi: 10.1056/NEJMoa1102873.

Phase 1 of the Business Plan begins with a market launch of CyPath® Lung as an LDT in Texas. bioAffinity Technologies has granted a license of its intellectual property associated with CyPath® Lung to Precision Pathology pursuant to the terms of a joint development agreement. Precision Pathology has completed the required analytical validation of the test in accordance with CLIA and the CAP standards that look at the performance characteristics of a test used to describe the quality of patient test results, and includes an analysis of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference interval, and other performance characteristics required for the test system in the laboratory that intends to use it. This analytical validation is limited to the specific conditions, staff, equipment and patient population of the particular laboratory. In this case, sale of CyPath® Lung is limited to Precision Pathology. Phase 1 initially is focused on proving both the commercial viability of CyPath® Lung and the sales and marketing approach in a controlled rollout targeted in Texas, which we anticipate will require six months. The rollout is expected to expand to regions of the southwestern U.S. through the first half of 2023. Following this initial market launch, sales of CyPath® Lung will expand to key markets nationwide. CyPath® Lung will be sold as an LDT until the test is cleared for sale by the FDA as an IVD test (See Phase 3). Reimbursement CPT codes have been identified for use with CyPath® Lung that are associated with the technology used by the test, specifically flow cytometry tests. These CPT codes are not specific to CyPath® Lung, but are used for flow cytometry assays and the accompanying antibody reagents and data interpretation used in CyPath® Lung. Precision Pathology has established a unit price of \$880 determined by the terms of the laboratory's contracts with private payors and the applicable CPT codes. See "Business—Reimbursement" on page 64.

Phase 2 is expected to result in the launch of CyPath® Lung as a CE-marked IVD laboratory-based test to be sold in the European Union via strategic laboratory channels. Phase 2 is expected to begin in mid-2023 with a country rollout starting with The Netherlands, followed by staged entry into other European countries. In order to CE mark CyPath® Lung as an IVD, the Company must fulfill all applicable regulatory requirements in the IVDR, which defines the necessary pre-conditions that must be fulfilled to CE mark a product. bioAffinity must provide objective evidence to regulatory agencies that these requirements have been fulfilled prior to placing our test on the EU market. To accomplish Phase 2, bioAffinity will establish a European-focused regulatory infrastructure (QA and ISO) including work with a global firm that can provide quality assurance, regulatory approval, and reimbursement, services. bioAffinity Technologies plans to execute agreements similar to the joint development agreement executed with Precision Pathology that allows commercial laboratories to sell our test in the EU. The Regulatory section of this Prospectus provides more information regarding EU regulatory requirements. Additionally, we will support our laboratory licensee with an internal EU commercial sales and marketing team.

Phase 3 is focused on finalizing and launching an FDA-cleared CyPath® Lung laboratory-based diagnostic test. FDA marketing authorization allows bioAffinity Technologies to directly sell CyPath® Lung to physicians and their patients as compared to LDT commercialization that limits the sale of the test to the specific conditions, staff, equipment and patient population of the particular laboratory that has completed analytical validation of the test under CAP/CLIA. bioAffinity will submit a *de novo* classification request to the FDA for CyPath® Lung. If the *de novo* request is granted by the FDA, we expect FDA marketing authorization will result in a larger market and greater market share for CyPath® Lung. Such marketing authorization also can lead to higher reimbursement, expanded claims and additional indications for use of CyPath® Lung for the early detection of lung cancer. The Regulatory section of this Prospectus provides more information regarding the U.S. regulatory process. Daniel Schultz, M.D., F.A.C.S., former FDA Director of Device Evaluation, is leading bioAffinity's advisory team, which includes Validant Consulting Ltd., a global consultancy. We are currently working with a CRO to finalize the design of the pivotal clinical trial and plan to submit a pre-submission package to the FDA in the third quarter of 2022 to obtain the Agency's feedback on the study design. A pivotal clinical trial is scheduled to begin in 2023. We are currently working with a CRO to finalize the design of the pivotal clinical trial. Final design of the pivotal trial has not been determined at this time, including the number of participants and patient follow-up. We expect to conduct a pivotal trial that requires between two to three years depending on the clinical trial's size, objectives and endpoints. Assuming the study is successful, we intend to submit a *de novo* classification request to the FDA within six months of study completion. Phase 3 of our Business Plan includes establishing a high-level U.S.-based technical diagnostic field sales team backed by a technical internal support team. bioAffinity will establish customer relationship management systems, including customer ordering and complaint handling systems. Our activities in Phases 1 and 2 will be designed to support and develop a foundation for an impactful launch and rollout of the IVD laboratory test in Phase 3.

Phase 4 accelerates CyPath® Lung market presence in the EU and U.S. and capitalizes on the Company's marketing and sales efforts with its LDT, CE-marked and FDA-cleared test. We expect to expand marketing into China, Southeast Asia, Australia and Central / Eastern Europe following FDA marketing authorization for the test. The estimated \$5 billion market in China offers significant potential as well as complexities in launching a laboratory test, including pricing, penetration, and market channels. bioAffinity Technologies has ongoing efforts to find the proper market channel partner. We will look for key distributors in Canada, Southeast Asia, Australia, and Central / Eastern Europe. Some of the same distributors in the Western EU will most likely be available to carry us into Central / Eastern Europe. bioAffinity will carefully choose the best partners for selling CyPath® Lung as an appropriate addition to distributors' product portfolios. bioAffinity Technologies plans on establishing a global commercial and business development management team to support our distributors and ensure success.

Reimbursement

A physician orders the CyPath® Lung test for his or her patients, and the laboratory conducting the test will seek to be reimbursed by third-party payers, including commercial health insurers and government health benefits programs (such as Medicare and Medicaid). In the absence of insurance reimbursement, a patient may pay for the test. Laboratory tests, as with most other health care services, are classified for reimbursement purposes under a coding system known as Current Procedure Terminology ("CPT"), which the laboratory conducting the test and our customers must use to bill and receive reimbursement for our diagnostic tests. There are CPT codes associated with the particular tests that we provide to the patient. Once the American Medical Association establishes a CPT code, CMS establishes payment levels and coverage rules under Medicare, while state Medicaid programs and commercial health plans establish rates and coverage rules independently in accordance with applicable rules. As such, the reimbursement rates for our diagnostic tests vary by third-party payer.

For most of the covered tests performed for Medicare or Medicaid beneficiaries, we are required to bill Medicare or Medicaid directly, and to accept Medicare or Medicaid reimbursement as payment in full.

We currently submit for reimbursement using CPT codes based on the guidance of coding experts and outside legal counsel. There is a risk that these codes may be rejected or withdrawn or that third-party payers will seek refunds of amounts that they claim were inappropriately billed to a specific CPT code or an incorrect diagnosis code. We have identified specific CPT codes assigned to flow cytometry tests. These codes use broad descriptors that describe the CyPath® Lung test. Descriptors do not limit use of the CPT codes to specific organs or conditions but reference the number of markers and physician interpretation that match the way CyPath® Lung is performed. CyPath® Lung is similar to other flow cytometry tests reimbursed by Medicare in its sample processing and labeling with antibodies, acquisition of data, use of flow cytometry and data analysis that identifies cell populations indicative of the disease state. Medicare treats the flow cytometry codes as physician services and thus tests using flow cytometry are paid under the physician fee schedule. The CyPath® Lung test has comparable technical and professional resources overall to other flow cytometry systems. Accordingly, the coding experts consulting with the Company have concluded that Medicare payment levels for conventional flow cytometry systems are appropriate for CyPath® Lung. For example, antibodies used in the CyPath® Lung test are within the scope of flow cytometry antibodies covered by Medicare and fall within the explicit reference to "cell surface, cytoplasmic or nuclear marker." Furthermore, CyPath® Lung is used for an oncology indication, like the other flow cytometry tests covered by Medicare. CyPath® Lung is performed on a classic flow cytometry technology platform, a common feature of all flow cytometry tests and the defining feature of the CPT codes. CLIA/CAP certification for the lab encompasses flow cytometry tests.

There remains a risk that we may not be able to use these specific codes for our test, or the specific CPT codes are not accepted for use with the appropriate diagnostic codes, or if accepted, we may not be able to negotiate favorable rates for one or more of the codes used in reimbursement of the test.

Reimbursement by third-party payers may depend on a number of factors, including the payer's determination that tests using our technologies are not experimental or investigational, are medically necessary, can demonstrate the test leads to improved patient outcomes, are appropriate for the specific patient, are cost-saving or cost-effective,

are supported by peer-reviewed medical journals, and are included in clinical guidelines. In making coverage determinations, third-party payers often rely on practice guidelines issued by professional societies. Precision Pathology has been in operation since 2007 and has executed contracts with multiple third-party insurance carriers in the state of Texas for reimbursement of the tests they run. Reimbursement of CyPath® Lung will be sought in accordance with those agreements with third-party carriers.

Novitas, the Medicare Administration Contractor (MAC) for Texas, has a specific coding policy that allows coverage for secondary malignant neoplasm of pleura. In this manner, the policy connects flow cytometry codes for use with diagnosing lung cancer. Furthermore, the Novitas coverage policy is sufficiently broad to include CyPath® Lung. Specifically, Novitas' coding and billing article recognize a lung cancer ICD-10-CM diagnosis code with flow cytometry codes. Novitas is the MAC that covers Texas and six other southwestern states plus four mid-Atlantic states. Precision Pathology is located in Texas and therefore the Novitas policy applies directly to the laboratory that is offering CyPath® Lung for sale. Other MACs do not have explicit policies and do not need to follow Novitas, but often a MAC will follow the policy of the region in which the laboratory is located.

The Competition for CyPath® Lung

bioAffinity Technologies completed a competitive analysis in 2022 that evaluated the claims, scientific studies, presentations and public documents of companies and academic institutions claiming to be advancing tests for early lung cancer. The Company has conducted ongoing competitive analyses since 2015. In 2022, we evaluated 67 companies advancing tests for the early detection of lung cancer that provided at least a scientific foundation for their tests. These competitors are investigating lung cancer screening and diagnostic methods that use various types of collected samples (blood, breath, nasal epithelial cells, saliva, sputum, and urine) or imaging systems. Of those 67 companies, we found that only eleven had conducted clinical studies in a manner and with results that could lead to further analysis. The majority of these eleven tests are in research and development, with only four tests on the market and one available to a limited number of medical centers. Although CyPath® Lung was never tested directly against any of these five tests, comparison of the published performance numbers suggests CyPath® Lung might outperform them all. (See *Summary of Comparative Performance Analysis of Tests on the Market, bioAffinity Technologies Internal Analysis, 2022*; attached as Appendix II to this prospectus). Furthermore, CyPath® Lung is noninvasive—not even requiring a needle stick—and cost-efficient, and processing and analysis procedures are easy to perform. The eleven tests are discussed below in more detail.

Based on published data and results of clinical trials,^{48–65} we grouped 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. Balanced tests can be the most cost effective. Those that perform well, like CyPath® Lung, 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, i.e., whether to move forward with more aggressive follow-up procedures (e.g., when the CyPath® Lung test reveals a “likely” or “highly likely” cancer result) or to stay more conservative (e.g., when the CyPath® Lung test reveals an “unlikely” or “very unlikely” cancer result). 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. Rule-in and rule-out tests are less useful as well-performing balanced tests.

From the 67 companies we evaluated, we found only seven tests, including CyPath® Lung, that represent a balanced test for early lung cancer detection and that have advanced to the point that there is sufficient data for evaluation. Of our six competitors with well-balanced tests (two sell the same test; one in the U.S. and one in China), four companies (20/20 GeneSystems^{48,49}; Nuclexi⁵⁰; Savicell⁵¹; Visongate⁵²) 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 suspect as it applies to the population of patients who actually will use the test. Our competitive analysis pays particular attention to the patient cohorts in a clinical trial, particularly when the non-cancer cohort includes participants who are not considered at high risk for lung cancer. The choice of cohorts is extremely important.⁵³ Healthy individuals who are not at risk for lung cancer are not recommended for screening due to an unacceptable risk of overdiagnosis and the potential harm from LDCT radiation or unnecessary follow-up procedures. Healthy individuals also have significantly different physiological traits when compared to cancer patients and high-risk individuals, making it much easier to find differences between those people with cancer and those who are not at high risk and who are cancer-free.

⁴⁸ Doseeva V, Colpitts T, Gao G, Woodcock J, Knezevic V. Performance of a multiplexed dual analyte immunoassay for the early detection of non-small cell lung cancer. *J Transl Med*. 2015;13:55. doi:10.1186/s12967-015-0419-y.

⁴⁹ Mazzone PJ, Wang XF, Han X, et al. Evaluation of a Serum Lung Cancer Biomarker Panel. *Biomark Insights*. 2018;13:1177271917751608. doi:10.1177/1177271917751608.

⁵⁰ Gaga M, Chorostowska-Wynimko J, Horváth I, et al. Validation of Lung EpiCheck, a novel methylation-based blood assay, for the detection of lung cancer in European and Chinese high-risk individuals. *Eur Respir J*. 2021;57(1):2002682. doi:10.1183/13993003.02682-2020.

⁵¹ Adir Y, Tirman S, Abramovitch S, et al. Novel non-invasive early detection of lung cancer using liquid immunobiopsy metabolic activity profiles. *Cancer Immunol Immunother*. 2018;67(7):1135-1146. doi:10.1007/s00262-018-2173-5.

⁵² Wilbur DC, Meyer MG, Presley C, et al. Automated 3-dimensional morphologic analysis of sputum specimens for lung cancer detection: Performance characteristics support use in lung cancer screening. *Cancer Cytopathol*. 2015;123(9):548-556. doi:10.1002/cncy.21565.

⁵³ Baldwin J, Pingault J, Schoeler T, Sallis H, Munafò M. Protecting against researcher bias in secondary data analysis: challenges and potential solutions. *Eur J Epidemiol*. 2022;37:1-10. https://doi.org/10.1007/s10654-021-00839-0.

The two remaining balanced tests are not on the market. One of these latter tests is LungLB, a FISH-based test that requires a significant amount of experience to conduct. LungLife AI (in the U.S.) and SanMed Biotech (in China) offer the LungLB test. (In China, it is called the MDA Test). The test uses a visualization instrument from BioView to read microscope slides. Studies from both companies have been consistent in result,^{54,55} but with significantly lower performance than a study from the original inventor,⁵⁶ perhaps an indication of the difference in expertise between the Company and the inventor's laboratory. LungLB is developing an automated system of analysis, but additional clinical trials are necessary to determine the efficacy of the test. The second balanced test is EPN Scan, developed by IONI Sciences, formerly known as proLung Dx. This test requires unique, expensive equipment. The clinical trials that tested the performance of the EPN scan have provided inconsistent results. An early trial with 41 patients showed promise,⁵⁷ but later clinical trial results were considerably less impressive.^{58,59}

There was insufficient data reported for the EPN Scan to determine the Area Under the Curve or AUC, a key indicator of a test's ability to discriminate between cancer and non-cancer. In general, an AUC of 0.5 suggests no ability to distinguish between people with cancer and people without cancer. An AUC of 0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent, and more than 0.9 is considered outstanding. CyPath® Lung trials have resulted in AUC of 0.89 and 0.9. The two trials conducted for the LungLB/MDA Test for which there is data resulted in an AUC of 0.823.^{54,55}

Two rule-out tests are currently on the market while one is available to a limited number of medical centers. Both the REVEAL, offered by MagArray, and Nodify-XL2, offered by Bodesix, are rule-out tests, meaning the tests aim to exclude patients without cancer. The REVEAL test is a blood test intended for patients with indeterminate nodules. In their 97-patient clinical validation trial,⁶⁰ only patients with an intermediate risk of cancer, based either on a physician's judgement or a clinical model, took part. This requirement led to 30% of high-risk patients being excluded at the onset of their analysis. In addition, the positive predictive value of the REVEAL test was 13.5% as compared

to CyPath® Lung's positive predictive value of 43.2%. Importantly, no patients were excluded from the CyPath® Lung test. The tests had negative predictive values of 98% and 97.8%, respectively. The second rule-out test, Nodify-XL2, is used only by people with a pre-test probability of cancer less than 50%. As with the REVEAL test, a large number of patients were excluded from analysis. In the case of Nodify-XL2, about 55% of patients with lung nodules that physicians considered indeterminate, namely lung nodules sized between 8-30 mm, were excluded from the study.⁶¹ In addition, Nodify XL-2 reported an AUC of 0.62 (unacceptable) and 0.76 (acceptable) for their two clinical trials,^{61,62} 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 currently available to a limited number of medical centers but expected to be fully launched in 2022. Initial performance parameters for this test were developed on samples obtained from people scheduled to undergo bronchoscopy. In this case, the AUC was not provided. The positive predictive value was only 16.9% and the negative predictive value was 99.3%.⁶³

The only rule-in test on the market is EarlyCDT Lung that has not reported the AUC for its two clinical trials.^{64,65} EarlyCDT Lung reports a positive predictive value of 34.5% as compared to CyPath® Lung's 43.2% positive predictive value. In addition, there is still a 10% chance for a person with a negative EarlyCDT test to have cancer. Thus, neither a positive nor negative EarlyCDT test result provides much more certainty after a positive LDCT screening.

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, bioAffinity's proprietary technology is straightforward. bioAffinity's CyPath® platform technology is not a molecular test and does not collect genetic material that requires immediate processing. CyPath® uses well-established flow cytometry techniques to investigate cells contained in the sputum for characteristics that indicate whether cancer is present. 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 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. Existing CPT cost codes that have a reimbursable track record have been identified for use with CyPath. Fifth and as important as any of our test's benefits, CyPath® Lung is patient friendly, providing at-home sample collection that is noninvasive and offers particular benefit during a public healthcare crisis like the coronavirus pandemic.

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- 55 Feng M, Ye X, Chen B, et al. Detection of circulating genetically abnormal cells using 4-color fluorescence in situ hybridization for the early detection of lung cancer. *J Cancer Res Clin Oncol*. 2021;147(8):2397-2405. doi:10.1007/s00432-021-03517-6.
- 56 Katz RL, Zaidi TM, Pujara D, et al. Identification of circulating tumor cells using 4-color fluorescence in situ hybridization: Validation of a noninvasive aid for ruling out lung cancer in patients with low-dose computed tomography-detected lung nodules. *Cancer Cytopathol*. 2020;128(8):553-562. doi:10.1002/cncy.22278.
- 57 Yung RC, Zeng MY, Stoddard GJ, Garff M, Callahan K. Transcutaneous computed bioconductance measurement in lung cancer: a treatment enabling technology useful for adjunctive risk stratification in the evaluation of suspicious pulmonary lesions. *J Thorac Oncol*. 2012;7(4):681-689. doi:10.1097/JTO.0b013e31824a8dcd.
- 58 Fresh Medical Laboratories. *A Multi-Center Trial of the ProLung Test™ (Transthoracic Bioconductance Measurement) as an Adjunct to CT Chest Scans for the Risk Stratification of Patients With Pulmonary Lesions Suspicious for Lung Cancer*. [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/NCT01566682); 2019. Accessed March 20, 2022. <https://clinicaltrials.gov/ct2/show/NCT01566682>.
- 59 Gariani J, Martin SP, Hachulla AL, et al. Noninvasive pulmonary nodule characterization using transcutaneous bioconductance: Preliminary results of an observational study. *Medicine (Baltimore)*. 2018;97(34):e11924. doi:10.1097/MD.00000000000011924.
- 60 Trivedi NN, Brown JK, Rubenstein T, et al. Analytical validation of a novel multi-analyte plasma test for lung nodule characterization. *Biomed Res Rev*. 2018;2(3):123. doi:10.15761/brr.1000123.
- 61 Silvestri GA, Tanner NT, Kearney P, et al. Assessment of Plasma Proteomics Biomarker's Ability to Distinguish Benign From Malignant Lung Nodules. *Chest*. 2018;154(3):491-500. doi:10.1016/j.chest.2018.02.012.
- 62 Vachani A, Pass HI, Rom WN, et al. Validation of a multiprotein plasma classifier to identify benign lung nodules. *J Thorac Oncol*. 2015;10(4):629-637. doi:10.1097/JTO.0000000000000447.
- 63 Lamb C, Hospital L, Center M, et al. Lung cancer detection via whole-transcriptome RNA sequencing of nasal epithelium. *Chest*. 2019;156(4):A1091-A1092. doi:10.1016/j.chest.2019.08.1005.
- 64 Chapman CJ, Healey GF, Murray A, et al. EarlyCDT®-Lung test: improved clinical utility through additional autoantibody assays. *Tumour Biol*. 2012;33(5):1319-1326. doi:10.1007/s13277-012-0379-2.
- 65 Jett JR, Peek LJ, Fredericks L, Jewell W, Pingleton WW, Robertson JFR. Audit of the autoantibody test, EarlyCDT®-lung, in 1600 patients: an evaluation of its performance in routine clinical practice. *Lung Cancer*. 2014;83(1):51-55. doi:10.1016/j.lungcan.2013.10.008.

Other Diagnostic Applications for the CyPath® Platform

The Company expects to expand bioAffinity's platform technology to detect and monitor other lung diseases and multiple cancers.

Chronic Obstructive Pulmonary Disease and Other Diseases of the Lung. The respiratory market was valued at \$4.4 billion in 2018 and is expected to reach \$6.4 billion by 2026.⁶⁶ COPD is the fourth leading cause of death in the world. The disease is characterized as an abnormal inflammatory response and airflow obstruction that cannot be fully reversed. Early detection allows for the use of therapies when the disease is less severe, which slow the progression of the disease. We plan to build on our expertise in using sputum as a sample for flow cytometric analysis to develop a test to detect COPD at an early stage and monitor for signs of impending exacerbations before clinical signs occur. CyPath® Lung's flow cytometry platform provides for identification of cell populations and other parameters of disease in the lung. Our test illuminates the microenvironment of the lung. We believe that our flow cytometric test can be designed to identify other lung diseases, such as COPD and asthma, using antibodies that characterize cell populations in sputum specific to the disease.

Prostate Cancer. Prostate cancer is the second most commonly diagnosed cancer in men and sixth in terms of mortality worldwide.⁶⁷ The global prostate cancer diagnostics market is expected to grow from \$3.11 billion in 2020 to \$8.25 billion in 2028.⁶⁸ Currently, the sensitivity and specificity of prostate cancer diagnostics are relatively low. The prostate-specific antigen ("PSA") screening test has a high specificity (91%) but a low sensitivity (21%) and 30% positive predictive value. The transrectal ultrasonography-guided biopsy, the current diagnostic benchmark, has a reported 50% sensitivity and 85% specificity. Its positive predictive value is 67%.⁶⁹ The PSA test suffers from a low sensitivity (21%), meaning that it misses 80% of men with cancer.⁷⁰ It is important to address this issue because if detected and treated prior to spreading, the five-year survival rate for prostate cancer is 97.8%, compared to only a 30.2% five-year survival rate when prostate cancer is diagnosed in later stages.⁷¹

66 Verified Market Research, Global Respiratory Diagnostics Market Size by Products and Services, By End User, By Geographic Scope and Forecast, August, 2020.

67 Culp MB, Soerjomataram I, Efstathiou JA, Bray F, Jemal A. Recent Global Patterns in Prostate Cancer Incidence and Mortality Rates. *Eur Urol*. 2020;77:38-52.

68 Prostate Cancer Diagnostics Market – Global Industry Trends and Forecast to 2028 | Data Bridge Market Research.

69 S. Nafie, et al., The role of transperineal template prostate biopsies in prostate cancer diagnosis in biopsy naïve men with PSA less than 20 ng ml⁻¹. *Prostate Cancer Prostatic Dis*. 2014;17(2):170-3.

70 R. Hoffman, Screening for prostate cancer. 2016. <http://www.uptodate.com/contents/screening-for-prostate-cancer>.

We plan to develop a urine test for prostate cancer based on the flow cytometry platform used in the successful development of CyPath® Lung. We aim to develop a test with high sensitivity. Prostate cancer research is expected to be conducted in collaboration with The University of Texas Health Science Center in San Antonio, where researchers are developing methods to harvest urine samples with a high prostate fluid content.

Bladder Cancer. Bladder cancer is estimated to strike more than 83,000 individuals in the U.S. each year, and nearly 18,000 people died in 2020 from the disease.⁷² Bladder cancer has the highest cancer recurrence rate, ranging between 31% and 78% within five years of initial diagnosis.⁷³ This risk continues for a lifetime. Early diagnosis and routine monitoring are the keys to survival. Five-year survival is greater than 95.8% if diagnosed when the cancer is contained to the lining of the bladder, but drops to only 5.5% if the cancer has metastasized.³¹ Monitoring the disease in the form of repeated cystoscopies, which are invasive and expensive, is required to ensure early detection. The bladder cancer market was estimated at \$3.34 billion in 2018 and is expected to reach \$4.71 billion by 2026, including diagnosis, monitoring, and treatment.⁷⁴ We believe we can build on our flow cytometry platform to detect other cancers using the porphyrin TCPP. In the case of bladder cancer, we will analyze urine for characteristics indicating early stage disease. We intend to develop a test that can noninvasively monitor and detect the early recurrence of bladder cancer. The Company plans to work with physicians and researchers at The University of Texas Health Science Center on feasibility studies and follow-up clinical trials.

OncoSelect® Therapeutic Platforms

Overview

It is undeniable that cancer is a very complex disease. Despite the many advances in our understanding of the disease, the U.S. cancer death rate, after adjustment for population age and size, has decreased by just 5% since 1950. In contrast, over the same period, the mortality rates due to stroke and heart disease have declined by 70%.⁷⁵ While improvements in early cancer diagnosis have had an impact on five-year survival rates in some cancers, the prognosis for patients with advanced or metastatic disease remains poor.

The worldwide market for oncology drugs has shown steady growth in recent years and is projected to continue at a CAGR of 20.2% through 2026.⁶ Oncology drug revenue is the highest of all pharmaceutical indications, with projected oncology drug sales projected to reach a value of \$394.24 billion by 2027, up from \$141.33 billion in 2019.⁷ The global market for RNA therapeutics, which include antisense and RNA interference drugs such as siRNAs, is projected to grow from \$1.11 billion in 2020 to \$1.2 billion in 2021 at a CAGR of 8.1%.⁷⁸

⁷² SEER, Cancer Stat Facts: Bladder Cancer (2021).

⁷³ A. van der Heijden and J.A. Witjes, Recurrence, Progression, and Follow-Up in Non-Muscle-Invasive Bladder Cancer. *Eur Urol. Suppl.* 2009;8(7):556–562.

⁷⁴ Verified Market Research, Global Bladder Cancer Market Size, 2020.

⁷⁵ Wishart DS. Is Cancer a Genetic Disease or a Metabolic Disease? *EBioMedicine*. 2015;2:478–479.

⁷⁶ Evaluate Pharma World Preview 2020, Outlook to 2026 (<https://perma.cc/WV63-2ZRZ>) (accessed Feb 26, 2021).

⁷⁷ Oncology Drugs Market Size, Share | Global Industry Report, 2020-2027.

⁷⁸ Antisense & RNAi Therapeutics Global Market Report 2021: COVID-19 Growth and Change to 2030. June 2021. ResearchAndMarkets.com.

The Company's discoveries have opened new opportunities to develop various drug combination therapies targeting multiple cancer vulnerabilities simultaneously. The Company is in a unique position to take advantage of this growing market. OncoSelect® Therapeutics, LLC, our wholly owned subsidiary, is a preclinical stage biopharmaceutical discovery company with a focus on therapeutics that deliver cytotoxic (cell-killing) effects on a broad selection of human cancers from diverse tissues while having little or no effect on normal cells.

Drugs targeting specific genetic aberrations in cancer cells have been widely pursued, but their efficacy is often limited by the development of drug resistance due to genetic or epigenetic changes or their applicability to select patient populations. As an alternative to the drug targeting of genetic aberrations, some researchers have begun to refocus on underlying factors that are common to many cancers, such as the altered cancer metabolism in cancer cells.⁷⁹⁻⁸⁴ At OncoSelect® Therapeutics, we are not pursuing therapies that are dependent upon specific gene mutations or other genetic and epigenetic abnormalities for their effect. We are pursuing research based on our own scientific discoveries.

From Diagnostic Research Comes A Key Therapeutic Discovery

Our therapeutic platforms originated from our research on how TCPP, the porphyrin used in CyPath® Lung, enters cancer cells. The higher affinity for porphyrins by cancerous versus normal tissues was discovered in the 1940s and has led to advances in cancer diagnostics and therapeutics.⁸⁵⁻⁸⁸ However, the mechanisms for porphyrin cancer cell selectivity are complex and remain poorly understood.⁸⁹⁻⁹³

⁷⁹ Seyfried TN, Flores RE, Poff AM, D'Agostino DP. Cancer as a metabolic disease: implications for novel therapeutics. *Carcinogenesis*. 2014;35:515–527.

⁸⁰ Ahmad F, Sun Q, Patel D, Stommel JM. Cholesterol Metabolism: A Potential Therapeutic Target in Glioblastoma. *Cancers (Basel)*. 2019;11.

⁸¹ DeBerardinis RJ, Chandel NS. Fundamentals of cancer metabolism. *Sci Adv*. 2016;2:e1600200.

⁸² Li X, Yu X, Dai D, Song X, Xu W. The altered glucose metabolism in tumor and a tumor acidic microenvironment associated with extracellular matrix metalloproteinase inducer and monocarboxylate transporters. *Oncotarget*. 2016;7. Available at: <http://www.oncotarget.com/fulltext/8153>. Accessed December 5, 2018.

⁸³ Kalyanaraman B. Teaching the basics of cancer metabolism: Developing antitumor strategies by exploiting the differences between normal and cancer cell metabolism. *Redox Biol*. 2017;12:833–842.

⁸⁴ Kim SM, Roy SG, Chen B, et al. Targeting cancer metabolism by simultaneously disrupting parallel nutrient access pathways. *J Clin Invest*. 2016;126:4088–4102.

⁸⁵ Rasmussen-Taxdal DS, Ward GE, Figge FH. Fluorescence of human lymphatic and cancer tissues following high doses of intravenous hematoporphyrin. *Surg Forum*. 1955;5:619–624.

⁸⁶ Berg K, Selbo PK, Weyergang A, et al. Porphyrin-related photosensitizers for cancer imaging and therapeutic applications. *J Microsc*. 2005;218:133–147.

⁸⁷ Josefsen LB, Boyle RW. Unique Diagnostic and Therapeutic Roles of Porphyrins and Phthalocyanines in Photodynamic Therapy, Imaging and Theranostics. *Theranostics*. 2012;2:916–966.

⁸⁸ Tsolekile N, Nelana S, Oluwafemi OS. Porphyrin as Diagnostic and Therapeutic Agent. *Molecules*. 2019;24..

⁸⁹ Boyle RW, Dolphin D. Structure and biodistribution relationships of photodynamic sensitizers. *J Photochem. Photobiol.* 1996;64:469–485.

⁹⁰ Cramers P, Ruevekamp M, Oppelaar H, et al. Foscan® uptake and tissue distribution in relation to photodynamic efficacy. *Br J Cancer*. 2003;88:283–290.

⁹¹ El-Far MA, Pimstone N. A comparative study of 28 porphyrins and their abilities to localize in mouse mammary carcinoma: uroporphyrin I superior to hematoporphyrin derivative. *Prog Clin Biol Res*. 1984;170:661–672.

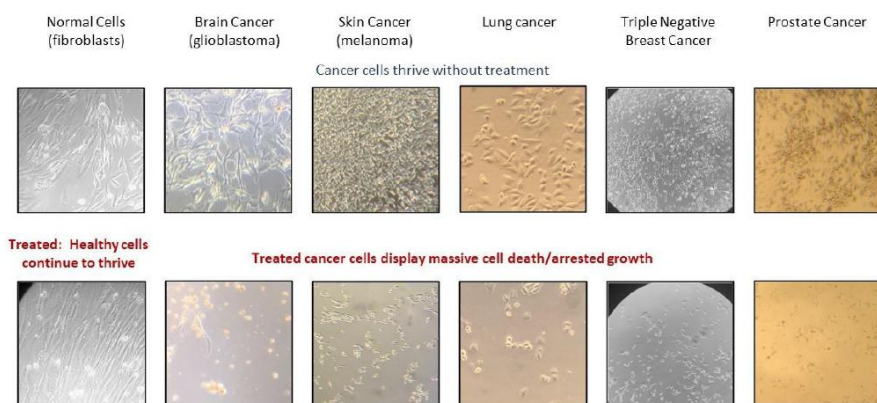
⁹² Hamblin R, Luke E. On the mechanism of the tumour-localising effect in photodynamic therapy. *J Photochem Photobiol B*. 1994 Apr;23(1):3-8.

⁹³ Hiyama K, Matsui H, Tamura M, et al. Cancer cells uptake porphyrins via heme carrier protein 1. *J Porphyrins Phthalocyanines*. 2012;17:36–43.

To increase the specificity of our diagnostic tests and develop new technologies, we needed to better understand the mechanism of TCPP's selective uptake in cancer cells. A group of structurally related cell-surface proteins were known to be involved in the cellular uptake of vitamin B12, which has a similar architecture as TCPP. Our research identified cell-membrane proteins which capture small molecules outside of the cell and bring them inside the cell, called receptors, that are associated with TCPP. Experiments at bioAffinity confirmed that at least two of these receptors called CD320 and LRP2, contributed to TCPP uptake by cancer cells. When these receptors were individually "knocked-down" in cancer cells and therefore could not be made by the cell, TCPP uptake was significantly decreased. Knock-down of CD320 and LRP2 receptors was achieved by introducing siRNA molecules into the cells that cause the destruction of CD320 and LRP2 gene products. These gene products were the messenger (m)RNAs that are the precursors of the receptor protein. An siRNA is a small, chemically synthesized piece of RNA that specifically binds to mRNA, prohibiting the further production of the corresponding proteins. Thus, the reduction of CD320 or LRP2 mRNAs reduced the CD320 or LRP2 protein, respectively, and resulted in decreased TCPP uptake in a variety of cancer cells, with a larger decrease observed when CD320 was knocked-down. We subsequently discovered that the simultaneous knockdown of these two cell-surface receptors, CD320 and LRP2, was deadly to cancer cells or inhibited their growth significantly but left normal cells virtually unharmed.

siRNAs can be easily synthesized and are easily introduced into cells growing in a petri dish by a process called transfection. siRNAs have been broadly adopted by academic and industrial researchers for the fundamental study of the function of genes and their proteins. At bioAffinity, 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 knockdown of CD320 and LRP2 in normal cells, including skin fibroblasts and breast epithelial cells, did not affect cell growth. However, knockdown 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%. The Figure below compares cells that were left alone (no treatment in the upper row pictures to cells treated with CD320/LRP2 siRNA treatment. Interestingly, in some cell lines, when either CD320 or LRP2 were silenced individually, a concurrent increase in protein expression of the other receptor was observed, suggesting that CD320 and LRP2 compensate for each other's function; hence, silencing *both* receptors is required for optimal cell killing. These discoveries can lead to novel and very promising therapeutic approaches for diverse cancers that do not appear to be dependent on any aberrant genetic or epigenetic profiles.

bioAffinity Technologies' Therapeutic Discovery: Killing Cancer Cells with Little or No Harm to Normal Cells



Research at OncoSelect[®] continues the optimization of the siRNAs used in knocking-down the CD320 and LRP2 receptors and testing their performance in additional cell lines grown in the laboratory. With the siRNAs that are most efficient in killing cancer cells in a petri dish while leaving normal cells virtually unharmed, we will test their effect on tumor in mice bearing human tumors (murine xenograft models). In an initial murine tumor xenograft study using human triple negative breast cancer cells, our approach was well tolerated by injecting our siRNAs directly into tumors, but the results of the study were inconclusive, in part due to animals dying from the unexpected metastatic nature of this disease (i.e., the spreading of the cancer cells to other areas of the body). Further studies are anticipated, as are investigations related to improving siRNA delivery for therapeutic efficacy.^{94,95,96} We seek to develop this technology to the advanced preclinical stage and undertake further development in conjunction with a partner who has greater clinical trial capabilities and expertise with siRNA delivery systems. Our ultimate goal is the development of a new class of cancer therapeutics with broad applicability in diverse human cancers.

⁹⁴ Chen, X., Mangala, L.S., Rodriguez-Aguayo, C. et al. RNA interference-based therapy and its delivery systems. *Cancer Metastasis Rev.*2018;37(1):107–124. doi: 10.1007/s10555-017-9717-6.

⁹⁵ Khvorova, A., Watts, J. The chemical evolution of oligonucleotide therapies of clinical utility. *Nat Biotechnol.* 2017;35(3):238–248. doi: 10.1038/nbt.3765.

⁹⁶ Setten, R.L., Rossi, J.J. & Han, Sp. The current state and future directions of RNAi-based therapeutics. *Nat Rev Drug Discov.*2019;18(6):421–446. doi: 10.1038/s41573-019-0017-4.

The Competition for Our Therapeutic Products

Interest in the RNAi therapeutics space has fluctuated since discovery of the phenomenon in the 1980s. This is likely due to the challenge of delivering siRNA drugs in the body and directing them to the tumor cells. There are several reasons for this: the chemical composition of siRNAs do not allow them to easily cross into cells from the outside. Second, proteins in the fluid component of blood (plasma) can damage and degrade the siRNAs, destroying them before they reach their intended destination. A third difficulty is that siRNAs have problems traveling to their target after they get into cells, and only a very small fraction of siRNAs that enter cells actually arrive at their intended destination within the cell to perform their therapeutic function. However, in the last seven years, the patent activity and capital investment in this area have increased considerably, especially after the approval of the first RNAi therapeutic, ONPATTRO (developed by Alnylam Pharmaceuticals), in August 2018 by the FDA and EMA.

Current competitors in the application of the RNAi strategy against cancer include Arrowhead Pharmaceuticals, which is investigating preclinically an siRNA/dynamic polyconjugate (DPC) peptide combination, ARC-HIF2, targeting Hif-2 α for renal cell carcinoma. Arbutus Biopharma is investigating a proprietary lipid nanoparticle technology for siRNA delivery, leading to a potential siRNA therapeutic (TKM-PLK1) targeted toward hepatocellular carcinoma and possibly other cancers. TKM-PLK1 is in multiple Phase I/II trials at this time. Dicerna may have a candidate in an expanded Phase I clinical trial for solid tumors (DCR-MYC). Silence Pharmaceuticals, Silenseed, and Apeiron Biologics separately report RNAi-based oncology drugs in Phase IIA clinical trials for pancreatic cancer.

The potential of the double knockdown strategy is exemplified by the recent announcement from Sirnaomics, Inc., describing FDA approval to launch a Phase I clinical trial for their lead product candidate, STP707, an anti-cancer siRNA therapeutic, in subjects with advanced/metastatic or refractory solid tumors.⁹⁷ STP707 takes advantage of a dual-targeted inhibitory property in which simultaneously knocking down TGF- β 1 and COX-2 gene expression in the tumor microenvironment increases active T cell infiltration. As in our studies with CD320 and LRP2 knockdown, each individual siRNA was demonstrated to inhibit the expression of their target mRNAs, and combining the two siRNAs produced a synergistic effect (which, in the case of STP707, was shown to diminish pro-inflammatory factors). Over-expressions of TGF- β 1 and COX-2 have been well-characterized in playing key regulatory roles in tumorigenesis. The company also employed a proprietary polypeptide nanoparticle (PNP)-enhanced targeted delivery to solid tumors and metastatic tumors via systemic administration. With respect to the market viability of therapeutics in this class, we note that, to date, three siRNA-based therapies have been approved by the FDA (patisiran, givosiran, and lumasiran) and seven other candidates are in Phase III trials.⁹⁸

OncoSelect® Therapeutics and Drug Delivery Commercialization

OncoSelect® therapies offer the exciting possibility of broad applications in cancer treatment. OncoSelect® Therapeutics will take full advantage of the current market that favors a licensing business model for selective chemotherapeutic compounds to be developed by the Company. The Company will leverage its current and growing body of expertise in porphyrin biology and siRNA technologies into the targeted therapeutics space.

bioAffinity Technologies will pursue its therapeutics business through its wholly owned subsidiary, OncoSelect® Therapeutics, LLC. Initial therapeutic compositions to be developed will be based on market and cost factors. Composition synthesis is being outsourced to one of several select vendors. bioAffinity will conduct initial testing of promising compounds with assistance from select vendors who have contractually relinquished any claim to discoveries, data, or intellectual property. Additional patents will be filed based on testing, and results will be publicized to evaluate the interest in individual compounds and pursue licensing opportunities.

⁹⁷ Cision PR Newswire, “Sirnaomics Receives FDA Approval of IND for Phase 1 Clinical Trial of Systemic RNAi Therapeutic STP707 for Solid Tumor Treatment,” July 6, 2021 (accessed 10/27/2021).

⁹⁸ Joszt, L. Market of siRNAs Poised to Expand Beyond 3 Currently Approved Drugs, AJMC, February 25, 2021.

Intellectual Property Portfolio

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

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

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

As of August 3, 2022, the Company and its subsidiary OncoSelect have a patent estate that includes 14 issued U.S. and foreign counterpart patents including three U.S. patents and eleven foreign counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, Italy, Mexico, Spain, Sweden, and the United Kingdom. The Company and its subsidiary wholly own all patents and trademarks in its intellectual property portfolio. Two awarded patents expire in 2022 directed at diagnostic applications, and one U.S. patent and nine counterpart foreign patents directed at diagnostic applications expire in 2030. Therapeutic patents have been registered in Australia and Mexico that expire in 2037. One therapeutic patent application that has been granted in China will expire in 2037 once registered. The patents expiring in 2022 relate to a method of making a solution of TCPP and using the TCPP solution for labeling cancer cells for detection will not have a material adverse effect on the Company’s business, financial condition or operations. There are other ways of making a TCPP solution for the same purpose and there will be a continued ability to do so in the absence of the patents. Therefore, those expiring patents will not have a material adverse effect on the Company’s business, financial condition or results of operations. The use of TCPP as a labeling agent is one part of the CyPath technology for which there are multiple patents and patent applications pertaining to the use of flow cytometry for the detection of diseases of the lung, including lung cancer.

With regard to our diagnostic test called CyPath® Lung and other diagnostic test candidates, we have three issued U.S. patents and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom. With regard to our diagnostic patent applications, there are two families of which one is directed at diagnosing lung health using flow cytometry and the other is directed at proprietary compensation beads used in analysis by flow cytometry. The diagnostic patent family of pending applications that is directed at diagnosing lung health includes one pending non-provisional U.S. patent application and eight foreign counterpart patent applications in Australia, Canada, China, European Patent Office, Japan, Hong Kong, Mexico, and Singapore filed in 2019, one provisional patent application filed in 2021, and two provisional patent applications filed in 2022. The patent application directed at the composition of compensation beads was filed as a provisional application in 2021.

With regard to our therapeutic product candidates, we have two pending U.S. patent applications, two foreign patents, three pending Patent Cooperation Treaty International patent applications, and ten foreign applications pending in Canada, China, European Patent Office, Hong Kong, India, and Japan. The therapeutic intellectual property is made up of four families, including two families directed at our siRNA product candidates, one family directed at soluble CD320 used in the treatment of cancer, and one family directed at our porphyrin conjugates for treating cancer. One therapeutic patent application has been granted in China that expires in 2037 once registered in 2022.

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 United States, medical devices, including in vitro diagnostic products (“**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 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 will enter the U.S. market as an LDT. The FDA considers LDTs to be tests that are developed, validated and performed within a single laboratory. The FDA has historically taken the position that it has the authority to regulate LDTs as IVDs under the FDCA, but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose IVD regulatory requirements on LDTs, such as requirements to obtain premarket approval, authorization, or clearance, it has to date generally chosen not to enforce those requirements. Although the FDA has generally exercised enforcement discretion for LDTs, the FDA has asserted authority over LDTs when the FDA deems it appropriate to address significant public health concerns. Separately, CMS oversees clinical laboratory operations through the CLIA program.

Legislative proposals addressing the FDA’s oversight of LDTs have been previously introduced. In March 2020, the Verifying Accurate, Leading-edge IVCT Development Act of 2020 (the “**VALID Act**”) was introduced in the Senate, which proposes a regulatory framework for IVDs and LDTs and would require premarket approval for some in vitro clinical tests, including LDTs that are not currently reviewed by the FDA. The VALID Act was reintroduced in July 2021. In March 2020, the Verified Innovative Testing in American Laboratories Act of 2020 (the “**VITAL Act**”) was introduced in the Senate, which would expressly shift the regulation of LDTs from the FDA to CMS. The VITAL Act was reintroduced in May 2021. Neither statute has been enacted. The likelihood that Congress will pass the VALID Act, VITAL Act, or similar legislation, and the extent to which such legislation may affect the FDA’s plans to regulate LDTs as medical devices, by either giving the FDA explicit authority to do so or, alternatively, stating that the FDA does not have authority to regulate LDTs, is difficult to predict. It is possible that the FDA’s general policy of enforcement discretion for LDTs may be changed in the future, such that FDA clearance or approval of LDTs is required.

Clinical Laboratory Improvement Amendments of 1988

Clinical laboratories testing specimens collected in the United States 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 in effect laws 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: (i) approved a PMA application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification (a “**510(k) submission**”), generally applicable to some Class I and most II devices; or (iii) authorized the device to be marketed through the *de novo* classification process, generally applicable for novel low or moderate risk devices. PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of user fees.

510(k) Premarket Notification

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

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

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

De Novo Classification

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

The FDA has a user fee goal to review a *de novo* request in 150 calendar review days. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be as long as 330 days, and in practice may be longer. During the COVID-19 Public Health Emergency, applicants have been 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 has significantly increased the FDA’s workload because of the need to review emergency use authorization requests for IVDs and other regulated products, which has delayed review timelines for some non-COVID-19 products and is expected to continue to extend timelines during 2022.

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

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

Clinical Trials

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

Clinical trials must be conducted in accordance with good clinical practice (“*GCP*”) requirements contained in federal regulations and in international guidelines. Clinical trials, for both significant and nonsignificant risk devices, as well as exempt studies, must be approved by an institutional review board (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 the 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 United States, 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 United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (an “*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: (i) in compliance with federal regulations; (ii) in compliance with GCP requirements; as well as (iii) 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 United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the NDA submission.

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 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 (a “*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 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 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.

Pediatric Information

Under the Pediatric Research Equity Act (the “*PREA*”), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and

The Best Pharmaceuticals for Children Act (the “*BPCA*”) provides a six-month extension of any patent or non-patent exclusivity for a drug if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

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. 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 postmarketing 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 IVDR defines the necessary pre-conditions that must be fulfilled to CE mark an IVD test or in vitro medical device in the EU. The manufacture of the test and/or device must fulfill all applicable regulatory requirements in the IVDR. Objective evidence of fulfillment of these requirements must be provided by the manufacturer prior to placing a test on the EU market. The manufacturer is required to establish a Quality Management System (QMS) as well as processes for manufacturing, importing, distribution, post-market surveillance, and vigilance. Regulations also require that the product is fully documented. In addition, it is likely that our 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 6-12 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 (an “*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 it is based. In addition to the CE mark and the registration done by the EAR, there is a need for an administrative national notification with certain member states of the EU.

European Data Collection

The collection and use of personal data (including health data) in the European Economic Area (the “*EEA*”) are governed by the EU General Data Protection Regulations (the “*EU GDPR*”) and national implementing legislation in EEA Member States. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for “high risk” processing, limitations on retention of personal data, special provisions for “special categories of personal data” including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), “privacy by design” requirements, and direct obligations on service providers acting as processors. The EU GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EEA States may result in fines up to 20 million euros or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. Moreover, the EU GDPR affords various data protection rights to individuals (e.g., 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 United States, 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.

Our Employees

The Company places significant emphasis on the attraction, development and retention of its employees who include award-winning scientists dedicated to advancing scientific discovery from bench to bedside. Of the Company’s 11 employees, all of whom are employed full-time by the Company, six hold PhDs in biology or medicinal chemistry. Our Executive Vice President and Chief Medical and Science Officer, Vivienne Rebel, holds an MD and PhD. Business development is led by our Vice President of Operations, 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. The innovative and collaborative culture at bioAffinity is in part responsible for the high degree of retention and professional advancement. Most employees have been with the Company more than five years of its eight-year history. Outside partnership and collaborations that advance business and scientific research are encouraged, allowing the Company to multiply workforce efforts without expending significant capital.

Property

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 monthly licensing fee of

\$3,081. 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.

We rent additional corporate office space from WorkHub Elite Business Center (formerly known as WerkPlaats) pursuant to a membership agreement that is renewable on a yearly basis. Currently, we rent one office suite for a fee of \$1,200 per month.

We do not own any real property.

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.

See Note 9 to our Consolidated Financial Statements for information with respect to our lease commitments for the years ended December 31, 2021 and 2020.

Legal Proceedings

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

MANAGEMENT

Our executive officers, Board, and key employees as of August 3, 2022 are provided below, all of whom are expected to serve in the capacities listed below following the completion of this Offering.

Executive Officers and Board of Directors

Name	Age	Position	Director Since
Maria Zannes, J.D.	66	Founder, President, Chief Executive Officer and Director	March 2014
Vivienne Rebel, M.D., Ph.D.	58	Executive Vice President and Chief Science and Medical Officer	—
Michael Edwards, MBA, CPA	55	Chief Financial Officer	—
Timothy P. Zannes, J.D.	69	Executive Vice President, Secretary and General Counsel	—
Steven Girgenti	76	Executive Chairman and Director	March 2014
Robert Anderson	81	Director	March 2014
Stuart Diamond	61	Director	January 2022
Peter Knight	71	Director	May 2018
Mohsin Meghji	57	Director	July 2018
Gary Rubin	66	Director	October 2017

Executive Officers and Employee Directors

Maria Zannes. Ms. Zannes brings more than 30 years of executive-level management experience to her position as a Director and President and Chief Executive Officer of bioAffinity Technologies. As an attorney and businesswoman, she has successfully overcome obstacles that face emerging growth companies including taking biomedical discoveries from bench to bedside. Ms. Zannes is a founder who established bioAffinity Technologies in 2014 and built its team of award-winning scientists and business leaders advancing breakthrough oncology-focused diagnostics and therapeutics. 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. During that time, Ms. Zannes was CEO of Biomoda, Inc. when it filed under Chapter 11 of the U.S. Federal Bankruptcy code, March 2014, leading to successful reorganization and development of its biomedical technology. Ms. Zannes was President of the Energy Recovery Council, the national trade group for the \$10 billion waste-to-energy industry, where she worked closely with the Administration, the Congress and state legislators to advance industry goals. Earlier in her career, she was 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 and financed the Company's renewable energy generation facilities. Ms. Zannes began her career as a journalist, and 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 Waste-to-Energy Research and Technology Council of Columbia University. She is the co-founder of two engineering research centers at Columbia University. Ms. Zannes received her B.A. in Journalism from the University of New Mexico and her J.D. from the University of Puget Sound in Washington State. As a Director, Ms. Zannes brings her experience as a lawyer and businesswomen in working with the FDA and other federal and state agencies, as well as her skill in defining and advancing the Company's strategic goals.

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

Michael Edwards. Mr. Edwards has more than 25 years of extensive experience in corporate finance and accounting. Most recently, he was the CFO for CytoBioscience, Inc. 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 B.B.A. from The University of Texas at San Antonio and an MBA from The University of Texas McCombs School of Business.

Timothy P. Zannes. Mr. Zannes has been corporate legal counsel to both public and private biomedical firms for more than 16 years, having begun his legal career as a sole practitioner accepting criminal, business, family, and tort litigation. Prior to receiving his J.D., 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 J.D. 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. Mr. Girgenti is a veteran healthcare executive with a foundation of expertise in healthcare marketing strategies, financing, and mergers and acquisitions. He has been Executive Chairman of bioAffinity Technologies, Inc. since November 2014. He is presently the Managing Partner of Medi-Pharm Consulting, LLC, providing

strategic services to medical device, pharmaceutical, and diagnostic businesses. 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 until 2008, a leading global healthcare marketing services network with offices in 36 countries. 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. As Executive Chairman, Mr. Girgenti brings his unparalleled experience in the healthcare field, particularly in marketing, and his skill in building emerging growth companies into multi-national corporations.

Non-Employee Directors

Robert Anderson. 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. Later, 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 B.A. in political science from Rutgers University. As a Director, Mr. Anderson brings his experience and skill in marketing and product positioning of medical products to bioAffinity Technologies.

Stuart Diamond. 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 outcomes-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 B.S. from the State University of New York, a Master of Science, Taxation degree from Pace University, and an MBA from Fordham University. As a Director, Mr. Diamond brings his substantial business and financial acumen to his position as Chairman of the Audit Committee and to the Board.

Peter S. Knight. Mr. Knight is a Partner at Cyan Capital Partners, a fund dedicated to helping new fund managers and asset owners in the field of sustainable investing. Prior to that, Peter was a Founding Partner at Generation Investment Management, where with his partners Al Gore and David Blood he helped build a leading global sustainable investing firm with assets under management now exceeding \$30 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 non-profit 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 fund boards of Generation Investment Management and on the board of 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 on tropical forest nations. He received a B.A. from Cornell University and a J.D. from the Georgetown Law School. As a Director, Mr. Knight brings 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.

Mohsin Meghji. Mr. Meghji is a Managing Partner of M3 Partners L.P., a New York-based merchant banking firm. He is a nationally recognized U.S. turnaround professional with an exemplary track record of accomplishment across a wide range of industries. His 25+ year career has focused primarily on maximizing value for stakeholders. He has accomplished this through management and/or advisory roles in partnership with some of the world's leading financial institutions, private equity, and distressed hedge fund investors. Mr. Meghji serves as Chairman of the Board of Infrastructure & Energy Alternatives, Inc., one of the country's leading renewables-focused engineering and construction firms, which merged with a special purpose acquisition company sponsored by M3 Partners in March 2018 and is now listed on Nasdaq. Mr. Meghji's most recent corporate role was as Executive Vice President and Head of Strategy at Springleaf Holdings, LLC as well as CEO of its captive insurance companies. Springleaf was listed on the NYSE in late 2013. Meghji co-founded Loughlin Meghji + Company, a financial advisory firm which became one of the leading restructuring boutiques in the U.S. Earlier in his career, Meghji spent over 12 years with Arthur Andersen & Co. in the firm's London, Toronto, and New York offices as a Partner in the Global Corporate Finance group. He has served as a director on a number of corporate boards including Mariner Healthcare Inc, Cascade Timberlands, LLC, Dan River, Inc., and MS Resorts. He is a director of the Equity Group International Foundation, which provides funding for underprivileged high-potential students in Kenya. Previously, he served on the boards of The Children's Museum of Manhattan as well as HealthRight International from 2004 to 2012. In his capacity as a restructuring and financial advisory professional, Mr. Meghji has periodically served as an independent director or Chief Restructuring Officer (or in an analogous position) of companies which elected to utilize bankruptcy proceedings as a part of their financial restructuring process and, as such, he served as a director or executive officer of various companies which filed bankruptcy petitions under federal law. Mr. Meghji is a graduate of the Schulich School of Business, York University, Canada. He has previously qualified as a U.K. and Canadian Chartered Accountant as well as a U.S. Certified Turnaround Professional. As a Director, Mr. Meghji brings his exemplary track record in maximizing shareholder value and managing companies to achieve financial and business success.

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

Family Relationships

Except for the sibling relationship between Ms. Maria Zannes and Mr. Tim Zannes as stated above, there are no family relationships among any of our executive officers or directors.

Research Collaborator in the Development of CyPath® Lung Automated Analysis Platform

The development of the Company's automated analysis platform for flow cytometry was developed in collaboration with Dr. Madeleine Lemieux, a bioinformatician and computational biologist who worked closely with Dr. Vivienne Rebel, Executive Vice President and Chief Medical and Science Officer and our team of scientists. Dr. Lemieux has assigned all rights to her work on behalf of bioAffinity Technologies to the Company. She is compensated at an hourly rate for her services to the Company and has been awarded stock options in compensation for her work. Her biography is provided below.

Madeleine Lemieux, Ph.D. is a bioinformatics and computational biologist who received her doctorate from the Genetics Program, University of British Columbia, Vancouver, B.C., under the supervision of Dr. Connie J. Eaves at the Terry Fox Laboratory for Hematology/Oncology. She developed an *in vitro* assay to distinguish blood stem cells, capable of long-term production of both myeloid and lymphoid cells, from more committed hematopoietic progenitors, and then used the assay to determine how the bone-marrow-repopulating ability of these stem cells evolves in culture. Before starting her own firm, Dr. Lemieux worked for the Department of Pediatric Oncology, Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA, where she developed bioinformatics pipelines to analyze data from high-throughput platforms, including next-generation sequencing for ChIP-seq and RNA-seq as well as tiling and expression microarrays, and integrated these data with other large-scale information sources, such as gene ontology and protein-protein interaction networks, to both test hypotheses and generate testable predictions. During her time at Harvard, she also provided guidance in studies involving hematopoietic cells and, more generally, in experimental design and analysis to post-doctoral fellows and mentored two junior bioinformatics post-docs.

Science and Medical Advisory Board

The members of bioAffinity Technologies, Inc.'s Science and Medical Advisory Board (the "**SMAB**") are leaders in the field of lung cancer diagnostics and flow cytometry. The SMAB provides new insights and advice to solve business problems and explore new opportunities by stimulating robust, high-quality conversations and exchange of information. The SMAB provides current knowledge, critical thinking and analysis to increase the confidence of Management in its decision-making. SMAB members have executed agreements whose provisions assure their independence and provide compensation of \$2,500 per meeting for their time in attending meetings. SMAB members include:

Neil Alexis, Ph.D., Principal Investigator at the University of North Carolina School of Medicine Center for Environmental Medicine, Asthma and Lung Biology. Dr. Alexis focuses on the use of sputum as a primary sampling tool for measuring cellular, biochemical, and genetic outcomes in the human airway. Dr. Alexis is a leading expert in the use of flow cytometry in the analysis of sputum.

Catherine Sears, M.D., Assistant Professor of Medicine at Indiana University School of Medicine. Dr. Sears is a physician scientist whose laboratory focuses on the impact of DNA damage and repair on the development of smoking-related lung cancers and on treatment response. She co-chairs the pulmonary oncology and lung cancer screening programs at the Indianapolis VA Medical Center and her clinical and research interests focus on improving lung cancer screening and early lung cancer detection and treatment.

Gerard Silvestri, M.D., M.S., FCCP, Professor of Medicine and Lung Cancer Pulmonologist at the Medical University of South Carolina. Dr. Silvestri specializes in the evaluation, management, and improvement of outcomes in lung cancer patients. He has experience in evaluating new technologies for the diagnosis and staging of lung cancer. His research includes lung cancer screening, diagnosis, and staging.

David G. Hill, M.D., member of the Lung Association's National Board of Directors and immediate past chair of the Northeast Regional Board of the American Lung Association. Dr. Hill is a practicing pulmonary and critical care physician with Waterbury Pulmonary Associates and serves as their director of clinical research. He is an assistant clinical professor of medicine at the Yale University School of Medicine, an assistant clinical professor at the Frank Netter School of Medicine at Quinnipiac University, and a clinical instructor at the University of Connecticut School of Medicine. He has been the principal investigator for more than 75 pulmonary research trials and the author of many papers.

Board of Directors Composition

Our business and affairs are managed under the direction of our Board.

Current Board of Directors

Currently, our Board is authorized to have eight directors. Pursuant to our current Certificate of Incorporation, as amended and in effect prior to the completion of this Offering (our "Pre-IPO Charter"), and our current bylaws (our "Pre-IPO Bylaws"), Robert A. Anderson, Stuart Diamond, Steven Girgenti, Peter S. Knight, Mohsin Y. Meghji, Gary Rubin, and Maria Zannes have been designated to serve as members of our Board. Mr. Rubin serves on our Board as the Series A Representative elected separately by the holders of our Series A Preferred Stock pursuant to the Series A Director Designation Right. Following the automatic conversion of the Series A Preferred Stock shares into Common Stock immediately prior to the closing of this Offering, the Series A Director Designation Right will cease to exist because fewer than 30% of the Series A Preferred Stock shares will be outstanding. Mr. Rubin, however, 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 by the holders of the Common Stock following the conversion of the Series A Preferred Stock into Common Stock in connection with this Offering.

Each director on our current Board will continue to serve until such director's successor is duly elected and qualified, or until such director's earlier death, resignation, retirement, disqualification, or removal from office.

In connection with going public, we will amend and restate our Pre-IPO Charter and our Pre-IPO Bylaws, which will become effective immediately prior to the completion of this Offering (upon such effectiveness, the "**A&R Charter**" and the "**A&R Bylaws**," respectively). After this Offering, we expect that the A&R Charter will provide for the authorized number of directors to be fixed by our Board, subject to the terms of the A&R Charter and the A&R Bylaws. The forms of our A&R Charter and our A&R Bylaws will be filed as exhibits to the registration statement of which this prospectus is a part.

Committees of the Board

Our Board has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each operating pursuant to a charter adopted by our Board and having the composition and responsibilities described below. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002 and with the rules and regulations of Nasdaq and the SEC. In addition, from time to time, other committees may be established under the direction of our Board to facilitate the management of our business or when necessary to address specific issues.

The members of each of our committees will serve on such committees for such term or terms as the Board may determine or until their earlier removal, resignation, or death. At least annually, each committee must review its charter and recommend any proposed changes to the Board for approval. Each committee must conduct an annual evaluation of its performance of the duties described in the committee's charter and must present the results of the evaluation to the Board.

Audit Committee

Our audit committee consists of Stuart Diamond (Chairman), Mohsin Meghji and Gary Rubin. Our Board has determined that all members of our audit committee are independent in accordance with the requirements of Rule 10A-3 of the Exchange Act and the rules of the Nasdaq Capital Market. Our Board has also determined that Stuart Diamond and Gary Rubin are “audit committee financial experts” as defined in Item 407(d)(5)(ii) of Regulation S-K. All members of our audit committee are financially literate, as determined by our Board, and can read and understand fundamental financial statements, including the Company’s balance sheet, income statement, and cash flow statement.

Our audit committee is primarily responsible for overseeing our financial reporting and disclosure process. Among other matters, our audit committee has the following responsibilities:

- selecting, retaining, compensating, overseeing, and determining the retention of an independent registered public accounting firm to audit the Company’s annual financial statements, books, records, accounts, and internal controls over financial reporting and any other registered public accounting firm engaged to prepare or issue an audit report or to perform other audit, review, or attest services for the Company;
- approving all audit engagement fees and terms and pre-approving all audit and permitted non-audit and tax services that the Company’s independent auditors or other registered public accounting firms may provide;
- establishing policies and procedures for pre-approving permitted services to be completed by the Company’s independent auditors or other registered public accounting firms on an ongoing basis;
- reviewing and discussing the results of a report prepared by the Company’s independent auditors concerning the accounting firm’s internal quality-control procedures; any material issues raised by the most recent internal quality-control review, peer review, or review by the Public Company Accounting Oversight Board (the “PCAOB”); and all relationships between the firm and the Company or any of its subsidiaries;
- reviewing and discussing with the Company’s independent auditors and management the Company’s annual audited financial statements; the adequacy and effectiveness of the Company’s internal controls; and any other matters required to be discussed by the applicable requirements of the SEC the PCAOB;

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- evaluating the qualifications, performance, and independence of the Company’s independent auditors and assuring the regulator rotation of the lead audit partner;
- reviewing and discussing with the Company’s independent auditors the responsibilities of the auditors under generally accepted auditing standards; the overall audit strategy; the scope and timing of the annual audit; any significant risks identified during the auditors’ risk-assessment procedures; and the results of the annual audit;
- reviewing and discussing with the Company’s independent auditors all critical accounting policies and practices to be used in the audit; all alternative treatments of financial information within generally accepted accounting principles; and other material written communications between the auditors and management;
- reviewing and discussing with the Company’s independent auditors and management any major issues regarding accounting principles and financial-statement presentation;
- reviewing, approving, and overseeing any transaction between the Company and any related person (as defined in Item 404 of Regulation S-K) on an ongoing basis;
- informing the Company’s independent auditors of the Company’s significant relationships and transactions with related parties and reviewing and discussing with the Company’s independent auditors the auditors’ evaluation of the Company’s identification of, accounting for, and disclosure of its related-party relationships and transactions;
- recommending to the Board that the audited financial statements be included in the Company’s annual report on Form 10-K and producing the audit committee report required to be included in the Company’s proxy statement;
- setting the Company’s hiring policies for employees or former employees of the Company’s independent auditors that participated in any capacity in any Company audit;
- establishing and overseeing procedures for the receipt, retention, and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters;
- monitoring the Company’s compliance with, investigating any alleged breach of, and enforcing the Company’s Code of Business Conduct and Ethics;
- reviewing with the Company’s General Counsel and outside legal counsel any legal and regulatory matters that could impact the Company’s financial statements;
- retaining and obtaining the advice and assistance of independent outside counsel and such other advisors as the audit committee deems necessary to fulfill its duties and responsibilities; and
- reporting regularly to the Board on the audit committee’s discussion and actions, including any significant issues or concerns that arise at the audit committee meetings.

Compensation Committee

Our compensation committee consists of Peter Knight (Chairman), Stuart Diamond and Robert Anderson. Our Board has determined that each member of our compensation committee is independent in accordance with the rules of the Nasdaq Capital Market and the Company’s independence guidelines. Our compensation committee carries out the responsibilities delegated by the Board relating to the review and determination of executive compensation. In addition to other matters, our compensation committee is responsible for:

- reviewing and approving annually the corporate goals and objectives applicable to the compensation of the chief executive officer (the “CEO”); evaluating the CEO’s performance in light of those goals and objectives; and determining and approving the CEO’s compensation level based on the compensation committee’s evaluation;

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- reviewing and approving the compensation of all of the Company’s other executive officers;

- reviewing, making recommendations to the Board regarding, and administering the Company's incentive-compensation plans and equity-based plans, including designating the recipients, amounts, and terms and conditions applicable to the awards to be granted under each plan;
- reviewing and discussing with management the Company's Compensation Discussion and Analysis (the "**CD&A**"); recommending that the CD&A be included in the Company's annual report on Form 10-K and proxy statement; and producing the compensation committee report on executive-officer compensation required to be included in the Company's annual report on Form 10-K and proxy statement;
- reviewing the Company's incentive-compensation arrangements to assess whether they encourage excessive risk-taking and evaluating compensation policies and practices that could mitigate any such risk;
- reviewing and discussing at least annually the relationship between compensation and risk-management policies and practices;
- reviewing at least annually all director compensation and benefits for service on the Board and Board committees and recommending any changes to the Board as necessary;
- selecting, retaining, and obtaining the advice of a compensation consultant, outside legal counsel, and any other advisors as deemed necessary by the compensation committee to assist with the compensation committee's execution of its duties and responsibilities as set forth in its charter; and
- reporting regularly to the Board regarding the compensation committee's actions and making recommendations to the Board as appropriate.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Gary Rubin (Chairman), Peter Knight and Robert Anderson. Our Board has determined that each member of our nominating and corporate governance committee is independent in accordance with the rules of the Nasdaq Capital Market. Our nominating and corporate governance committee functions to carry out the responsibilities delegated by the Board relating to the Company's director-nominations process and the development and maintenance of the Company's corporate-governance policies. Among other matters, the responsibilities of our nominating and corporate governance committee include:

- identifying and screening individuals qualified to become members of the Board, consistent with Board-approved criteria;
- making recommendations to the Board concerning the selection and approval of director-nominees to be submitted to a stockholder vote at the annual meeting of stockholders, subject to the Board's approval;
- identifying and making recommendations to the Board regarding the selection and approval of candidates to fill any vacancy on the Board or any Board committee either by the stockholders' election or the Board's appointment;
- developing and recommending to the Board for approval standards for determining whether a director has a relationship with the Company that would impair the director's independence;
- selecting, retaining, and obtaining the advice of a director-search firm, outside counsel, and any other advisors deemed necessary to assist with the nominating and corporate governance committee's execution of its duties and responsibilities as set forth in its charter; and
- reporting regularly to the Board regarding the nominating and corporate governance committee's actions and making recommendations to the Board as appropriate.

Code of Ethics and Business Conduct

We have adopted a code of conduct applicable to our principal executive, financial and accounting officers and all persons performing similar functions. Upon the effectiveness of the registration statement of which this prospectus forms a part, our code of conduct will be available on our principal corporate website at www.bioaffinitytech.com. Information contained on our website or connected thereto does not constitute a part of, and is not incorporated by reference into, this prospectus or the registration statement of which it forms a part.

Limitations on Liability and Director and Officer Indemnification

Our A&R Charter will contain 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 A&R Charter and our A&R Bylaws will 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 A&R Charter will also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We believe that including the limitation of liability and indemnification provisions in our A&R 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.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. We face a number of risks, including those described under the section titled "Risk Factors" included in this prospectus. Our Board will play an active role in overseeing and managing our risks. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through its standing committees that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure. Our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements, in addition to

oversight of the performance of our external audit function. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee will be responsible for evaluating certain risks and overseeing the management of such risks, our full Board will be regularly informed of such risks through committee reports and otherwise. While the Board oversees our risk management, management is responsible for day-to-day risk management processes. We believe this division of responsibilities enables us to address our risks most effectively.

EXECUTIVE COMPENSATION

We are currently considered an “emerging growth company,” within the meaning of the Securities Act, for purposes of the SEC’s executive compensation disclosure rules. In accordance with such rules, we are required to provide a Summary Compensation Table and an Outstanding Equity Awards at Fiscal Year End Table, as well as limited narrative disclosures regarding executive compensation for our last completed fiscal year. Further, our reporting obligations extend only to our “named executive officers” (“NEOs”), meaning our principal executive officer and our next two most highly compensated executive officers in respect of their service to our Company at the end of the last completed fiscal year. Accordingly, our NEOs are:

- Maria Zannes, J.D.: President and Chief Executive Officer
- Vivienne I. Rebel, M.D., Ph.D., Executive Vice President and Chief Science and Medical Officer
- Steven Girgenti, Executive Chairman

Summary Compensation Table

The following table sets out the compensation for our NEOs for the years ended December 31, 2021 and 2020:

Name and Principal Position	Year	Salary	Bonus	Equity Awards ⁽¹⁾	All Other Compensation	Total Compensation
Maria Zannes, J.D. <i>President and Chief Executive Officer</i>	2021	\$ 220,000	\$ 0	\$ 42,593	\$ 7,196	\$ 269,789
	2020	\$ 220,000	\$ 0	\$ 49,695	\$ 16,280	\$ 285,975
Vivienne I. Rebel, M.D., Ph.D. <i>Executive Vice President and Chief Science and Medical Officer</i>	2021	\$ 225,000	\$ 0	\$ 13,200	\$ 11,590	\$ 249,790
	2020	\$ 225,000	\$ 0	\$ 15,116	\$ 12,196	\$ 252,312
Steven Girgenti <i>Executive Chairman</i>	2021	\$ 60,000 ⁽²⁾	\$ 30,000 ⁽³⁾	\$ 90,000 ⁽⁴⁾	\$ 0	\$ 180,000
	2020	\$ 60,000 ⁽²⁾	\$ 30,000 ⁽³⁾	\$ 90,000 ⁽⁴⁾	\$ 0	\$ 180,000

(1) Amounts do not reflect compensation actually received by the officer. Instead, the amounts represent aggregate grant date fair value of options 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 our Consolidated Financial Statements for the years ended December 31, 2021 and 2020.

(2) Pursuant to the terms of Mr. Girgenti’s employment agreement, Mr. Girgenti’s base salary is \$120,000/year and is paid one-half in cash and one-half in the form of a grant of restricted stock. The amount reported here is the cash portion of Mr. Girgenti’s base salary.

(3) Pursuant to the terms of Mr. Girgenti’s employment agreement, Mr. Girgenti’s bonus is paid one-half in cash and one-half in the form of a grant of restricted stock. Mr. Girgenti was awarded a bonus of \$60,000 in each of 2020 and 2021, and the amount reported here is only the cash portion of Mr. Girgenti’s bonus.

(4) Pursuant to the terms of Mr. Girgenti’s employment agreement, Mr. Girgenti’s base salary and bonus are paid one-half in cash and one-half in the form of a grant of restricted stock. The amount reported here reflects the stock portion of Mr. Girgenti’s base salary (\$60,000) and the stock portion of his bonus (\$30,000).

Base Salaries

We use base salaries to recognize the experience, skills, knowledge, and responsibilities required of all our employees, including our 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 2020 and 2021, the annual base salaries of our NEOs were: \$220,000 for Ms. Zannes; \$225,000 for Dr. Rebel; and \$120,000 for Mr. Girgenti.

Retirement Plans

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

Employee Benefits

The Company’s Named Executive Officers are eligible to participate in employee benefit plans and programs, including medical and dental benefit plans.

Other Elements of Compensation

Employment Agreements

The following discussion contains a summary of the terms of the Named Executive Officer 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 our Chief Executive Officer and is entitled to an annual base salary of \$220,000. 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.

Rebel Employment Agreement

The Company entered into an employment agreement with Dr. Rebel on April 4, 2016, which sets forth the terms and conditions of her employment (the “Rebel Agreement”). Pursuant to the Rebel Agreement, Dr. Rebel serves as our Executive Vice President of Research and Development and Chief Medical and Science Officer and is entitled to an annual base salary of \$225,000 currently. The Rebel Agreement may be terminated by either party at any time, provided that Dr. Rebel is required to give the Company at least 90 days advance notice of termination.

In the event the Company terminates Dr. Rebel’s employment without “Cause” (as defined in the Rebel 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.

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 our 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. In addition, Mr. Girgenti has been awarded a bonus in 2019 and 2020 in the amount of \$60,000 of which one-half is paid in cash and one-half is paid in the form of restricted stock grants. The cash portion of his compensation and bonus 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.

Grants of Plan-Based Awards

The following table presents information regarding each grant of a plan-based award made to an NEO under the Company’s 2014 Equity Incentive Plan during the year ended December 31, 2021:

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards
		Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (#)	Target (#)	Maximum (#)				
Maria Zannes	7/26/2021	—	—	—	—	—	—	—	7,142 ⁽¹⁾	\$ 7.70	\$ 14,112
	7/26/2021	—	—	—	—	—	—	3,571 ⁽²⁾	—	—	\$ 10,999
	12/16/2021	—	—	—	—	—	—	—	7,142 ⁽³⁾	\$ 4.20	\$ 17,482
Vivienne I. Rebel	7/26/2021	—	—	—	—	—	—	4,285 ⁽⁴⁾	—	—	\$ 13,198
Steven Girgenti	2/19/2021	—	—	—	—	—	—	3,896 ⁽⁵⁾	—	—	\$ 19,636
	12/16/2021	—	—	—	—	—	—	—	7,142 ⁽⁶⁾	\$ 4.20	\$ 17,482
	12/31/2021	—	—	—	—	—	—	14,285 ⁽⁷⁾	—	—	\$ 59,997

- (1) This option vests in 36 equal monthly installments beginning on August 26, 2021.
- (2) This is a restricted stock award that vests in 36 equal monthly installments beginning on August 26, 2021.
- (3) This option vests in 12 equal monthly installments beginning on January 16, 2022.
- (4) This is a restricted stock award that vests in 12 equal monthly installments beginning on August 26, 2021.
- (5) This is a restricted stock award that vests upon the earlier of (i) February 19, 2024, (ii) a change of control of the Company, or (iii) upon termination of Mr. Girgenti’s employment without Cause (as defined in the Girgenti Agreement).
- (6) This option vests in 12 equal monthly installments beginning on January 16, 2022.
- (7) This is a restricted stock award that vests upon the earlier of (i) December 31, 2024, (ii) a change of control of the Company, or (iii) upon termination of Mr. Girgenti’s employment without Cause (as defined in the Girgenti Agreement).

Outstanding Equity Awards as of December 31, 2021

The following table presents information regarding outstanding equity awards held by our NEOs as of December 31, 2021:

Option Awards	Stock Awards
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Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock that Have Not Vested (#)	Market Value of Shares of Stock that Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units, or Other Rights that Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units, or Other Rights that Have Not Vested (\$)
Maria Zannes	64,848	0	0	\$ 1.155	4/28/2024	—	—	—	—
	3,571	0	0	\$ 4.20	7/27/2025	—	—	—	—
	3,571	0	0	\$ 7.00	7/25/2026	—	—	—	—
	3,571	0	0	\$ 7.00	4/24/2027	—	—	—	—
	7,142	0	0	\$ 7.70	5/7/2028	—	—	—	—
	2,857	0	0	\$ 7.70	2/25/2029	—	—	—	—
	7,142	0	0	\$ 7.70	7/29/2029	—	—	—	—
	7,142	0	0	\$ 7.70	2/5/2030	—	—	—	—
	7,142	0	0	\$ 7.70	7/27/2030	—	—	—	—
	1,189	5,953	0	\$ 7.70	7/26/2031	—	—	—	—
	595	6,547	0	\$ 4.20	12/16/2031	—	—	—	—
	—	—	—	—	—	3,076	\$ 12,919	0	\$ 0
Vivienne I. Rebel	2,857	0	0	\$ 7.00	7/25/2026	—	—	—	—
	2,857	0	0	\$ 7.70	4/24/2027	—	—	—	—
	4,285	0	0	\$ 7.70	2/25/2029	—	—	—	—
	4,285	0	0	\$ 7.70	2/5/2030	—	—	—	—
	—	—	—	—	—	2,500	\$ 10,500	0	\$ 0
Steven Girgenti	64,848	0	0	\$ 1.155	4/28/2024	—	—	—	—
	3,571	0	0	\$ 4.20	7/27/2025	—	—	—	—
	3,571	0	0	\$ 7.00	7/25/2026	—	—	—	—
	3,571	0	0	\$ 7.00	4/24/2027	—	—	—	—
	7,142	0	0	\$ 7.70	5/7/2028	—	—	—	—
	7,142	0	0	\$ 7.70	7/29/2029	—	—	—	—
	7,142	0	0	\$ 7.70	7/27/2030	—	—	—	—
	595	6,547	0	\$ 4.20	12/16/2031	—	—	—	—
	—	—	—	—	—	3,896	\$ 16,363	0	\$ 0
	—	—	—	—	—	14,285	\$ 59,997	0	\$ 0
	—	—	—	—	—	3,896	\$ 16,363	0	\$ 0
	—	—	—	—	—	7,792	\$ 32,726	0	\$ 0

Director Compensation

Our Board intends to adopt a compensation plan for independent directors following the consummation of this Offering, pursuant to which each independent director will be compensated for services as a director of the Company.

For the year ended December 31, 2021, our independent directors did not receive any cash compensation for their services.

On December 16, 2021, we issued 7,142 options to each of Robert Anderson, Steven Girgenti, Peter Knight, Mohsin Meghji, Gary Rubin, and Maria Zannes. The new options vest in 12 equal monthly installments, have a \$4.20 exercise price, and expire on December 16, 2031. On March 17, 2022, we issued 7,142 options to Stuart Diamond. The new options vest in 12 equal monthly installments, have a \$4.20 exercise price, and expire on March 17, 2032.

Independent Director Compensation

The following table sets forth the compensation of our independent directors for the year ended December 31, 2021:

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Robert Anderson	0	0	17,482	0	0	0	17,482
Stuart Diamond	0	0	0	0	0	0	0
Peter Knight	0	0	17,482	0	0	0	17,482
Mohsin Meghji	0	0	17,482	0	0	0	17,482
Gary Rubin	0	0	17,482	0	0	0	17,482

PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us regarding the beneficial ownership of Common Stock as of August 3, 2022 by:

- each person known by us to be the beneficial owner of more than 5% of outstanding Common Stock;
- each of our executive officers and directors; and
- all of our 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 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 would vest based on service-based vesting conditions within 60 days of August 3, 2022. These shares were not deemed outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

We are aware that 14 of our current stockholders have indicated an interest in purchasing Units in this Offering and we currently anticipate they may purchase approximately

10.66% of the Units in this Offering, assuming that the underwriters will not exercise the Over-Allotment Option. There is no ceiling on the amount of securities that may be purchased by any of the Company's current stockholders. Our current stockholders who have indicated an interest in purchasing Units in this Offering include the following individuals and entities appearing in the table below: Maria Zannes, Steven Girgenti, Robert Anderson, Stuart Diamond, Peter Knight, and the Harvey Sandler Revocable Trust. The amount of Units that each of these individuals have indicated they are interested in purchasing is included in the number of shares of Common Stock and the percentage of class they will own after this Offering and is set forth in the footnotes.

The beneficial ownership of our Common Stock is based on 2,727,583 shares of our Common Stock outstanding as of August 3, 2022, including 33,124 shares of unvested restricted stock units.

Unless otherwise indicated, we believe 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 him.

Name and Address of Beneficial Owners⁽¹⁾	Number of Shares of Common Stock	Percent of Class	Number of Shares of Common Stock After this Offering	Percent of Class Owned After Offering⁽²⁾
Directors and Executive Officers:				
Maria Zannes ⁽³⁾	118,689	4.18%	126,852 ⁽¹⁵⁾	1.71%
Vivienne Rebel ⁽⁴⁾	21,426	0.78%	21,426	0.29%
Steven Girgenti ⁽⁵⁾	1,334,840	35.17%	1,375,656 ⁽¹⁶⁾	17.53%
Michael Edwards ⁽⁶⁾	44,196	1.61%	44,196	0.60%
Timothy Zannes ⁽⁷⁾	76,987	2.75%	76,987	1.04%
Robert Anderson ⁽⁸⁾	102,343	3.62%	106,424 ⁽¹⁷⁾	1.44%
Stuart Diamond ⁽⁹⁾	3,570	0.13%	7,651 ⁽¹⁸⁾	0.10%
Mohsin Meghji ⁽¹⁰⁾	89,118	3.20%	89,118	1.22%
Peter Knight ⁽¹¹⁾	41,067	1.49%	49,230 ⁽¹⁹⁾	0.67%
Gary Rubin ⁽¹²⁾	2,235,139	54.37%	2,251,465 ⁽²⁰⁾	30.59%
All Directors and Executive Officers as a Group (10 individuals)	4,067,375	72.69%	4,149,005	50.18%
Five Percent Holders:				
The Harvey Sandler Revocable Trust ⁽¹³⁾	2,136,150	52.77%	2,152,476 ⁽²¹⁾	27.30%
Nathan Perlmutter ⁽¹⁴⁾	494,789	16.19%	494,789	6.62%

(1) Unless otherwise indicated, the address for each person is c/o bioAffinity Technologies, Inc., 22211 W Interstate 10, Suite 1206, San Antonio, Texas, 78257.

- (2) Based on 7,311,970 shares after the completion of this Offering, assuming the Tradeable and Non-tradeable Warrants underlying the Units and the Underwriters' Over-Allotment Option are not exercised.
- (3) Includes (i) 3,571 shares of Common Stock issued to Ms. Zannes as restricted stock; and (ii) 115,118 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$3.64 per share granted to Ms. Zannes that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (4) Includes (i) 7,142 shares of Common Stock issued to Dr. Rebel as restricted stock; and (ii) 14,284 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$7.56 per share granted to Dr. Rebel that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (5) Includes (i) 219,411 shares of Common Stock owned directly by Mr. Girgenti of record; (ii) 29,870 shares of Common Stock issued to Mr. Girgenti as restricted stock; (iii) 138,993 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Girgenti of record; (iv) 393,634 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Girgenti; (v) 309,538 shares of Common Stock underlying warrants with a term of five years having an exercise price equal to the initial Offering Price in this Offering; (vi) 123,811 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share; (vii) 102,343 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$3.164 per share granted to Mr. Girgenti that are either immediately exercisable or exercisable within 60 days of this prospectus; (viii) 1,298 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned by the Cranye Girgenti Testamentary Trust, for which Mr. Girgenti serves as trustee; (ix) 7,613 shares of Common Stock issuable upon conversion of convertible promissory notes held by the Cranye Girgenti Testamentary Trust; and (x) 5,952 shares of Common Stock underlying warrants having an exercise price equal to the initial Offering Price in this Offering held by the Cranye Girgenti Testamentary Trust; and (xi) 2,380 shares of Common Stock underlying warrants having an exercise price of \$5.25 per share held by the Cranye Girgenti Testamentary Trust.
- (6) Includes (i) 27,875 shares of Common Stock owned directly by Mr. Edwards of record; (ii) 2,229 shares of Common Stock issuable upon conversion of a convertible promissory note held directly by Mr. Edwards; (iii) 1,903 shares of Common Stock underlying a warrant with a term of five years having an exercise price equal to the initial Offering Price in this Offering; (iv) 761 shares of Common Stock underlying a warrant with a term of five years having an exercise price of \$5.25 per share; and (v) 11,428 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$7.70 per share granted to Mr. Edwards that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (7) Includes 76,987 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$2.121 per share granted to Mr. Zannes that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (8) Includes 102,343 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$3.164 per share granted to Mr. Anderson that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (9) Includes 3,570 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$4.20 per share granted to Mr. Diamond that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (10) Includes (i) 28,571 shares of Common Stock owned directly by Mr. Meghji of record; (ii) 40,907 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Meghji of record; and (iii) 19,640 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$7.308 per share granted to Mr. Meghji that are either immediately exercisable or exercisable within 60 days of this prospectus.
- (11) Includes (i) 14,285 shares of Common Stock owned directly by Mr. Knight of record; and (ii) 26,782 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$7.434 per share granted to Mr. Knight that are either immediately exercisable or exercisable within 60 days of this prospectus.

- (12) Includes (i) 35,714 shares of Common Stock owned directly by Mr. Rubin of record; (ii) 15,785 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Rubin; (iii) 12,241 shares of Common Stock underlying warrants with a term of five years having an exercise price equal to the initial Offering Price in this Offering; (iv) 4,896 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share; (v) 30,353 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of \$7.469 per share granted to Mr. Rubin that are either immediately exercisable or exercisable within 60 days of this prospectus; (vi) 816,016 shares of Common Stock owned by the Harvey Sandler Revocable Trust, for which Mr. Rubin serves as co-trustee; (viii) 230,309 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned by the Harvey Sandler Revocable Trust; (ix) 518,452 shares of Common Stock issuable upon conversion of convertible promissory notes held by the Harvey Sandler Revocable Trust; (x) 408,125 shares of Common Stock underlying warrants with a term of five years having an exercise price equal to the initial Offering Price in this Offering held by the Harvey Sandler Revocable Trust; and (xi) 163,248 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share held by the Harvey Sandler Revocable Trust.
- (13) Includes (i) 816,016 shares of Common Stock owned directly by the Trust of record; (ii) 230,309 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by the Trust of record; (iii) 518,452 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by the Trust; (iv) 408,125 shares of Common Stock underlying warrants with a term of five years having an exercise price equal to the initial Offering Price in this Offering; and (v) 163,248 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25 per share held by the Trust. Mr. Gary Rubin, as co-trustee of the Trust, may be deemed to beneficially own and to exercise voting or dispositive control over the Common Stock held by the Trust.
- (14) Includes (i) 166,089 shares of Common Stock owned directly by Mr. Perlmutter of record; (ii) 14,811 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Perlmutter of record; (iii) 146,115 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Perlmutter; (iv) 119,839 shares of Common Stock underlying warrants with a term of five years having an exercise price equal to the initial Offering Price in this Offering; and (v) 47,935 shares of Common Stock underlying warrants with a term of five years having an exercise price of \$5.25.
- (15) Includes 8,163 shares of Common Stock that Ms. Zannes has indicated an interest to purchase in this Offering.
- (16) Includes 40,816 shares of Common Stock that Mr. Girgenti has indicated an interest to purchase in this Offering.
- (17) Includes 4,081 shares of Common Stock that Mr. Anderson has indicated an interest to purchase in this Offering.
- (18) Includes 4,081 shares of Common Stock that Mr. Diamond has indicated an interest to purchase in this Offering.
- (19) Includes 8,163 shares of Common Stock that Mr. Knight has indicated an interest to purchase in this Offering.
- (20) Includes 16,326 shares of Common Stock that the Harvey Sandler Revocable Trust, for which Mr. Rubin serves as co-trustee, has indicated an interest to purchase in this Offering.
- (21) Includes 16,326 shares of Common Stock that the Harvey Sandler Revocable Trust has indicated an interest to purchase in this Offering. Mr. Gary Rubin, as co-trustee of the Trust, may be deemed to beneficially own and to exercise voting or dispositive control over the Common Stock held by the Trust.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements with directors and executive officers described under “Executive Compensation,” the following is a description of each transaction since January 1, 2020 and each currently proposed transaction in which:

- the Company has been or is to be a participant;
- the amount involved exceeds or will exceed one percent of the average of the Company’s total assets at year end for 2020 and 2021 (or \$7,994.57); and
- any of the Company’s directors, executive officers or beneficial holders of more than 5% of the Company’s capital stock, or any immediate family member of, or person sharing the household with, any of these individuals (other than tenants or employees), had or will have a direct or indirect material interest.

Edwards Note

On June 12, 2020, Michael Edwards purchased a convertible promissory note from the Company with a principal amount of \$7,995. The note bears interest at 8% per annum and matures on October 31, 2022. The unpaid principal and accrued interest under the note may be converted into shares of the Company’s Common Stock at a conversion price of \$4.20 per share. The note will automatically convert into approximately 2,229 shares of Common Stock upon the completion of this Offering based on the outstanding principal balance and accrued and unpaid interest under such note as of August 3, 2022 at a conversion price of \$4.20 per share. On July 25, 2022, Mr. Edwards agreed to extend the maturity date of his note to October 31, 2022, on the same terms provided to all other convertible noteholders in exchange for the Company’s issuance to him of a warrant to purchase 761 shares of Common Stock at an exercise price equal to \$5.25 per share.

Perlmutter Note

On October 22, 2020, Nathan Perlmutter purchased a convertible promissory note from the Company with a principal amount of \$100,000. The note bears interest at 8% per annum and matures on October 31, 2022. The unpaid principal and accrued interest under the note may be converted into shares of the Company’s Common Stock at a conversion price of \$4.20 per share. The note will automatically convert into approximately 27,201 shares of Common Stock upon the completion of this Offering based on the outstanding principal balance and accrued and unpaid interest under such note as of August 3, 2022 at a conversion price of \$4.20 per share. On July 25, 2022, Mr. Perlmutter agreed to extend the maturity date of his note to October 31, 2022, on the same terms provided to all other convertible noteholders in exchange for the Company’s issuance to him of a warrant to purchase 47,935 shares of Common Stock at an exercise price equal to \$5.25 per share.

Girgenti Notes

Steven Girgenti purchased the following convertible promissory notes from the Company on the dates, in the amounts and with the maturity dates set forth in the table below:

Date of Promissory Note	Principal Amount	Maturity Date	Approximate Number of Shares of Common Stock Expected to Be Issued from Automatic Conversion upon Completion of this Offering ⁽¹⁾
October 22, 2020	\$ 100,000.00	October 31, 2022	27,201
October 26, 2020	\$ 17,957.23	October 31, 2022	4,880
January 13, 2021	\$ 10,000.00	October 31, 2022	2,676
March 10, 2021	\$ 50,000.00	October 31, 2022	13,238

March 24, 2021	\$	40,000.00	October 31, 2022	10,561
June 8, 2021	\$	150,000.00	October 31, 2022	39,009
July 3, 2021	\$	60,000.00	December 31, 2022	15,525
Total	\$	427,957.23		113,090

- (1) The number of shares of the Company's Common Stock expected to be issued upon the automatic conversion of Mr. Girgenti's notes upon the completion of this Offering is based on the outstanding principal balance and accrued and unpaid interest under such notes as of August 3, 2022 at a conversion price of \$4.20 per share.

All of the notes bear interest at 8% per annum. The unpaid principal and accrued interest under the notes may be converted into shares of the Company's Common Stock at a conversion price of \$4.20 per share. The notes will automatically convert into shares of the Company's Common Stock upon the completion of this Offering. On July 25, 2022, Mr. Girgenti agreed to extend the maturity date of his notes to October 31, 2022, on the same terms provided to all other convertible noteholders in exchange for the Company's issuance to him of a warrant to purchase 123,811 shares of Common Stock at an exercise price equal to \$5.25 per share.

Policies and Procedures for Related Party Transactions

Our Board has adopted a written Code of Business Conduct, which includes a conflict of interest or related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related-person transactions. In reviewing and approving any such transactions, our General Counsel and Board are tasked to consider all relevant facts and circumstances. The Code of Business Conduct will be available on our website. We intend to disclose any amendments to the Code of Business Conduct, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements.

Director and Officer Indemnification

We anticipate that our A&R Charter and our A&R Bylaws, which will become effective immediately prior to the completion of this Offering, will provide indemnification for our directors and officers to the fullest extent permitted by the DGCL, subject to certain limited exceptions. We currently have directors' and officers' liability insurance as a private company for each of our directors and executive officers, and we have applied for directors' and officers' liability insurance to hold as a public company. See "Management—Limitations on Liability and Indemnification of Officers and Directors."

DESCRIPTION OF SECURITIES

We are offering Units in this Offering at an initial offering price within the Price Range of \$6.00 and \$6.25. The assumed Offering Price for purposes of this prospectus is \$6.125 per Unit, which is the midpoint of the Price Range. Each Unit consists of one share of our Common Stock, one five-year Tradeable Warrant to purchase one share of our Common Stock at an exercise price equal to \$7.35, which is 120% of the assumed Offering Price per Unit, and one Non-tradeable Warrant to purchase one share of our Common Stock at an exercise price equal to \$7.656, which is 125% of the assumed Offering Price per Unit. The Units will not be certificated or issued in stand-alone form. The shares of our Common Stock and the Warrants underlying the Units are immediately separable upon issuance and will be issued separately in this Offering. We are also registering the shares of Common Stock issuable upon exercise of the Warrants. These securities are being issued pursuant to an underwriting agreement between us and the underwriters. You should review the underwriting agreement, the form of Tradeable Warrant, and the form of Non-tradeable Warrant, each filed as exhibits to the registration statement of which this prospectus is a part, for a complete description of the terms and conditions applicable to the Warrants.

General

The following summary describes the material terms of our capital stock and provisions of our A&R Charter and our A&R Bylaws, as amended and in effect upon the completion of this Offering. This summary does not purport to be complete and is qualified in its entirety by reference to all of the provisions of our A&R Charter and our A&R Bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

Our Board of Directors and stockholders approved an amendment to our Certificate of Incorporation to effect a 1-for-7 reverse stock split of our Common Stock in connection with this Offering. As a result of the reverse stock split every seven shares of our outstanding Common Stock was combined and reclassified into one share of our Common Stock. No fractional shares were issued in connection with the reverse stock split, and any of our stockholders that were entitled to receive a fractional share as a result of the reverse stock split instead received cash in lieu of a fractional share valued at the per-Unit price of this Offering. The reverse stock split became effective on June 23, 2022 prior to the effective date of the registration statement of which this prospectus is a part. The reverse stock split was intended to allow us to meet the minimum share price requirement of the Nasdaq Capital Market. All share numbers in this prospectus have been adjusted to give effect to this reverse stock split.

Authorized Capital Stock

We are currently authorized to issue up to 14,285,714 shares of Common Stock, par value \$0.007 per share, and 20,000,000 shares of Preferred Stock, par value \$0.001 per share.

As of August 3, 2022, there were 2,727,583 shares of Common Stock, including 34,670 shares of unvested restricted stock units issued and outstanding that were held of record by 46 stockholders. As of August 3, 2022, there were 5,296,044 shares of Preferred Stock outstanding that were held of record by 40 stockholders. As permitted by the Company's Certificate of Incorporation, 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 5,296,044 shares are outstanding.

In accordance with Section 3(B)(ii) of the Certificate of Designation of the Series A Preferred Stock, all of the issued and outstanding shares of Series A Preferred Stock will be automatically converted into fully paid and nonassessable shares of Common Stock at the then-effective conversion rate of the Series A Preferred Stock immediately prior to the closing of this Offering. 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.

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 holders of Series A Preferred Stock are entitled to receive dividends when, as, and if declared by the Board, out of any assets legally available for dividends, prior and in preference to any declaration or payment of any dividend (payable other than in Common Stock or other securities or rights convertible into, or entitling the holder thereof to receive directly or indirectly, additional shares of Common Stock) on the Company's Common Stock at the rate of 8% per share (as adjusted for any stock dividend, stock split, or combination with respect to such share) per annum. The right to receive dividends on Series A Preferred Stock is not cumulative. Upon conversion of Series A Preferred Stock, all dividends declared but unpaid on such share must be paid in cash and/or shares of the Company's Common Stock.

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.

Subject to applicable law, our Pre-IPO Charter, and preferences that may apply to any shares of Preferred Stock outstanding at the time, the Common Stock holders are entitled to receive dividends out of funds legally available therefor as may be declared by the Board at any regular or special meeting of the Board. Any such dividends may be paid in cash, in property, or in shares of the Company's capital stock, unless otherwise provided by applicable law or our Pre-IPO Charter. The Board is not obligated to declare a dividend and has never declared or paid cash dividends on our capital stock. We do not anticipate paying dividends on our Common Stock for the foreseeable future. See "Description of Securities—Dividend Policy" below.

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.

Warrants

Warrants to Be Issued in the Offering

Overview. The following summary of certain terms and provisions of the Warrants included in the Units offered 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 forms of Tradeable Warrant and Non-tradeable Warrant, all of which are filed as exhibits to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the Warrant Agent Agreement, including the annexes thereto, and forms of Warrants. The Tradeable Warrant and the Non-tradeable Warrant have identical terms except that (i) unlike the Non-tradeable Warrant, the Tradeable Warrant is tradeable and, pending the approval of our Nasdaq listing application, will be listed on the Nasdaq Capital Market, and (ii) the exercise price per share of Common Stock is \$7.35 for the Tradeable Warrant and \$7.656 for the Non-tradeable Warrant.

Exercisability. The Warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder of a Warrant may, in its sole discretion, elect to exercise the Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the Warrant.

Exercise Limitation. A holder of a Warrant will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 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 Warrants.

Exercise Price. The exercise price per whole share of Common Stock purchasable upon exercise of (i) the Tradeable Warrants is \$7.35 per share, which is 120% of the assumed Offering Price of the Units, and (ii) the Non-tradeable Warrants is \$7.656 per share, which is 125% of the assumed Offering Price of the Units. The exercise price of both the Tradeable Warrants and the Non-tradeable Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Fractional Shares. No fractional shares of Common Stock will be issued upon exercise of the Warrants. If, upon exercise of a Warrant, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, pay a cash adjustment in respect of such fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share. If multiple Warrants are exercised by the holder at the same time, we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

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

Exchange Listing. We have applied for listing of our Common Stock and the Tradeable Warrants on The Nasdaq Capital Market under the symbols "BIAF," and "BIAFW," respectively. No assurance can be given that our listing application will be approved.

Warrant Agent; Global Certificate. The Warrants will be issued in registered form under a Warrant Agent Agreement between the Warrant Agent and us. The Tradeable Warrants shall initially be represented only by one or more global warrants deposited with the Warrant Agent, as custodian on behalf of The Depository Trust Company ("**DTC**") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. The Non-tradeable 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 Transactions. In the event of a fundamental transaction, as described in the 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 more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction.

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

Cashless Exercise. If at the time of exercise there is no effective registration statement registering the issuance of the Warrant Shares, the Warrant shall only be exercisable on a cashless basis. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments or net cash settlement to the Warrantholder in lieu of delivery of the Warrant Shares. Upon a "cashless exercise," the Warrantholder shall be entitled to receive the number of Warrant Shares equal to the quotient obtained by dividing (A-B) (X) by (A), where:

(A) = the last VWAP immediately preceding the date of exercise giving rise to the applicable "cashless exercise," as set forth in the applicable Election to Purchase (to clarify,

the “last VWAP” will be the last VWAP as calculated over an entire trading day such that, in the event that the Warrant is exercised at a time that the trading market is open, the prior trading day’s VWAP shall be used in this calculation);

(B) = the Exercise Price of the Warrant, as adjusted as set forth herein; and

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

Governing Law; and Exclusive Forum. The Warrants and the Warrant Agent Agreement are governed by New York law. The warrant certificates governing the Tradeable Warrants and the Non-tradeable Warrants provide that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by the warrant certificate (whether brought against a party to the warrant certificate or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. 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.

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Placement Agent’s Warrant

In connection with the sale of our convertible bridge notes, we will pay commissions of nine percent (9.0%) on the gross proceeds from the sale of convertible bridge notes made to parties introduced to the Company by the Placement Agent and will issue the Placement Agent’s Warrant to the Placement Agent to purchase 29,464 shares of our Common Stock. The Placement Agent’s Warrant will have substantially the same terms as the warrants issued to our noteholders, but will have an exercise price per share equal to 120% of the initial Offering Price of one Unit in this Offering. The Placement Agent’s Warrant will have a five-year term commencing 180 days after the commencement of the sale of the Units in this Offering.

Representative’s Warrant

As additional compensation to the underwriters, upon consummation of this Offering, we will issue to the Representative or its designees a non-redeemable Representative’s Warrant to purchase an aggregate number of shares of our Common Stock equal to two percent (2.0%) of the number of shares of Common Stock underlying the Units issued in this Offering, at an exercise price per share equal to 115% of the assumed Offering Price, which may be via a “cashless exercise.” If more than twenty-five percent (25%) of the shares offered hereby are sold to existing investors, then the Representative’s Warrant will cover only two and one-half percent (2.5%) of the number of shares of Common Stock purchased by the existing investors.

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The Representative’s Warrant will be exercisable, in whole or in part, commencing on the six-month anniversary of the commencement of the sales of the public securities in this Offering and will expire on the fifth anniversary of the effective date of the registration statement related to the Offering. In addition, we have granted the underwriters the ability to exercise them in a “cashless” manner, a one-time demand registration right at our expense, an additional demand registration at the holder’s expense, and unlimited “piggyback” registration rights with respect to the underlying shares. See “Underwriting—Representative’s Warrant.”

Series A Preferred Stock

The Company has designated 5,400,000 shares of our Preferred Stock as Series A Preferred Stock. Holders of shares of the Series A Preferred Stock are entitled to receive dividends, in preference to any declaration or payment of a dividend to holders of the Common Stock, of 8% per share per annum when, as and if declared by the Board. Such dividends are not cumulative. See “Description of Securities—Dividend Policy” below.

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.

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 IPO 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. We expect that holders of a more than a majority of our outstanding shares of Series A Preferred Stock will execute a written consent so that all of the issued and outstanding shares of Series A Preferred Stock will be automatically converted into fully paid and nonassessable shares of Common Stock immediately prior to the closing of this 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.

Holders of the shares of Series A Preferred Stock have the right to one vote for each share of Common Stock into which such Series A Preferred Stock could then be converted. In addition, for so long as 30% of the shares of Series A Preferred Stock remain outstanding, the Series A Preferred Stock holders, voting together as a single class, may exercise the Series A Director Designation Right, pursuant to which they are entitled to elect one director of the Company as the Series A Representative. Any Series A Representative elected by the holders of Series A Preferred Stock may be removed from office only by the Series A Preferred Stock holders, 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.

Following the automatic conversion of the Series A Preferred Stock shares into Common Stock immediately prior to the closing of this Offering, the Company will never again issue the shares so converted, and all such converted shares will cease to be part of the Company’s authorized stock. Furthermore, the Series A Director Designation Right will cease to exist because fewer than 30% of the Series A Preferred Stock shares will be outstanding. The director who currently serves as the Series A Representative 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 in connection with this Offering.

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.

Convertible Bridge Notes and Warrants

In the fourth quarter of 2021 and the first quarter of 2022, the Company issued a total of \$2.4 million in bridge notes convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bear interest at six percent (6%). Additionally, each noteholder will receive a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to \$5.25 per share. With one exception, the convertible bridge notes were amended in May 2022 to have a maturity date of August 31, 2022. The maturity date of one note with a principal amount of \$100,000 was not extended and has been repaid in full. In July 2022, all but six of the bridge notes with an aggregate principal amount of \$325,000 were further amended to have a maturity date of October 31, 2022. As consideration for the maturity-date extension, each noteholder received a warrant with a term of five years to purchase that number of shares of Common Stock equal to the quotient obtained by dividing the principal amount of such holder's note by 10.5 at an exercise price equal to \$5.25 per share of Common Stock, representing 50% warrant coverage on the principal amount of the note.

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

Certain provisions of the DGCL and of our A&R Charter and our A&R Bylaws, which will become effective immediately prior to the completion of this Offering, 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

Upon completion of this Offering, we will be 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 A&R Charter and A&R Bylaws

Our A&R Charter and A&R Bylaws to be in effect immediately prior to completion of this Offering 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 will authorize the Board to fill vacant directorships and will 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 will 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 A&R Charter and A&R Bylaws will 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 will 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 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 A&R Charter must first be approved by a majority of our Board, and if required by law or our A&R 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 will provide for amendment by a majority of our Board or by a majority of the outstanding shares entitled to vote on the amendment.

Exclusive Forum

Both our A&R 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 A&R 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 A&R Charter and A&R Bylaws. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, employees, or agents, which may discourage lawsuits against us and our directors, officers, employees, and agents.

Limitations on Liability and Indemnification of Officers and Directors

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

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this Offering, there has been no public market for our Common Stock. Future sales of our Common Stock in the public market, including shares issued upon exercise of outstanding Warrants, or the availability of such shares for sale in the public market could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares of our Common Stock will be available for sale in the public market due to contractual and legal restrictions on resale. Nevertheless, sales of our Common Stock in the public market after such restrictions lapse or the perception that such sales may occur could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future. Although we have applied to list our Common Stock on The Nasdaq Capital Market, we cannot assure you that there will be an active market for our Common Stock.

Based on the number of shares of our Common Stock outstanding as of August 3, 2022, upon the closing of this Offering, 7,311,970 shares of our Common Stock will be outstanding assuming: (i) the automatic conversion of all outstanding shares of our convertible Series A Preferred Stock into an aggregate of 756,558 shares of Common Stock immediately prior to the closing of this Offering; and (ii) the automatic conversion of all outstanding convertible promissory notes into an aggregate of 2,542,504 shares of Common Stock immediately prior to the closing of this Offering.

Of the shares of Common Stock to be outstanding immediately after the completion of this Offering, we expect that all of the shares to be sold in this Offering will be freely tradeable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. All remaining shares of our Common Stock held by existing stockholders immediately prior to the closing of this Offering will be "restricted securities" as that term is defined in Rule 144. However, our stockholders who beneficially own less than 5% of our outstanding shares of Common Stock, who own approximately 1,350,000 shares of our Common Stock in the aggregate, are not subject to any lock-up agreements and their shares will be eligible for sale in the public market immediately after effectiveness of this registration statement, subject to Rule 144 under the Securities Act.

Lock-Up Agreements

We have agreed with the underwriters not to sell additional equity securities for a period of 180 days after the effective date of this Offering. In addition, certain of our directors, executive officers, and holders of 5% or more of our outstanding Common Stock have entered into "lock-up" agreements pursuant to which they have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our Common Stock or securities convertible into Common Stock, subject to certain exceptions, for a period of 180 days after the date of this prospectus, which restriction may be waived in the discretion of the Representative. See "Underwriting—Lock-Up Agreements" on page 111.

Following the lock-up periods set forth in the agreements described above, and assuming that no parties are released from these agreements and that there is no extension of the lock-up period, shares of our Common Stock will be eligible for sale in the public market in compliance with Rule 144 or another exemption under the Securities Act or pursuant to the registration statement of which this prospectus forms a part.

Rule 144

Affiliate Resales of Restricted Securities

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our Common Stock in the public market, whether or not those shares are "restricted securities." "Restricted securities" are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our Common Stock issued prior to the closing of the Offering made hereby, are considered to be restricted securities. The shares of our Common Stock sold in this Offering are not considered to be restricted securities.

Non-Affiliate Resales of Restricted Securities

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our Common Stock. Subject to the lock-up agreements described below, those persons may sell shares of our

Common Stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our Common Stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our Common Stock for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our Common Stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

Under Rule 701, a stockholder who purchased shares of our Common Stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days is generally permitted to sell its shares of Common Stock in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144.

Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the lock-up period described below.

Registration Rights

The Company has not granted any registration rights to any of its security holders and no stockholder of the Company has the right to participate in this Offering.

Equity Incentive Plans

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this Offering to register the shares of Common Stock that are issuable pursuant to our 2014 Equity Incentive Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this Offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangements described below, if applicable.

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MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax considerations applicable to Non-U.S. Holders (as defined below) with respect to their acquisition, ownership and disposition of shares of our Common Stock underlying the Units issued pursuant to this Offering. This summary does not provide a complete analysis of all potential U.S. federal income tax considerations relating thereto. The information provided below is based upon provisions of the U.S. Internal Revenue Code of 1986, as amended (the “*Code*”), Treasury regulations promulgated thereunder, administrative rulings, and judicial decisions currently in effect. These authorities may change at any time, possibly retroactively, or the Internal Revenue Service (the “*IRS*”) might interpret the existing authorities differently. In either case, the tax considerations of owning or disposing of our Common Stock could differ from those described below. As a result, we cannot assure you that the tax consequences described in this discussion will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent provided below. In addition, this discussion does not address tax considerations applicable to an investor’s particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- partnerships or entities or arrangements treated as partnerships or other pass-through entities for U.S. federal tax purposes (or investors in such entities);
- corporations that accumulate earnings to avoid U.S. federal income tax;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or tax-qualified retirement plans;
- controlled foreign corporations or passive foreign investment companies;
- dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- certain former citizens or former long-term residents of the United States;
- persons who hold our Common Stock as a position in a hedging transaction, “straddle,” “conversion transaction” or other risk reduction transaction;
- persons who do not hold our Common Stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); or
- persons deemed to sell our Common Stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes is a beneficial owner of our Common Stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Accordingly, this summary does not address tax considerations applicable to partnerships that hold our Common Stock, and partners in such partnerships should consult their tax advisors.

INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, STATE OR LOCAL LAWS, AND TAX TREATIES.

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Non-U.S. Holder Defined

For purposes of this summary, a Non-U.S. Holder is any beneficial owner of our Common Stock, other than a partnership, that is not:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state therein or the District of Columbia;
- a trust if it (i) is subject to the primary supervision of a U.S. court and one of more U.S. persons have authority to control all substantial decisions of the trust or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person; or
- an estate whose income is subject to U.S. income tax regardless of source.

If you are a non-U.S. citizen that is an individual, you may, in many cases, be treated as a resident alien, as opposed to a nonresident alien, by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For these purposes, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. Such an individual is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the ownership or disposition of our Common Stock.

Dividends

As discussed under “Dividend Policy” above, we do not currently expect to declare or pay dividends to our Common Stockholders in the foreseeable future. In the event that we do make distributions of cash or other property on our Common Stock, those distributions 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. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital, which will first reduce a Non-U.S. Holder’s adjusted tax basis in shares of our Common Stock, but not below zero. Any remaining excess will be treated as gain realized on the sale or other disposition of our Common Stock and will be treated as described below under “Gain on Sale or Other Taxable Disposition of Our Common Stock.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our Common Stock that is not effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States will generally be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable or successor form) certifying the Non-U.S. Holder’s qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty. If the Non-U.S. Holder holds the stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to the agent. The holder’s agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under “Information Reporting and Backup Withholding” and “Foreign Account Tax Compliance Act,” a Non-U.S. Holder will generally not be subject to U.S. federal income tax on any gain realized upon the sale, exchange, or other taxable disposition of our Common Stock unless:

- the gain (i) is effectively connected with the conduct by the Non-U.S. Holder of a U.S. trade or business, and (ii) if required by an applicable income tax treaty between the United States and the Non-U.S. holder’s country of residence, is attributable to a permanent establishment maintained by the Non-U.S. Holder in the United States (in which the special rules described below apply);
- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our Common Stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by certain U.S. source capital losses, even though the individual is not considered a resident of the United States); or
- the rules of the Foreign Investment in Real Property Tax Act (“*FIRPTA*”) treat the stock as a “U.S. real property interest” as defined in Section 897 of the Code.

The *FIRPTA* rules may apply to a sale, exchange or other disposition of our Common Stock if we are, or were within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder’s holding period, a “U.S. real property holding corporation” (a “*USRPHC*”), as defined in Section 897 of the Code. In general, we would be a *USRPHC* if interests in U.S. real estate comprised at least half of the value of our business assets. We do not believe that we are a *USRPHC* and we do not anticipate becoming one in the future. Even if we become a *USRPHC*, as long as our Common Stock is regularly traded on an established securities market, such Common Stock will be treated as U.S. real property interests only if beneficially owned by a Non-U.S. Holder that actually or constructively owned more than 5% of our outstanding Common Stock at sometime within the five-year period preceding the disposition.

If any gain from the sale, exchange or other disposition of our Common Stock (1) is effectively connected with a U.S. trade or business conducted by a Non-U.S. Holder, and (2) if required by an applicable income tax treaty between the United States and the Non-U.S. Holder’s country of residence, is attributable to a permanent establishment maintained by such Non-U.S. Holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. If the Non-U.S. Holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a “branch profits tax.” The branch profits tax rate is 30% unless reduced by applicable income tax treaty.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

U.S. Federal Estate Tax

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our Common Stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise.

Informational Reporting and Backup Withholding

The Code and the Treasury regulations require those who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by "backup withholding" rules. These rules require the payors to withhold tax from payments subject to information reporting if the recipient fails to cooperate with the reporting regime by failing to provide his taxpayer identification number to the payor, furnishing an incorrect identification number, or failing to report interest or dividends on his returns. The backup withholding tax rate is currently 24%. The backup withholding rules do not apply to payments to corporations, whether domestic or foreign, provided they establish such exemption.

Payments to Non-U.S. Holders of dividends on our Common Stock generally will not be subject to backup withholding, and payments of proceeds made to Non-U.S. Holders by a broker upon a sale of Common Stock will not be subject to information reporting or backup withholding, in each case so long as the Non-U.S. Holder certifies its status as a Non-U.S. Holder (and we or our paying agent do not have actual knowledge or reason to know the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied) or otherwise establishes an exemption. The certification procedures to claim treaty benefits described under "Distributions" will generally satisfy the certification requirements necessary to avoid the backup withholding tax. We must report annually to the IRS any dividends paid to each Non-U.S. Holder and the tax withheld, if any, with respect to these dividends. Copies of these reports may be made available to tax authorities in the country where the Non-U.S. Holder resides. However, under the Treasury regulations, information returns are required to be filed with the IRS in connection with any dividends on our Common Stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our Common Stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the beneficial owner certifies, under penalties of perjury, among other things, its status as a Non-U.S. Holder (and the broker does not have actual knowledge or reason to know the holder is a U.S. person) or otherwise establishes an exemption. The payment of proceeds from the disposition of shares of our Common Stock by a Non-U.S. Holder made to or through a non-U.S. office of a broker generally will not be subject to backup withholding and information reporting, except as noted below. Information reporting, but not backup withholding, will apply to a payment of proceeds, even if that payment is made outside of the United States, if you sell our Common Stock through a non-U.S. office of a broker that is:

- a U.S. person (including a foreign branch or office of such person);
- a "controlled foreign corporation" for U.S. federal income tax purposes;
- a foreign person 50% or more of whose gross income from certain periods is effectively connected with a U.S. trade or business; or
- a foreign partnership if at any time during its tax year (a) one or more of its partners are U.S. persons who, in the aggregate, hold more than 50% of the income or capital interests of the partnership or (b) the foreign partnership is engaged in a U.S. trade or business, unless the broker has documentary evidence that the beneficial owner is a Non-U.S. Holder and certain other conditions are satisfied, or the beneficial owner otherwise establishes an exemption (and the broker has no actual knowledge or reason to know to the contrary).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Foreign Account Tax Compliance Act

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our Common Stock paid to a foreign financial institution (as specifically defined by the applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds of a disposition of our Common Stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States or by providing an IRS Form W-8BEN or similar documentation. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules and certifies as such on a Form W-8BEN-E (or any successor of such form). Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders should consult with their own tax advisors regarding the possible implications of the withholding described herein.

The withholding provisions described above generally apply to proceeds from a sale or other disposition of Common Stock if such sale or other disposition occurs on or after January 1, 2019 and to payments of dividends on our Common Stock.

THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL, AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated [], 2022, the underwriters named below, for whom WallachBeth Capital, LLC is acting as the lead managing underwriter and sole book runner and the representative of the several underwriters (the "**Representative**"), have severally agreed to purchase, and we have agreed to sell to them, severally, the number of Units indicated below:

Underwriters	Number of Units
WallachBeth Capital, LLC	[]
Craft Capital Management LLC	
WestPark Capital, Inc.	
Totals:	

The underwriters are collectively referred to as the "underwriters," and the Representative of the underwriters is WallachBeth Capital, LLC. The underwriters are offering the Units subject to their acceptance of the Units from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the Units offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters

are obligated to take and pay for all of the Units offered by this prospectus if any such Units are taken. However, the underwriters are not required to take or pay for any of the Common Stock or Warrants covered by the underwriters' Over-Allotment Option described below.

The underwriters initially propose to offer part of the Units directly to the public at the Offering Price listed on the cover page of this prospectus and part to certain dealers. After the initial offering of the Units, the offering price and other selling terms may from time to time be varied by the Representative.

Over-Allotment Option

We have granted to the underwriters an Over-Allotment Option, exercisable for 45 days from the date of this prospectus, to purchase up to an additional 192,799 shares of Common Stock, each share at the initial Offering Price per Unit less \$0.02, and/or 192,799 Tradeable Warrants at the price of \$0.01 per Tradeable Warrant, and/or 192,799 Non-tradeable Warrants at the price of \$0.01 per Non-tradeable Warrant, or 15% of the total number of Units sold in the Offering in shares of Common Stock or in Warrants or any combination of shares of Common Stock or Warrants, less the underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the Offering of the Units offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of Common Stock or Warrants as the number listed next to the underwriter's name in the preceding table bears to the total number of Units listed next to the names of all underwriters in the preceding table.

Discounts and Commissions and Expenses

We have agreed to pay the underwriters a cash fee equal to nine percent (9.0%) (subject to reduction) of the aggregate gross proceeds from the sale of the Units. If more than twenty-five percent (25.0%) of the Units offered hereby are sold to existing investors in the Company, then the cash fee to the underwriters will be reduced to four percent (4.0%) of the aggregate gross proceeds from the existing investors.

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The Representative has advised us that the underwriters propose to offer the Units directly to the public at the Offering Price set forth on the cover of this prospectus. In addition, the Representative may offer some of the Units to other securities dealers at such price less a concession of up to \$[] per Unit. After the Offering to the public, the offering price and other selling terms may be changed by the Representative without changing the Company's proceeds from the underwriters' purchase of the Units.

The following table shows the Offering Price, underwriting discounts and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their Over-Allotment Option. The underwriting discounts are equal to the Offering Price per Unit less the amount per Unit the underwriters pay us for the Units.

	Per Unit	Total without Over-Allotment Option	Total with Over-Allotment Option
Public Offering Price	\$	\$	\$
Underwriting discounts (9.0%) ⁽¹⁾	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

(1) If more than twenty-five percent (25.0%) of the Units offered hereby are sold to existing investors in the Company, then the cash fee to the underwriters will be reduced to four percent (4.0%) of the aggregate gross proceeds from the existing investors.

We estimate that the total expenses of this Offering, including registration, filing, and listing fees, printing fees and legal and accounting expenses, will be approximately \$900,000. This figure includes expense reimbursements we have agreed to pay the Representative for reimbursement of its expenses related to the Offering up to a maximum aggregate expense allowance of \$145,000. In accordance with FINRA Rule 5110, the reimbursement fee described in the preceding sentence is deemed underwriting compensation for this Offering.

Representative's Warrant

As additional compensation to the underwriters, upon consummation of this Offering, we will issue to the Representative or its designees a non-redeemable Representative's Warrant to purchase an aggregate number of shares of our Common Stock equal to two percent (2.0%) of the number of shares of Common Stock underlying the Units issued in this Offering, at an exercise price per share equal to \$7.044, which is equal to 115% of the \$6.125 assumed Offering Price, which may be via a "cashless exercise." If more than twenty-five percent (25%) of the Units offered hereby are sold to existing investors, then the Representative's Warrant will cover only two and one-half percent (2.5%) of the number of shares of Common Stock underlying the Units purchased by the existing investors. The Representative's Warrant and the underlying shares of Common Stock shall not be sold during the Offering, or sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of six months immediately following the commencement of the sale of the public securities in accordance with FINRA Rule 5110(e)(1). The Representative's Warrant will be exercisable, in whole or in part, commencing on the six month anniversary of the commencement of the sales of the public securities and will expire on the fifth anniversary of the effective date of the registration statement related to the Offering. In addition, we have granted the underwriters the ability to exercise them in a "cashless" manner, a one-time demand registration right at our expense, an additional demand registration at the holder's expense, and unlimited "piggyback" registration rights with respect to the underlying shares. The demand registration rights will not be greater than five years from the effective date of the registration statement related to the Offering in compliance with FINRA Rule 5110(G)(8)(C). The piggyback registration rights will not be greater than seven (7) years from the effective date of the registration statement related to the Offering in compliance with FINRA Rule 5110(G)(8)(D).

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Placement Agent's Warrant

In connection with the sale of the convertible bridge notes and issuance of the warrants in the fourth quarter of 2021 and the first quarter of 2022 (none of which were purchased by the Placement Agent), we have agreed to issue to WallachBeth Capital, LLC, the exclusive placement agent for the convertible bridge notes and the associated warrants, the Placement Agent's Warrant to purchase a total of 29,464 shares of our Common Stock. The exercise price of the Placement Agent's Warrant will be equal to 120% of the per-Unit Offering Price in this Offering, or \$7.35 per share based on the assumed Offering Price of \$6.125 per Unit set forth in this prospectus. The Placement Agent's Warrant will expire five (5) years from the date of the commencement of the sale of our Common Stock in this Offering in compliance with FINRA Rule 5110(e)(1)(A). The Placement Agent's Warrant has been deemed compensation by FINRA and is therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(e)(1) commencing on the closing date of the Offering and running for 180 days thereafter. The Placement Agent (or its respective permitted assignees under Rule 5110(e)(2)(B)) will not sell, transfer, assign, pledge, or hypothecate the Placement Agent's Warrant or the securities underlying such warrant, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such warrant or the underlying securities for a period of 180 days following the date of commencement of sales of the Units pursuant to the Offering. The Placement Agent's Warrant contains the same adjustment provisions as the warrants issued to the investors in the bridge notes. In addition, we have granted the underwriters the ability to exercise them in a "cashless" manner. The Placement Agent's Warrant and the underlying shares of Common Stock that may be issued upon exercise are being registered in the Registration Statement of which this prospectus is a part. The Placement Agent's Warrant is non-exercisable for 180 days following the commencement of the sales of the public securities in this Offering. The shares of Common Stock underlying the Placement Agent's Warrant are being registered in the Registration Statement of which this prospectus is a part.

Advisory Fees

We have also agreed to pay to the Representative, for any sale, merger, acquisition or other similar agreements executed with any party introduced to us occurring on or before May 3, 2022 (a “**Transaction**”), a cash fee equal to 2% of the Aggregate Consideration (or 1% if the Transaction is with parties we have agreed with the Representative are known to us). “Aggregate Consideration” will be calculated as the total proceeds and other consideration paid to or received by, or to be paid to or received by, the Company, or any of its affiliates or other parties in interest in connection with a Transaction, including, without limitation, cash, notes, securities, and other property; payments made in installments; or Contingent Payments (as defined below). In addition, if any of the Company’s liabilities are assumed or otherwise paid off in conjunction with a Transaction (by the Company or any investor, in the form of “cure” payments or otherwise), the Aggregate Consideration will be increased to reflect the face value of any such liabilities and the fair market value of any such assets. “Contingent Payments” are defined as the fair market value of consideration received or receivable by the Company or any of its affiliates, and/or any other parties in the form of deferred Aggregate Consideration based on “earn-outs,” or other contingent payments based upon the future performance of the Company or any of its businesses or assets, and shall not include any payments made pursuant to any employment or consulting agreements which requires the services of such individual for market rate compensation.

Pricing of the Offering

Prior to this Offering, there has been no public market for our Common Stock. In determining the Offering Price, we and the Representative have considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the underwriters;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this Offering;
- the recent market prices of, and demand for, publicly traded securities of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our Common Stock, or that the shares will trade in the public market at or above the Offering Price.

Lock-Up Agreements

The Company, on behalf of itself and any successor entity, has agreed that, without the prior written consent of the Representative, it will not, for a period of 180 days after the date of the underwriting agreement (the “**Lock-Up Period**”), without the Representative’s consent: (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, other than shares issued primarily as equity incentives or securities issued in transactions not primarily for capital raising; (ii) file or caused to be filed any registration statement with the SEC relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (iii) complete any offering of debt securities of the Company, other than entering into a line of credit with a traditional bank; or (iv) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (i), (ii), (iii) or (iv) above is to be settled by delivery of shares of capital stock of the Company or such other securities in cash or otherwise.

Our directors, executive officers and the holders of substantially all of our equity securities have agreed, subject to certain exceptions, with the underwriters that for a period of 180 days after the date of this prospectus, they will not, except with the prior written consent of the Representative, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of or otherwise dispose of or transfer any shares of our Common Stock or any securities convertible into or exercisable or exchangeable for shares of our Common Stock, request or demand that we file a registration statement related to our Common Stock, or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock. All of our option holders and warrant holders are subject to a market stand-off agreement with us which imposes similar restrictions.

The Representative may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the Representative will consider, among other factors, the security holder’s reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

According to the terms of the underwriting agreement, the Representative shall have the right of first refusal for a period of sixteen (16) months after the closing of this Offering to participate in each and every future public and private equity and debt offerings of the Company, or any successor to or any subsidiary of the Company. The right of first refusal granted hereunder may be terminated by us for “cause,” which shall mean a material breach by the Representative of the underwriting agreement or a material failure by the Representative to provide the services as contemplated by the underwriting agreement in which case we will not be obligated to honor the right of first refusal.

Tail Rights

If the Company, within twelve (12) months after the termination of the engagement agreement with the Representative, effects a sale of any securities with a party introduced by the Representative, the Company shall pay to the Representative the cash discount and warrants set forth above upon the completion of such transaction, provided that such tail financing is by a party actually introduced to the Company in an offering in which the Company has direct knowledge of such party’s participation. In compliance with FINRA Rule 5110(g)(5)(B), the “tail fee” will not be payable for greater than one year and our entire underwriting agreement with the Representative is terminable if the Representative materially breaches the engagement agreement or fails to materially perform the underwriting services contemplated in the underwriting agreement. The termination of such agreement will eliminate the obligation of the Company to pay the tail fee.

Indemnification

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

Electronic Offer, Sale and Distribution of Units

A prospectus in electronic format may be made available on a website maintained by the Representative and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of Units to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the Representative to underwriters that may make internet distributions on the same basis as other allocations. In connection with the Offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this Offering.

The underwriters have informed us that they do not expect to confirm sales of Units offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Price Stabilization, Short Positions and Penalty Bids

The underwriters have advised us that, following the completion of this Offering, they currently intend to make a market in our Common Stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for our Common Stock, that you will be able to sell any of the Common Stock held by you at a particular time, or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the Offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions, or the imposition of penalty bids in connection with this Offering. These activities may have the effect of stabilizing or maintaining the market price of the Common Stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our Common Stock and/or Warrants in this Offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our Common Stock and/or Warrants or purchasing shares of our Common Stock and/or Warrants in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our Common Stock and/or Warrants. The underwriters must close out any naked short position by purchasing shares of our Common Stock and/or Warrants in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our Common Stock in the open market after pricing that could adversely affect investors who purchase in this Offering.

A stabilizing bid is a bid for the purchase of shares of Common Stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the Common Stock. A syndicate covering transaction is the bid for or the purchase of shares of Common Stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the Offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our Common Stock or preventing or retarding a decline in the market price of our Common Stock. As a result, the price of our Common Stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the Offering if the Common Stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our Common Stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our Common Stock on The Nasdaq Capital Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our Common Stock in this Offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

Certain of the underwriters and their affiliates have provided and may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they have or may in the future receive customary fees, however, except for the right of first refusal disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

The Representative and certain of its affiliates are full service financial institutions engaged in, and may in the future engage in, various activities, which may include securities trading, investment banking and other commercial dealings, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses. In addition, from time to time, the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the Common Stock offered hereby. Any such short positions could adversely affect future trading prices of the Common Stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Other than in the United States of America, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in

any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the Offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Transfer Agent

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

Application for Nasdaq Capital Market

We have applied to list our Common Stock on the Nasdaq Capital Market under the symbol "BIAF." **If we are unable to obtain a listing on the Nasdaq Capital Market, we will not close this Offering.** If our Common Stock is listed on the Nasdaq Capital Market, we will be subject to continued listing requirements and corporate governance standards. We expect these new rules and regulations to significantly increase our legal, accounting and financial compliance costs.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Dykema Gossett PLLC, San Antonio, Texas. Certain legal matters in connection with this Offering will be passed upon for the Underwriter by Carmel, Milazzo & Feil LLP, New York, New York.

EXPERTS

The consolidated financial statements of bioAffinity Technologies, Inc. at December 31, 2020, and for the year ended December 31, 2020, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, 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.

The consolidated financial statements of bioAffinity Technologies, Inc. at December 31, 2021, and for the year ended December 31, 2021, 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.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 relating to the shares of Common Stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement. For further information regarding us and the shares of Common Stock offered by this prospectus, we refer you to the full registration statement, including its exhibits and schedules, filed under the Securities Act.

The SEC maintains a website at <http://www.sec.gov> that contains reports, information statements, and other information regarding issuers that file electronically with the SEC. Our registration statement, of which this prospectus constitutes a part, and the exhibits and schedules thereto can be downloaded from the SEC's website. After the completion of this Offering, we will file with or furnish to the SEC periodic reports and other information. These reports and other information may be obtained from the SEC's website as provided above.

Following the completion of this Offering, our website will be located at <https://www.bioaffinitytech.com/>. We intend to make our periodic reports and other information filed with or furnished to the SEC available, free of charge, through our website, as soon as reasonably practicable after those reports and other information are electronically filed with or furnished to the SEC. Information on our website or any other website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus.

We intend to furnish or make available to our shareholders annual reports containing our audited financial statements prepared in accordance with GAAP. We also intend to furnish or make available to our shareholders quarterly reports containing our unaudited interim financial information, including the information required by Form 10-Q, for the first three fiscal quarters of each fiscal year.

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’ (Conformité Européenne) 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)”).
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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.

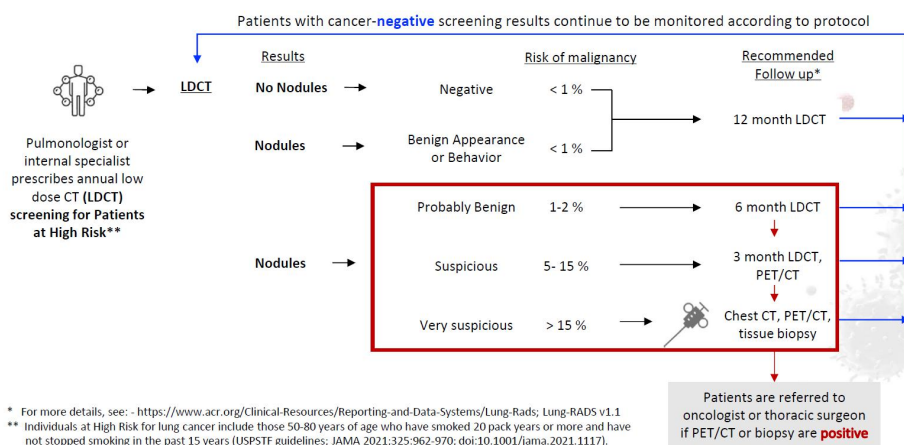
LRP2 Gene	A gene that provides instructions for making the LRP2 receptor that facilitates the uptake of many proteins and some nutrients that includes vitamin B12. Cancer cells can express a large number of LRP2 receptors on their cell surface.
Metabolism	The set of life-sustaining chemical reactions 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 <u>not</u> 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”).

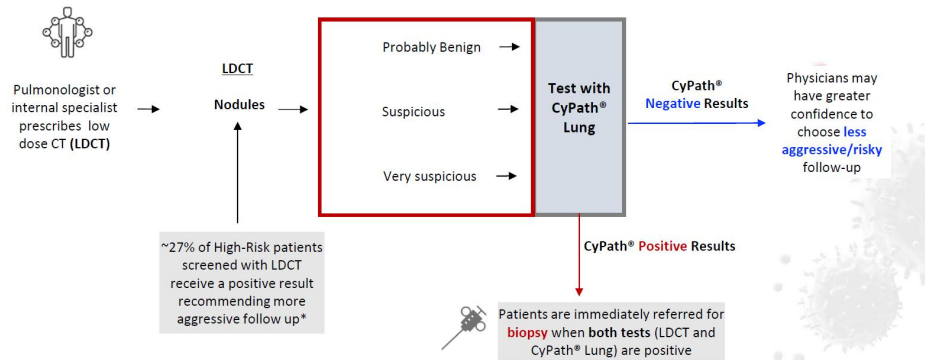
Pre-malignant	A term used to describe a condition that may (or is likely to) become cancer. Also called precancerous.
RNA interference (RNAi)	A natural process in which small pieces of RNA shut down a cell's ability to make certain proteins. To do so, RNAi binds to the messenger RNA (mRNA) that carries 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. 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 on 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 <i>meso-tetra(4-carboxyphenyl)porphine</i> .
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.

ANALYSIS OF THE POTENTIAL DIAGNOSTIC, PATIENT AND ECONOMIC IMPACT OF CYPATH® LUNG WHEN USED AFTER LDCT SCREENING TO DETECT LUNG CANCER

bioAffinity Technologies Internal Analysis, 2022

Current Diagnostic Workflow for Lung Cancer





* Church TR, Black WC, Aberle DR, et al. Results of initial low-dose computed tomographic screening for lung cancer. N. Engl. J. Med. 2013;368:1980-1991

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3

When BOTH LDCT and CyPath® Lung results are POSITIVE

- Physicians may be more confident to pursue more aggressive follow-up
- Lung Cancer may be found sooner, at an earlier stage when treatment may be more successful

When LDCT results are positive but CyPath® Lung results are NEGATIVE

- Physicians may be more confident to pursue less aggressive follow-up
- Fewer patients may be unnecessarily subjected to the risks of follow-up procedures (including radiation exposure, bleedings, collapsed lungs, infections and even death)

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4



CyPath® Lung Test Validation Trial including 150 sputum samples from individuals at High Risk for lung cancer (N=122) and Lung Cancer patients (N=28). High Risk means 30+ pack-year smokers aged 55 and older.



Automated data analysis generates patient reports for physicians minutes after flow cytometry acquisition of data from sputum that averages less than 20 minutes per sample.



Analysis reveals four cancer-specific parameters including our porphyrin label (TCPP).



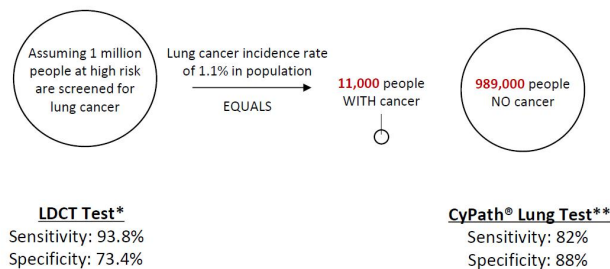
Results of 150-Patient Test Validation Trial of CyPath® Lung showed 88% Specificity and 82% Sensitivity overall for cancer stages I-IV. For the subset of high-risk patients (N= 132) in this trial who had lung nodules smaller than 20 mm or no nodules at all, CyPath® Lung had 92% sensitivity and 87% specificity.

*M.E. Lemieux, et al., Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning, 2022, submitted for publication.

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The Numbers: CyPath® Lung and LDCT Performance Considered Separately

Applying Overall Test Sensitivity and Specificity to 1 Million People at High Risk

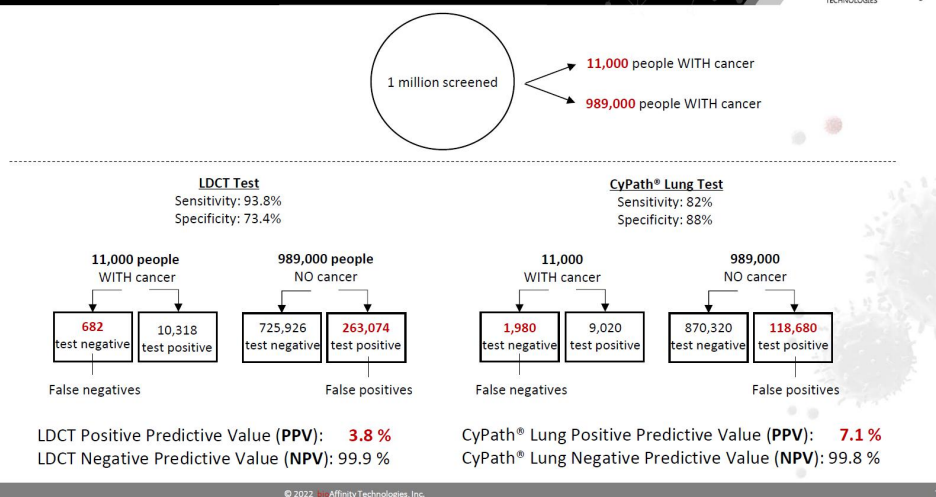


* Figures and calculations based on the National Lung Screening Trial Research Team, Church TR, Black WC, Aberle DR, Berg CD, Clingan KL, et al. N Engl J Med. 2013 May 23;368(21):1980-911.

** Trial results of CyPath® Lung test validation trial of 150 participants, all of whom were at high risk for lung cancer, including 28 participants with confirmed cancer diagnosis and 122 people who were diagnosed as cancer-free.

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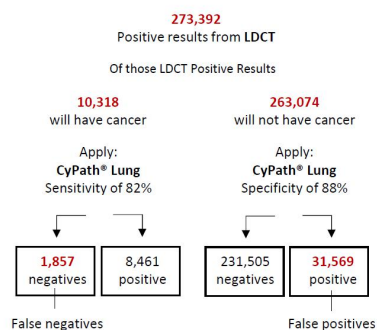
LDCT and CyPath® Lung Performance Considered Separately



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Potential Impact of CyPath® Lung on patients when it is used after LDCT

Assuming 1 million screened for lung cancer



→ 231,505 fewer patients (88%) may face unnecessary follow-up procedures with LDCT and CyPath® Lung combined testing compared to LDCT testing alone

PPV of combined tests: **21.1 %**
NPV of combined tests: 99.7 %

Assumptions

- LDCT and CyPath® Lung are independent tests
- Patients with positive LDCT results (27.3%* of all screened individuals) receive a CyPath® Lung follow-up test

*Percentage of high risk individuals testing positive for lung cancer by LDCT in the National Lung Screening Trial Research Team, Church TR, Black WC, Aberle DR, Berg CD, Clingan KL, et al. N Engl J Med. 2013 May 23;368(21):1980-911.

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A Cost Analysis Study* of nearly 9,000 patients with a chest CT suspicious for lung cancer found:

- Patients who were falsely diagnosed as positive: Average Cost to Medicare \$3,558
- Patients who correctly diagnosed as positive: Average Cost to Medicare \$7,567
- CT chest scan: Average Cost to Medicare \$184

* Lokhandwala T, Dann R, Johnson M, D'Souza AO. Costs of diagnostic workup for lung cancer: a Medicare claims analysis. Int J Radiat Oncology*Biolog*Physic. 2014;90(5S):S9-S10. This study, with a cancer prevalence of 14%, showed that 20% of all patients underwent biopsies and that 20% of those had complications as a result of that. Moreover, the study found that 43% of the total costs were related to negative biopsies.

Economic Calculations: LDCT + CyPath® Lung Testing

Healthcare Cost* of Follow Up per 1 million tested:

LDCT only

263,074 False positives	x \$3,558 = \$	936,017,292
10,318 True positives	x \$7,567 = \$	78,076,306
		\$1,014,093,598

*See previous slide for average costs, Lokhandwala T, et. al.

→ Savings in Health Care Costs for every 1 million people screened in which CyPath® Lung is used after LDCT

— \$1,014,093,598 (LDCT Alone)
\$ 459,870,457 (LDCT + CyPath® Lung)
\$ 554,223,141

Healthcare Cost* of Follow Up per 1 million tested:

LDCT followed by CyPath® Lung

273,392 Receive CyPath Lung test	x \$880 = \$	240,584,960
31,569 False positives	x \$3,558 = \$	112,322,502
8,461 True positives	x \$7,567 = \$	64,024,387
233,362 Negatives	x \$184 = \$	42,938,608
		\$ 459,870,457

Assumptions

- LDCT and CyPath® Lung are independent tests
- Patients with positive LDCT results (27.3%) receive a CyPath® Lung follow-up test.

The Positive Predictive Value (PPV) of CyPath® Lung alone is nearly twice that of LDCT. CyPath® Lung's use *with* LDCT can increase PPV of lung cancer detection from 3.8% (LDCT alone) to 21.1% (combined tests). LDCT + CyPath® Lung represents a 5.6-fold improvement of the PPV as compared to LDCT alone.

For every 1 million people screened by Low Dose CT (LDCT), up to 231,500 people could be spared invasive procedures by testing with CyPath® Lung after a positive LDCT.

Combined testing using LDCT and CyPath® Lung could save the U.S. healthcare system more than \$550,000,000 for every 1 million people screened as compared to the cost of using LDCT alone

APPENDIX II

Summary of comparative performance analysis of tests on the market

Test name	n*	Model performance AUC [#]	Clinical predictors (10% LC prevalence)		Reference **
			PPV	NPV	
bioAffinity***	150	0.89	43.2	97.8	Lemieux et al, Manuscript Submitted
	32	0.90	32.3	98.1	
2020 GeneSystems §	150	0.85	30.0	96.9	Doseeva et al; <i>J Trans Med.</i> 2015 ¹ Mazzone et al; <i>Biomar Insights</i> 2018 ²
	400	0.86	38.3	96.0	
Biodesix	141	0.62	11.3	95.7	Vachani et al; <i>J Thorac Oncol.</i> 2015 ³ Silvestry et al; <i>Chest</i> 2018 ⁴
	172	0.76	16.1	99.2	
MagArray	97	0.86	13.5	98.0	Trivedi et al; <i>Biomed Res Rev.</i> 2018 ⁵
Veracyte ‡	264	ND	16.9	99.3	Lamb et al; <i>Chest</i> 2019 ⁶ Chapman et al, <i>Tumour Biol.</i> 2012 ⁷ Jett et al; <i>Lung Cancer</i> 2014 ⁸
Oncimmune	836	ND	34.5	93.9	
	847	ND	31.4	92.9	

* n = total number of patients who were analyzed to achieve the data presented.

[#] Area Under the Curve (AUC) is a key indicator of a test's ability to discriminate between cancer and non-cancer. In general, an AUC of 0.5 suggests no ability to distinguish between people with cancer and people without cancer. An AUC of 0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent, and more than 0.9 is considered outstanding. CyPath® Lung trials have resulted in AUC of 0.89 (excellent) and 0.9, (outstanding).

*** The AUC, PPV and NPV of CyPath® Lung was calculated based on the overall sensitivity (82%) and specificity (88%) resulting from analysis of 150 high risk patients of whom the cancer cohort included stages I-IV. Higher sensitivity (92%) and similar specificity (87%) was seen in the subgroup of these patients (N=132) who had no nodules or lung nodules smaller than 20 mm on their LDCT scan. Eight out of 10 (80%) of Stage I tumors were correctly identified.

¶ Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated based on the sensitivity and specificity numbers provided in each study. Since these predictors are influenced by the cancer prevalence in the study population, they were recalculated for a population with a 10% lung cancer (LC) prevalence so that the numbers could be compared.

§ PAULA's test from 2020 GeneSystems is intended to be used for high-risk individuals (as defined by the U.S. Preventative Service Task Force) *prior* to LDCT, to help physicians and patients decide who should pursue LDCT-mediated lung cancer screening. However, the test has never been evaluated on that population prospectively, which requires a large "screening-type clinical trial". The intended use of the PAULA test thus differs from the other tests. It is possible this test may be useful in diagnosing indeterminate lung nodules; however, it has never been validated for that purpose either.

‡ The Veracyte test is currently available at limited medical centers and is expected to be fully launched in 2022.

** Full references:

1. Doseeva V, Colpitts T, Gao G, Woodcock J, Knezevic V. Performance of a multiplexed dual analyte immunoassay for the early detection of non-small cell lung cancer. *J Transl Med*. 2015;13:55. doi:10.1186/s12967-015-0419-y
2. Mazzone PJ, Wang XF, Han X, et al. Evaluation of a Serum Lung Cancer Biomarker Panel. *Biomark Insights*. 2018;13:1177271917751608. doi:10.1177/1177271917751608
3. Vachani A, Pass HI, Rom WN, et al. Validation of a multiprotein plasma classifier to identify benign lung nodules. *J Thorac Oncol*. 2015;10(4):629-637. doi:10.1097/JTO.0000000000000447
4. Silvestri GA, Tanner NT, Kearney P, et al. Assessment of Plasma Proteomics Biomarker's Ability to Distinguish Benign From Malignant Lung Nodules. *Chest*. 2018;154(3):491-500. doi:10.1016/j.chest.2018.02.012
5. Trivedi NN, Brown JK, Rubenstein T, et al. Analytical validation of a novel multi-analyte plasma test for lung nodule characterization. *Biomed Res Rev*. 2018;2(3):123. doi:10.15761/brr.1000123
6. Lamb C, Hospital L, Center M, et al. Lung cancer detection via whole-transcriptome RNA sequencing of nasal epithelium. *Chest*. 2019;156(4):A1091-A1092. doi:10.1016/j.chest.2019.08.1005
7. Chapman CJ, Healey GF, Murray A, et al. EarlyCDT®-Lung test: improved clinical utility through additional autoantibody assays. *Tumour Biol*. 2012;33(5):1319-1326. doi:10.1007/s13277-012-0379-2
8. Jett JR, Peek LJ, Fredericks L, Jewell W, Pingleton WW, Robertson JFR. Audit of the autoantibody test, EarlyCDT®-lung, in 1600 patients: an evaluation of its performance in routine clinical practice. *Lung Cancer*. 2014;83(1):51-55. doi:10.1016/j.lungcan.2013.10.008

bioAffinity Technologies, Inc.

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bioAffinity Technologies, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,028,034	\$ 1,360,638
Accounts and other receivables, net	6,861	1,530
Inventory	5,803	—
Prepaid expenses and other current assets	64,922	76,065
Total current assets	1,105,620	1,438,233
Deferred offering costs	241,301	7,942
Property and equipment, net	3,594	4,633
Other assets	2,500	2,500
Total assets	\$ 1,353,015	\$ 1,453,308
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 247,691	\$ 230,407
Accrued expenses	569,225	483,501
Accrued interest	1,290,692	1,121,392
Current portion of Paycheck Protection Program loan	62,567	52,074

Convertible notes payable	11,713,608	11,152,151
Total current liabilities	13,883,783	13,039,525
Paycheck Protection Program loan, less current portion	149,691	160,184
Total liabilities	14,033,474	13,199,709
Commitments and contingencies (See Note 9)		
Convertible preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; 756,558 issued and outstanding as of March 31, 2022, and December 31, 2021; aggregate liquidation preference of \$5,825,497	4,044,318	4,044,318
Stockholders' deficit:		
Common stock, par value \$0.007 per share; 14,285,714 shares authorized; 2,692,911 shares issued and outstanding as of March 31, 2022, and 2,677,139 shares issued and outstanding as of December 31, 2021, respectively	18,850	18,740
Additional paid-in capital	13,241,748	12,703,896
Accumulated deficit	(29,985,375)	(28,513,355)
Total stockholders' deficit	(16,724,777)	(15,790,719)
Total liabilities, convertible preferred stock, and stockholders' deficit	\$ 1,353,015	\$ 1,453,308

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

F-2

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months ended March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 322,020	\$ 295,340
Clinical development	52,503	8,882
General and administrative	352,520	186,987
Total operating expenses	727,043	491,209
Loss from operations	(727,043)	(491,209)
Other income (expense):		
Interest income	571	5
Interest expense	(1,147,583)	(111,545)
Fair value adjustments on convertible notes payable	404,194	(111,479)
Net loss before income taxes	(1,469,861)	(714,228)
Income tax expense	(2,159)	(1,950)
Net loss	\$ (1,472,020)	\$ (716,178)
Net loss per common share, basic and diluted	\$ (0.55)	\$ (0.27)
Weighted average common shares outstanding	2,681,221	2,674,859

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

F-3

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Convertible preferred stock and Stockholders' Deficit

	Three Months Ended March 31, 2022						
	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	756,558	\$ 4,044,318	2,677,139	\$ 18,740	\$ 12,703,896	\$ (28,513,355)	\$ (15,790,719)
Stock-based compensation expense	—	—	15,772	110	105,937	—	106,047
Beneficial conversion feature for bridge notes	—	—	—	—	213,942	—	213,942
Debt discount for warrants issued	—	—	—	—	217,973	—	217,973
Net loss	—	—	—	—	—	(1,472,020)	(1,472,020)

Balance at March 31, 2022 (Unaudited)	<u>756,558</u>	<u>\$ 4,044,318</u>	<u>2,692,911</u>	<u>\$ 18,850</u>	<u>\$ 13,241,748</u>	<u>\$ (29,985,375)</u>	<u>\$ (16,724,777)</u>
Three Months Ended March 31, 2021							
	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2020	756,558	\$ 4,044,318	2,674,859	\$ 18,724	\$ 7,095,355	\$ (22,186,942)	\$ (15,072,863)
Stock-based compensation expense	—	—	—	—	58,254	—	58,254
Net loss	—	—	—	—	—	(716,178)	(716,178)
Balance at March 31, 2021 (Unaudited)	<u>756,558</u>	<u>\$ 4,044,318</u>	<u>2,674,859</u>	<u>\$ 18,724</u>	<u>\$ 7,153,609</u>	<u>\$ (22,903,120)</u>	<u>\$ (15,730,787)</u>

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

F-4

bioAffinity Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (1,472,020)	\$ (716,178)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,039	1,642
Accretion of debt issuance costs	978,217	—
Fair value adjustments on convertible notes payable	(404,194)	111,479
Stock-based compensation expense	106,047	58,254
Changes in operating assets and liabilities:		
Accounts and other receivables	(5,331)	(613)
Inventory	(5,803)	—
Prepaid expenses and other assets	11,143	(422)
Accounts payable	17,284	57,235
Accrued expenses	(29,649)	(15,488)
Accrued interest	169,300	111,546
Net cash used in operating activities	<u>(633,967)</u>	<u>(392,545)</u>
Cash flows from financing activities		
Proceeds from loan payable	—	212,258
Proceeds from issuance of convertible notes payable	475,000	325,000
Payment of deferred offering costs	(117,986)	—
Payment of debt issuance costs	(55,651)	—
Net cash provided by financing activities	<u>301,363</u>	<u>537,258</u>
Net (decrease) increase in cash and cash equivalents	<u>(332,604)</u>	<u>144,713</u>
Cash and cash equivalents at beginning of period	1,360,638	83,108
Cash and cash equivalents at end of period	<u>\$ 1,028,034</u>	<u>\$ 227,821</u>
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	\$ 2,159	\$ 1,950
Fair value of warrants issued to placement agents	\$ 217,973	—
Beneficial conversion feature for bridge notes	\$ 213,942	—

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

F-5

BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

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

bioAffinity Technologies, Inc. (the “Company,” “we,” or “our”) is a biotechnology company developing noninvasive diagnostic tests and targeted cancer therapeutics. The Company has developed a proprietary platform technology for in vitro diagnostics, the first of which is a highly accurate, noninvasive test for early detection of lung cancer. Research has also led to discoveries and advancement of novel cancer therapeutics that specifically and selectively target cancer cells. We believe our platform technologies are applicable to many types of cancer and potentially other diseases.

On March 26, 2014, the Company was formed as a Delaware corporation with the corporate offices located in San Antonio, Texas. On June 15, 2016, the Company formed OncoSelect Therapeutics, LLC (“OncoSelect”), a Delaware limited liability company which is a wholly-owned subsidiary.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and the rules of the U.S. Securities and Exchange Commission (“SEC”). Certain information

and note disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading. In the opinion of management, all necessary adjustments, which consisted only of normal recurring items, have been included in the accompanying unaudited financial statements to present fairly the results of the interim periods. The results of operations for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 or any future periods.

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 \$30.0 million at March 31, 2022 and limited capital resources to fund ongoing operations. The Company believes its capital resources are insufficient to fund the Company’s ongoing operations for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements.

The Company’s liquidity could be materially affected over this period by, among other things: (1) its ability to raise additional capital through equity offerings, debt financings, or other non-dilutive third-party funding; (2) costs associated with new or existing strategic alliances, or licensing and collaboration arrangements; (3) negative regulatory events or unanticipated costs related to its development of CyPath Lung; or (4) any other unanticipated material negative events or costs. Should one or more of these negative events or costs materially affect its liquidity, the Company’s available capital resources may not be sufficient for it to continue to meet its obligations as they become due over the next twelve (12) months. If the Company is unable to meet its obligations when they become due, the Company may have to delay expenditures, reduce the scope of its research and development programs, or make significant changes to its operating plan. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To date, we have generated no sales or revenues, have incurred significant losses and expect to incur significant additional losses as we advance our in vitro diagnostic tests and targeted cancer therapies. Consequently, our operations are subject to all the risks inherent in the establishment of a pre-revenue enterprise, as well as those risks associated with a company engaged in the research and development.

Our cash and cash equivalents at March 31, 2022 were approximately \$1.0 million, representing 76% of our total assets. Based on our current expected level of operating expenditures, we expect to be able to fund our operations through September 2022. We will require additional cash to fund and continue our operations beyond that point. This period could be shortened if there are any unanticipated increases in planned spending on development programs or other unforeseen events. We anticipate raising additional funds through collaborative arrangements, licensing agreements, public or private sales of debt or equity securities, or some combination thereof. There is no assurance that any such arrangement will be entered into or that financing will be available when needed in order to allow us to continue our operations, or if available, on terms favorable or acceptable to us. The accompanying financial statements have been prepared under the assumption that we will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of us to continue as a going concern.

COVID-19

The rapid global spread of the COVID-19 virus since December 2019 has affected production and sales, and disrupted supply chains across a range of industries. The impact of COVID-19 on the Company’s operations and financial performance will depend on numerous factors, including but not limited to the duration and spread of the virus, and the impact on the Company’s customers, employees, clinical trial sites and vendors.

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

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include: the fair value of the Company’s Common Stock used to measure stock-based compensation for options granted to employees and nonemployees; the valuation allowance on the Company’s deferred tax assets; and the fair value of the convertible notes payable.

Principles of Consolidation

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

Cash and Cash Equivalents

For the purpose of the 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 maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits set by the Federal Deposit Insurance Corporation. The Company has not incurred any losses related to this credit risk in its history, and in an effort to minimize its credit risk associated with cash, the Company periodically evaluates the credit quality of its primary financial institution and believes the risk of loss to be minimal.

Inventories

Inventories consist of diagnostic test kits held for sale and distribution. Inventories are stated at the lower of cost or net realizable value, and is determined using the first-in, first-out (“FIFO”) method. The Company periodically reviews its inventory to identify obsolete, slow-moving, or otherwise unsalable inventories, and establishes allowances

for situations in which the cost of the inventory is not expected to be recovered.

Prepaid Expenses and Other Assets

Prepaid expense and other assets consist of prepaid insurance, maintenance contracts, dues and legal retainers, etc. Expense is calculated using the straight-line method over the estimated useful lives of the respective assets.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other fees and expenses directly associated with financings as deferred offering costs until such financings are completed. After the financing is completed, these costs are recorded to stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of March 31, 2022, and December 31, 2021, the Company recorded deferred offering costs of approximately \$240,000 and \$8,000, respectively, incurred in connection with the Company's initial public offering and reported as a non-current asset on the accompanying consolidated balance sheets.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets, generally three years. Capitalized software costs are amortized on a straight-line basis over the estimated useful life of the assets, which is three years.

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company recognizes an impairment charge in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to the asset group. No impairment losses were incurred during the three months ended March 31, 2022, and 2021, respectively.

Patent Expenses

Costs related to filing and pursuing patent applications, as well as costs related to maintaining the Company's existing patent portfolio, are recorded as expense as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation Expense

Compensation expense related to stock options granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model.

The Black-Scholes option pricing model used to compute share-based compensation expense requires use of accounting judgment and financial estimates. Items requiring estimation include the fair market value on the date of grant, the expected term option-holders will retain their vested stock options before exercising them and the estimated volatility of the Company's Common Stock price over the expected term of a stock option. Application of alternative assumptions could result in different share-based compensation amounts being recorded in the financial statements. See Note 11 for additional disclosures related to stock-based compensation.

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 three months ended March 31, 2022 and 2021, and the Company had no accruals for interest and penalties at March 31, 2022 or at December 31, 2021.

Segment Information

The Company is organized as a single operating segment, whereby its chief operating decision maker assess the performance of and allocates resources to the business as a whole.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Income (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to common stockholders by the sum of the weighted-average number of common shares outstanding during the period and the weighted-average number of dilutive common share equivalents outstanding during the period, using the treasury stock method. Dilutive common share equivalents are comprised of in-the-money stock options, convertible notes payable, and warrants, based on the average stock price for each period using the treasury stock method.

The following potentially dilutive securities have been excluded from the computations of weighted average shares outstanding as of March 31, 2022 and 2021, as they would be anti-dilutive:

	Three Months Ended March 31,	
	2022	2021
Convertible preferred stock	756,558	756,558
Shares underlying options outstanding	884,094	824,104
Shares underlying warrants outstanding	2,057,740	6,428
Shares underlying convertible notes outstanding	2,511,345	1,553,298
	<u>6,209,737</u>	<u>3,140,388</u>

Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1 inputs consist of unadjusted quoted prices in active markets for identical assets or liabilities and have the highest priority.
- Level 2 valuations are based on quoted prices in markets that are not active.
- Level 3 valuations are based on inputs that are unobservable and supported by little or no market activity.

See Note 8 for the fair value hierarchy table and inputs used in the fair value measurement for assets and liabilities.

The Company analyzes all financial instruments with features of both liabilities and equity under the Financial Accounting Standard Board's ("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.

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 lab 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 balance sheets and within research and development expense in the accompanying consolidated statements of operations.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

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 United States are a significant factor in providing medical care. In the United States, drugs, biological products, and medical devices are regulated by the United States Food, Drug and Cosmetic Act, which is administered by the U.S. Food and Drug Administration. The Company's has not finalized the regulatory pathway to obtain marketing authorization from the FDA as of the date of these statements. Countries outside of the United States may require a separate regulatory pathway for approval to local standards before the product can be sold and distributed.

Reclassifications

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

Recent Accounting Pronouncements

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

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

Note 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are summarized below:

March 31, 2022

December 31, 2021

Insurance	\$	10,031	\$	16,765
Legal and professional		37,475		55,081
Other		17,416		4,219
Total prepaid expenses and other current assets	\$	64,922	\$	76,065

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment are summarized below:

	March 31, 2022	December 31, 2021
Lab equipment	\$ 242,168	\$ 242,168
Computers and software	21,463	21,463
	263,631	263,631
Accumulated depreciation	(260,037)	(258,998)
Total property and equipment, net	\$ 3,594	\$ 4,633

Depreciation and amortization expense was approximately \$1,000 and \$2,000 for the three months ended March 31, 2022, and 2021, respectively.

Note 5. ACCRUED EXPENSES

Accrued expenses are summarized below:

	March 31, 2022	December 31, 2021
Compensation	\$ 287,887	\$ 277,185
Legal and professional	243,024	166,069
Clinical	38,514	39,482
Other	—	766
Total accrued expenses	\$ 569,225	\$ 483,501

Note 6. LOAN PAYABLE

The Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) provides stimulus measures, including the Paycheck Protection Program (“PPP”), to provide certain small businesses with liquidity to support their operations during the COVID-19 pandemic. In April 2020, the Company received a \$0.2 million PPP Loan (the “PPP Loan”) bearing interest at a one percent (1.0%) fixed annual rate, will mature in two years, and is eligible for forgiveness under certain conditions. The first payment due date was never scheduled and the deferral period for payment of principal and interest continues to be delayed for all PPP borrowers. In October 2020, the Company submitted an application for forgiveness with its lender. In June 2021, the Company received forgiveness from the SBA.

In March 2021, the Company received a second PPP Loan for \$0.2 million bearing interest at a one percent (1.0%) fixed annual rate, and will mature in two years, and is eligible for forgiveness under certain conditions. In light of the technical two-year nature of the loan, the Company presented a portion of the PPP balance as a current liability. In April 2022, the Company received forgiveness from the SBA.

Note 7. CONVERTIBLE NOTES PAYABLE

From August 2018 through July 2020, the Company has issued a total of \$5.0 million in notes payable, including \$2.6 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price is determined as seventy percent (70%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing has occurred, and the note is still outstanding, the noteholder may elect to convert the outstanding principal and accrued interest into shares of the Company’s Common Stock at a price of \$6.62 per share. The convertible notes payable had a maturity date of December 31, 2020, and bear interest at 8% annually, and are secured by the intellectual property of the Company. In November 2021, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to May 31, 2022.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

From October 2020 through June 2021, the Company has issued a total of \$1.0 million in notes payable, including \$0.4 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price is determined as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing has occurred, and the note is still outstanding, the noteholder may elect to convert the outstanding principal and accrued interest into shares of the Company’s Common Stock at a price of \$6.62 per share. The convertible notes payable bear interest at 8% annually and had a maturity date in October 2021. In December 2021, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to May 31, 2022.

In the second and third quarters of 2021, the Company issued a total of approximately \$0.9 million in additional notes payable, including \$0.1 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price is determined as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing has occurred, and the note is still outstanding, the noteholder may elect to convert the outstanding principal and accrued interest into shares of the Company’s Common Stock at a price of \$6.62 per share. Upon completion of a bridge financing sufficient to provide working capital to complete an initial public offering, the notes will be convertible into the Company’s equity securities on same terms as the conversion feature established in the bridge financing. The convertible notes payable have a maturity date in December 2022, bear interest at 8% annually, and are secured by the intellectual property of the Company.

Bridge Notes

In the fourth quarter of 2021 and the first quarter of 2022, the Company issued a total of \$2.4 million in bridge notes convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bear interest at 6% and have a maturity date of May 31, 2022. Additionally, each noteholder shall receive a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to the Company's IPO price or \$5.25 per share if the Company does not complete an IPO by the maturity date. In connection with the offering, we paid commissions of nine (9) percent and issued our placement agent Common Stock purchase warrants equal to ten (10) percent of the Common Stock issuable by the Company. For noteholders that were not introduced to the Company by the placement agent, we paid commissions of four and one-half (4.5) percent and issued our placement agent Common Stock purchase warrants equal to five (5.0) percent of the Common Stock issuable by the Company. The warrants have substantially the same terms as the warrants issued to our noteholders.

Convertible notes payable consisted of the following:

	March 31, 2022	December 31, 2021
Secured convertible notes payable	\$ 5,041,957	\$ 5,041,957
Unsecured convertible notes payable	4,215,000	3,740,000
Principal amount of convertible notes payable	9,256,957	8,781,957
Debt issuance costs	(694,731)	(1,185,382)
Fair value adjustments on convertible notes payable	3,151,382	3,555,576
Total convertible notes payable	<u>\$ 11,713,608</u>	<u>\$ 11,152,151</u>

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the consolidated statements of operations until the convertible notes are settled. The fair value of the convertible notes was determined with the assistance of a third-party specialist, considering the value of the notes payable that would be received by converting into common stock in each scenario, plus a put option.

Note 8. FAIR VALUE MEASUREMENTS

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

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

	Fair value measured at March 31, 2022			
	Total at March 31, 2022	Using Quoted Prices in active markets (Level 1)	Using Significant other observable inputs (Level 2)	Using Significant unobservable inputs (Level 3)
Convertible notes payable	\$ 11,713,608	\$ —	\$ —	\$ 11,713,608
	Fair value measured at December 31, 2021			
	Total at December 31, 2021	Using Quoted Prices in active markets (Level 1)	Using Significant other observable inputs (Level 2)	Using Significant unobservable inputs (Level 3)
Convertible notes payable	\$ 11,152,151	\$ —	\$ —	\$ 11,152,151

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

A description of the valuation techniques and the values used for significant unobservable inputs to derive fair value measurements for those assets and liabilities measured at fair value at March 31, 2022 and December 31, 2021:

	Fair Value	Valuation Technique	Unobservable Input	Range (Weighted Average)
Convertible notes payable at March 31, 2022	\$ 11,713,608	Risky Put + Stock Payoff	Probability weighting assigned to automatic and optional conversion scenarios	90%/10%
			Applied discount rate	358.3%
			Common share class volatility	78.4%
			Preferred stock class volatility	6.5%
			Negotiation discount	4.2%

			Probability weighting assigned to automatic and optional conversion scenarios	
Convertible notes payable at December 31, 2021	\$	11,152,151	Risky Put + Stock Payoff	90%/10%
			Applied discount rate	79.1%
			Common share class volatility	46.1%
			Preferred stock class volatility	3.9%
			Negotiation discount	1.6%

There were no transfers into or out of level 3 during the three months ended March 31, 2022, and 2021, respectively. The Company issued a total of \$0.3 million and \$0.5 million in convertible notes during for the three months ended March 31, 2022, and 2021, respectively, which are included in level 3 liabilities. The following table summarizes the fair values of convertible note payables and the change in fair value at each measurement date:

Fair value of convertible notes payable at December 31, 2021	\$	11,152,151
Additional convertible notes payable issued		475,000
Debt discount for warrants issued		(487,566)
Accretion of debt issuance costs		978,217
Change in fair value of convertible notes payable		(404,194)
Fair value of convertible notes payable at March 31, 2022 (Unaudited)	\$	11,713,608
Fair value of convertible notes payable at December 31, 2020	\$	9,767,461
Additional convertible notes payable issued		3,295,000
Debt discount for warrants issued		(1,665,956)
Accretion of debt issuance costs		480,574
Change in fair value of convertible notes payable		(724,928)
Fair value of convertible notes payable at December 31, 2021	\$	11,152,151

Note 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its corporate offices under an agreement that is renewable and will expire May 31, 2022, and its laboratory and additional office space under an operating lease that is renewable annually by written notice by the Company and will require renewal in February 2023. Rent expense for office and lab space amounted to approximately and \$13,000 for each of the three months ended March 31, 2022 and 2021, respectively.

Legal Matters

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

BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Note 10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

Convertible Preferred Stock

The Company has authorized a total of 20,000,000 shares of \$0.001 per share par value preferred stock. The Company has issued 756,558 shares of preferred stock, designated as Series A. In July 2017, the Company completed a private placement of securities in which 0.2 million shares of Series A preferred stock were sold, resulting in net proceeds of \$1.5 million. As part of the closing, the Company issued 0.6 million shares in exchange for \$2.6 million of the Company's convertible notes payable and related accrued interest.

The Company classifies convertible preferred stock outside of stockholders' deficit because the shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of the Company. The holders of the Series A preferred stock have various rights, preferences and privileges as follows:

Voting Rights

Each share of Series A preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which each share of Series A preferred stock could be converted at the record date for determination of the stockholders entitled to vote. The voting rights and powers are equal to the voting rights and powers of the common stock. For so long as 30% or more of the shares of Series A preferred stock remain outstanding, the holders of the Series A preferred stock, voting together as a single class, shall be entitled to elect one director of the Company.

Dividends

The holders of shares of Series A preferred stock shall be entitled to receive dividends, when, as and if declared by the Company's board of directors, out of any assets legally available therefor, prior and in preference to any declaration of payment of any dividend on the Company's Common Stock at the rate of 8% per share. The right to receive dividends shall not be cumulative, and no right to such dividends shall accrue to the holders of Series A preferred stock by reason of the fact that dividends on such shares are not declared or paid in any year.

Optional Conversion Rights

Each share of Series A preferred stock shall be convertible, at the option of the holder, at any time after the date of issuance of such share into such number of fully paid and nonassessable shares of common stock as is determined by dividing the Series A original issuance price by the conversion price in effect at the time of conversion. As of March 31, 2022, and 2021, each of the 756,558 shares of Series A preferred stock is convertible into one share of common stock. The respective applicable conversion prices for the Series A preferred stock is subject to adjustment upon any future stock split, stock dividend, combination, reclassification or similar event affecting the convertible preferred stock or any series thereof.

Mandatory Conversion Rights

Each share of Series A preferred stock automatically converts into the number of shares of common stock determined in accordance with the conversion rate upon the earlier of:

(a) the closing of a public offering of common stock at a price of at least \$3.00 per share resulting in at least \$10,000,000 of gross proceeds, or (b) written consent of a majority of the holders of the then outstanding shares of Series A preferred stock.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A preferred stock shall be entitled to receive an amount equal to \$7.70 per share (subsequent to the reverse-stock-split calculation) plus an additional amount equal to any dividends declared or accrued but unpaid on each share. If, upon such liquidation event, the assets and funds distributed are insufficient to permit the payment to each holder of the Series A preferred stock of the full preferential amount, the entire assets and funds legally available for distribution to the holders of Series A preferred stock shall be distributed ratably among the holders of the Series A preferred stock based on the number of shares held. Deemed liquidation events include the sale of the Company or grant of an unlimited exclusive license to the Company's technology or intellectual property rights.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

Common Stock

The Company has authorized a total of 14,285,714 shares of \$0.007 per share par value common stock. In November 2021, the Company received shareholder approval to increase the number of authorized shares from 7,142,857 to a total of 14,285,714 shares of \$0.007 per share par value common stock. As of March 31, 2022, the Company has issued 2,692,911 shares of common stock.

Note 11. STOCK-BASED COMPENSATION

The Company grants options under its 2014 Equity Incentive Plan (the "Plan"). The Plan is authorized to grant options for up to 1.1 million shares of common stock, or twenty percent (20%) of the total issued and outstanding common stock, whichever is greater. The Company has reserved 1.0 million shares to be under the plan. Options may be granted to employees, the Company's board of directors and external consultants who provide service to the Company and have vesting schedules with terms of one to four years and become fully exercisable based on specific terms imposed at the date of grant. The Plan will terminate according to the respective terms of the Plan in September 2026.

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 4,643	\$ 5,669
General and administrative	101,404	52,585
	<u>\$ 106,047</u>	<u>\$ 58,254</u>

The following table summarizes stock option activity under the Plan:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2021	878,380	\$ 4.12		
Granted	7,142	4.20		
Exercised	—	—		
Forfeited	(1,428)	7.70		
Outstanding at March 31, 2022	<u>884,094</u>	<u>\$ 4.05</u>	<u>4.6</u>	<u>\$ 1,324,740</u>
Vested and exercisable at March 31, 2022	<u>826,527</u>	<u>\$ 4.05</u>	<u>4.3</u>	<u>\$ 1,324,740</u>

As of March 31, 2022, there was approximately \$110,000 of total unrecognized compensation cost related to non-vested stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 0.9 years. During the three months ended March 31, 2022, and 2021, no options were exercised.

During the three months ended March 31, 2022, the Company issued options to purchase 7,142 shares of common stock to a non-employee. The per share weighted-average fair value of the options granted during 2022 was estimated at \$2.84 on the date of grant.

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BIOAFFINITY TECHNOLOGIES, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2022 and 2021

During the three months ended March 31, 2022, the Company issued restricted stock units (RSUs) for 14,999 shares of common stock to an employee and a non-employee. The shares vest in equal monthly installments over terms of between immediately to one year, subject to the employee and non-employee providing continuous service through the vesting date. During the three months ended March 31, 2022, approximately 1,400 shares vested from RSUs issued in previous periods.

During the three months ended March 31, 2021, the Company issued no options to purchase shares of common stock. During the three months ended March 31, 2021, the Company did not issue any RSUs.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the three months ended March 31, 2022:

	2022
Fair value of Common Stock	\$ 4.20

Volatility	63.9%
Expected term (years)	6.0
Risk-free interest rate	2.20%
Dividend yield	0%

Note 12. WARRANTS

We account for Common Stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Warrants are accounted for as derivative liabilities if the warrants allow for cash settlement or provide for modification of the warrant exercise price in the event subsequent sales of Common Stock by the Company are at a lower price per share than the then-current warrant exercise price. We classify derivative warrant liabilities on the balance sheet at fair value, and changes in fair value during the periods presented in the statement of operations, which is revalued at each balance sheet date subsequent to the initial issuance of the stock warrant. During the three months ended March 31, 2022 and 2021, no warrants were exercised into an equivalent number of common shares.

In January 2022, the Company issued \$475,000 in convertible promissory notes, or Bridge Notes, that accrue interest at a rate of 6% per year and all principal and unpaid interest is due, if not settle prior, on May 31, 2022. All principal and unpaid interest will automatically convert into Common Stock and at \$4.20 per share upon completion of a qualified IPO. In the event of default all principal and unpaid interest are due on demand. In the event the notes mature prior to completion of an IPO, the holders may, at their option, elect to convert all outstanding principal and unpaid interest into Common Stock and at \$4.20 per share. Each Bridge Note was issued with an accompanying warrant to purchase one share of the Company's Common Stock for each conversion share based on the principal balance of each Bridge Note at an exercise price equal to the Company's IPO price or \$5.25 per share if the IPO is not completed by the maturity date.

The Company issued an aggregate of 167,557 equity-classified Common Stock warrants. Proceeds from the Bridge Notes were allocated to the notes and warrants on a relative fair value basis resulting in a beneficial conversion feature ("BCF") of \$0.2 million and equal to the excess fair value of the Company's Common Stock over the effective conversion price of the Bridge Notes. The BCF was recorded as a debt discount and is being amortized over the life of the Bridge Notes using the effective interest method. For the three months ended March 31, 2022, the Company recognized approximately \$1.0 million in interest expense related to the amortization of the debt discount and issuance costs.

The following table summarizes the calculated aggregate fair values for the warrants using the Black-Scholes method based on the following assumptions at March 31, 2022:

Exercise price per share of warrant	\$	5.25
Fair market closing price per share of Common Stock	\$	4.13
Volatility		119-121%
Expected term (years)		5.0
Risk-free interest rate		1.37-1.62%
Dividend yield		0%

Note 13. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to July 25, 2022, the date that the financial statements were available to be issued. Based upon this review, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

In March 2021, the Company received a second PPP Loan for \$0.2 million bearing interest at a one percent (1%) fixed annual rate, maturing in two years, and was eligible for forgiveness under certain conditions. In April 2022, the Company received notice the loan was forgiven by the SBA.

In April 2022, the Company established a 401(k) tax deferred saving plan, which permits participants to make contributions by salary deduction. The Company may, at its discretion, make matching contributions to the plan. The Company is responsible for administrative cost of the Plan. The Company has made no contributions to the plan since its inception.

The 1-for-7 reverse stock split became effective with the State of Delaware on June 23, 2022. All share and per share amounts have been adjusted on a retroactive basis in these condensed consolidated financial statements to reflect the effect of the reverse stock split. The Company will make a cash payment to stockholders for all fractional shares which would otherwise be required to be issued as a result of the stock split. In addition, the par value of the Company's Common Stock has been increased to \$0.007 per share.

In July 2022, the Company obtained approval from a majority of noteholders to extend the maturity date of certain convertible and bridge notes from August 31, 2022 to October 31, 2022. As consideration for the maturity-date extension, each noteholder received a warrant to purchase that number of shares of Common Stock equal to the principal amount of such holder's note divided by 10.5. As a result, the Company issued warrants to purchase 758,227 shares of the Company's Common Stock. The warrants have a five-year term and an exercise price equal to \$5.25 per share.

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 sheet of bioAffinity Technologies, Inc. (the "Company") as of December 31, 2021, the related consolidated statements of operations, changes in convertible preferred stock and stockholders' deficit, and cash flows, for the year ended December 31, 2021, 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 consolidated financial position of the Company as of December 31, 2021 and the consolidated results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the entity has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists 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 the Company's consolidated financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

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

New York, New York

April 22, 2022, except as to Note 16, as to which the date is June 23, 2022.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of bioAffinity Technologies, Inc. (the Company) as of December 31, 2020, the related consolidated statements of operations, changes in convertible preferred stock and stockholders' deficit, and cash flows for the year ended December 31, 2020, 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 at December 31, 2020, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

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 suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provided a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2021 to 2022.

San Antonio, Texas

January 10, 2022, except as to Note 16, as to which the date is June 23, 2022.

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bioAffinity Technologies, Inc. consolidated Balance Sheets

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,360,638	\$ 83,108
Accounts and other receivables, net	1,530	1,530
Prepaid expenses and other current assets	76,065	34,017
Total current assets	1,438,233	118,655

Deferred offering costs	7,942	—
Property and equipment, net	4,633	9,450
Other assets	2,500	17,500
Total assets	\$ 1,453,308	\$ 145,605
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 230,407	\$ 191,387
Accrued expenses	483,501	375,757
Accrued interest	1,121,392	600,345
Current portion of Paycheck Protection Program loan	52,074	185,734
Convertible notes payable at fair value	11,152,151	9,767,461
Total current liabilities	13,039,525	11,120,684
Paycheck Protection Program loan, less current portion	160,184	53,466
Total liabilities	13,199,709	11,174,150
Commitments and contingencies (See Note 9)		
Convertible preferred stock, par value \$0.001 per share; 20,000,000 shares authorized; 756,558 issued and outstanding as of December 31, 2021 and 2020, respectively; aggregate liquidation preference of \$5,825,497	4,044,318	4,044,318
Stockholders' deficit:		
Common Stock, par value \$0.007 per share; 14,285,714 shares authorized; 2,677,139 and 2,674,859 shares issued and outstanding as of December 31, 2021 and 2020, respectively	18,740	18,724
Additional paid-in capital	12,703,896	7,095,355
Accumulated deficit	(28,513,355)	(22,186,942)
Total stockholders' deficit	(15,790,719)	(15,072,863)
Total liabilities, convertible preferred stock, and stockholders' deficit	\$ 1,453,308	\$ 145,605

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

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bioAffinity Technologies, Inc.
consolidated Statements of Operations

	For the Year ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 1,195,575	\$ 1,415,285
Clinical development	130,475	194,757
General and administrative	880,772	994,343
Total operating expenses	2,206,822	2,604,385
Loss from operations	(2,206,822)	(2,604,385)
Other income (expense):		
Interest income	424	1,073
Interest expense	(1,001,854)	(382,171)
Gain on extinguishment of debt	239,200	—
Fair value of warrants issued	(4,080,339)	—
Fair value adjustments on convertible notes payable	724,928	(4,280,504)
Net loss before income taxes	(6,324,463)	(7,265,987)
Income tax expense	(1,950)	(2,750)
Net loss	\$ (6,326,413)	\$ (7,268,737)
Net loss per common share, basic and diluted	\$ (2.36)	\$ (2.72)
Weighted average common shares outstanding	2,675,270	2,674,859

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

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bioAffinity Technologies, Inc.
consolidated Statements of Changes in Convertible preferred stock and Stockholders' Deficit

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	756,558	\$ 4,044,318	2,674,859	\$ 18,724	\$ 6,819,623	\$ (14,918,205)	\$ (8,079,858)
Stock-based compensation expense	—	—	—	—	275,732	—	275,732
Net loss	—	—	—	—	—	(7,268,737)	(7,268,737)
Balance at December 31, 2020	756,558	\$ 4,044,318	2,674,859	\$ 18,724	\$ 7,095,355	\$ (22,186,942)	\$ (15,072,863)
Stock-based compensation expense	—	—	2,280	16	42,996	—	43,012
Fair value of warrants issued	—	—	—	—	4,080,339	—	4,080,339
Beneficial conversion feature for bridge notes	—	—	—	—	739,602	—	739,602
Debt discount for warrants issued	—	—	—	—	745,604	—	745,604
Net loss	—	—	—	—	—	(6,326,413)	(6,326,413)
Balance at December 31, 2021	<u>756,558</u>	<u>\$ 4,044,318</u>	<u>2,677,139</u>	<u>\$ 18,740</u>	<u>\$ 12,703,896</u>	<u>\$ (28,513,355)</u>	<u>\$ (15,790,719)</u>

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

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bioAffinity Technologies, Inc.
consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (6,326,413)	\$ (7,268,737)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,817	22,242
Accretion of debt issuance costs	480,574	—
Fair value adjustments on convertible notes payable	(724,928)	4,280,504
Stock-based compensation expense	43,012	275,732
Fair value of warrants issued	4,080,339	—
Gain on extinguishment of debt	(239,200)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(34,990)	(1,524)
Accounts payable	39,020	87,969
Accrued expenses	107,744	14,005
Accrued interest	521,047	382,170
Net cash used in operating activities	<u>(2,048,978)</u>	<u>(2,207,639)</u>
Cash flows from investing activities		
Purchase of property and equipment	—	(2,888)
Net cash used in investing activities	<u>—</u>	<u>(2,888)</u>
Cash flows from financing activities		
Proceeds from loan payable	212,258	239,200
Proceeds from issuance of convertible notes payable	3,295,000	1,475,952
Payment of debt issuance costs	(180,750)	—
Net cash provided by financing activities	<u>3,326,508</u>	<u>1,715,152</u>
Net increase (decrease) in cash and cash equivalents	1,277,530	(495,375)
Cash and cash equivalents at beginning of year	83,108	578,483
Cash and cash equivalents at end of year	<u>\$ 1,360,638</u>	<u>\$ 83,108</u>
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	\$ 1,950	\$ 2,750
Fair value of warrants issued to placement agents	\$ 74,556	\$ —
Beneficial conversion feature for bridge notes	\$ 739,602	\$ —

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

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

bioAffinity Technologies, Inc. (the “Company,” “we,” or “our”) is a biotechnology company developing noninvasive diagnostic tests and targeted cancer therapeutics. The Company has developed a proprietary platform technology for in vitro diagnostics, the first of which is a noninvasive test for early detection of lung cancer. Research has also led to discoveries and advancement of novel cancer therapeutics that specifically and selectively target cancer cells. We believe our platform technologies are applicable to many types of cancer and potentially other diseases.

On March 26, 2014, the Company was formed as a Delaware corporation with the corporate offices located in San Antonio, Texas. On June 15, 2016, the Company formed Oncoselect Therapeutics, LLC, a Delaware limited liability company, which is a wholly-owned subsidiary.

Basis of Presentation

The consolidated financial statements of the Company have been prepared in accordance with U.S. accounting principles generally accepted (“GAAP”).

In accordance with Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties About an Entity’s Ability to Continue as a 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 \$28.5 million at December 31, 2021 and limited capital resources to fund ongoing operations. The Company believes its capital resources are insufficient to fund the Company’s ongoing operations for a period of at least twelve (12) months subsequent to the issuance of the accompanying consolidated financial statements.

The Company’s liquidity could be materially affected over this period by, among other things: (1) its ability to raise additional capital through equity offerings, debt financings, or other non-dilutive third-party funding; (2) costs associated with new or existing strategic alliances, or licensing and collaboration arrangements; (3) negative regulatory events or unanticipated costs related to its development of CyPath® Lung; or (4) any other unanticipated material negative events or costs. Should one or more of these negative events or costs materially affect its liquidity, the Company’s available capital resources may not be sufficient for it to continue to meet its obligations as they become due over the next twelve (12) months. If the Company is unable to meet its obligations when they become due, the Company may have to delay expenditures, reduce the scope of its research and development programs, or make significant changes to its operating plan.

To date, we have generated no sales or revenues, have incurred significant losses and expect to incur significant additional losses as we advance our in vitro diagnostic tests and targeted cancer therapies. Consequently, our operations are subject to all the risks inherent in the establishment of a pre-revenue enterprise, as well as those risks associated with a company engaged in the research and development.

Our cash and cash equivalents at December 31, 2021 were approximately \$1.4 million, representing 94% of our total assets. Based on our current expected level of operating expenditures, including approximately \$0.5 million we raised in 2022, we expect to be able to fund our operations through September 2022. We will require additional cash to fund and continue our operations beyond that point. This period could be shortened if there are any unanticipated increases in planned spending on development programs or other unforeseen events. We anticipate raising additional funds through collaborative arrangements, licensing agreements, public or private sales of debt or equity securities, or some combination thereof. There is no assurance that any such arrangement will be entered into or that financing will be available when needed in order to allow us to continue our operations, or if available, on terms favorable or acceptable to us. The accompanying consolidated financial statements have been prepared under the assumption that we will continue as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of us to continue as a going concern.

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

COVID-19

The rapid global spread of the COVID-19 virus since December 2019 has affected production and sales, and disrupted supply chains across a range of industries. The impact of COVID-19 on the Company’s operations and financial performance will depend on numerous factors, including but not limited to the duration and spread of the virus, and the impact on the Company’s customers, employees, clinical trial sites and vendors.

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

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include: the fair value of the Company’s Common Stock used to measure stock-based compensation for options granted to employees and nonemployees; the valuation allowance on the Company’s deferred tax assets; and the fair value of the convertible notes payable.

Principles of Consolidation

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

Cash and Cash Equivalents

For the purpose of the 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 maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits set by the Federal Deposit Insurance Corporation. The Company has not incurred any losses related to this credit risk in its history, and in an effort to minimize its credit risk associated with cash, the Company periodically evaluates the credit quality of its primary financial institution and believes the risk of loss to be minimal.

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bioAffinity Technologies, Inc.
Notes to Consolidated Financial Statements
For the Years Ended December 31, 2021 and 2020

Prepaid Expenses and Other Assets

Prepaid expense and other assets consist of prepaid insurance, maintenance contracts, dues and legal retainers, etc. Expense is calculated using the straight-line method over the estimated useful lives of the respective assets.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other fees and expenses directly associated with financings as deferred offering costs until such financings are completed. After the financing is completed, these costs are recorded to stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of December 31, 2021, the Company recorded deferred offering costs of approximately \$8,000, respectively, incurred in connection with the Company's anticipated initial public offering and reported as a non-current asset on the accompanying consolidated balance sheets.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets, generally three (3) years.

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company recognizes an impairment charge in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to the asset group. No impairment losses were incurred during the years ended December 31, 2021, and 2020, respectively.

Patent Expenses

Costs related to filing and pursuing patent applications, as well as costs related to maintaining the Company's existing patent portfolio, are recorded as expense as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation Expense

Compensation expense related to stock options granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model.

The Black-Scholes option pricing model used to compute share-based compensation expense requires use of accounting judgment and financial estimates. Items requiring estimation include the expected term option-holders will retain their vested stock options before exercising them and the estimated volatility of the Company's Common Stock price over the expected term of a stock option. Application of alternative assumptions could result in different share-based compensation amounts being recorded in the financial statements. See Note 11 for additional disclosures related to stock-based compensation.

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, 2021 and 2020, and the Company had no accruals for interest and penalties at December 31, 2021 or 2020.

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bioAffinity Technologies, Inc.
Notes to Consolidated Financial Statements
For the Years Ended December 31, 2021 and 2020

Income (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to Common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to Common stockholders by the sum of the weighted-average number of common shares outstanding during the period and the weighted-average number of dilutive common share equivalents outstanding during the period, using the treasury stock method. Dilutive common share equivalents are comprised of in-the-money stock options, convertible notes payable, and warrants, based on the average stock price for each period using the treasury stock method. The following potentially dilutive securities have been excluded from the computations of weighted average shares outstanding as of December 31, 2021 and 2020, as they would be anti-dilutive:

	Year Ended December 31,	
	2021	2020
Convertible preferred stock	756,558	756,558
Shares underlying options outstanding	878,380	824,104
Shares underlying warrants outstanding	1,890,183	6,428

Shares underlying convertible notes outstanding	2,357,941	920,227
	<u>5,883,062</u>	<u>2,507,317</u>

Segment Information

The Company is organized as a single operating segment, whereby its chief operating decision maker assess the performance of and allocates resources to the business as a whole.

Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1 inputs consist of unadjusted quoted prices in active markets for identical assets or liabilities and have the highest priority.
- Level 2 valuations are based on quoted prices in markets that are not active.
- Level 3 valuations are based on inputs that are unobservable and supported by little or no market activity.

See Note 7 for the fair value hierarchy table and inputs used in the fair value measurement for assets and liabilities.

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 lab operations, preclinical studies, compensation and consulting costs.

The Company incurred research and development expenses of \$1.2 million and \$1.4 million for the years ended December 31, 2021 and 2020, respectively.

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

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 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 United States are a significant factor in providing medical care. In the United States, drugs, biological products, and medical devices are regulated by the United States Food, Drug and Cosmetic Act, which is administered by the U.S. Food and Drug Administration. The Company's has not finalized the regulatory pathway to obtain marketing authorization from the FDA as of the date of these statements. Countries outside of the United States may require a separate regulatory pathway for approval to local standards before the product can be sold and distributed.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. For operating leases, a lessee is required to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in the balance sheet. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. The accounting applied by a lessor is largely unchanged from that applied under previous GAAP. This ASU is effective for nonpublic entities for fiscal years beginning after December 15, 2021. Earlier application is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is currently evaluating the effect that the adoption of this ASU will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12)*. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistency in application. ASU 2019-12 will be effective for public entities for interim and annual periods beginning after December 15, 2020, with early adoption permitted. The Company plans to adopt ASU 2019-12 for the fiscal year beginning January 1, 2022 and is currently assessing the impact, if any, the guidance will have on the Company's consolidated financial statements.

In August 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and simplifies the diluted earnings per share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. The new standard will be effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company has not yet determined the potential impact the adoption may have on our consolidated financial statements.

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Note 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2021 and 2020 are summarized below:

	December 31,	
	2021	2020
Prepaid insurance	\$ 16,765	\$ 11,574
Legal and professional	55,081	16,778
Other	4,219	5,665
Total prepaid expenses and other current assets	<u>\$ 76,065</u>	<u>\$ 34,017</u>

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment at December 31, 2021 and 2020 are summarized below:

	December 31,	
	2021	2020
Lab equipment	\$ 242,168	\$ 242,168
Computers and software	21,463	21,463
	263,631	263,631
Less: accumulated depreciation and amortization	(258,998)	(254,181)
Total property and equipment, net	<u>\$ 4,633</u>	<u>\$ 9,450</u>

Depreciation and amortization expense was \$4,817 and \$22,242 for the years ended December 31, 2021, and 2020, respectively.

Note 5. ACCRUED EXPENSES

Accrued expenses at December 31, 2021 and 2020 are summarized below:

	December 31,	
	2021	2020
Compensation	\$ 277,185	\$ 174,435
Legal and professional	166,069	167,370
Clinical	39,481	26,298
Other	766	7,654
Total accrued expenses	<u>\$ 483,501</u>	<u>\$ 375,757</u>

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Note 6. LOAN PAYABLE

The Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) provides stimulus measures, including the Paycheck Protection Program (“PPP”), to provide certain small businesses with liquidity to support their operations during the COVID-19 pandemic.

In April 2020, the Company received an initial \$0.2 million PPP Loan (the “PPP Loan”) bearing interest at a one percent (1%) fixed annual rate, with a maturity date of two years, and was eligible for forgiveness under certain conditions. In October 2020, the Company submitted an application for forgiveness with its lender. In June 2021, the Company received forgiveness from the SBA and recorded a gain of \$239,000 on the extinguishment of debt in the accompanying consolidated statements of operations.

In March 2021, the Company received a second PPP Loan for \$0.2 million bearing interest at a one percent (1%) fixed annual rate, and will mature in five years, and is eligible for forgiveness under certain conditions. In April 2022, the Company received notice the loan was forgiven by the SBA.

Note 7. FAIR VALUE MEASUREMENTS

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

The estimated fair value of certain financial instruments, including cash and cash equivalents, accounts receivable, prepaid and other expenses, accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments. The table below summarizes the Company’s assets and liabilities that are measured at fair value at December 31, 2021 and 2020:

	Fair value measured at December 31, 2021			
	Total at December 31, 2021	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Convertible notes payable	\$ 11,152,151	—	—	\$ 11,152,151
Fair value measured at December 31, 2020				

	Total at December 31, 2020	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Convertible notes payable	\$ 9,767,461	—	—	\$ 9,767,461

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

A description of the valuation techniques and the values used for significant unobservable inputs to derive fair value measurements for those assets and liabilities measured at fair value at December 31, 2021 and 2020:

	Fair Value	Valuation Technique	Unobservable Input	Range (Weighted Average)
Convertible notes payable at 12/31/21	\$ 11,152,151	Risky Put + Stock Payoff	Probability weighting assigned to automatic and optional conversion scenarios Applied discount rate Common share class volatility Preferred stock class volatility Negotiation discount	90%/10% 79.1% 46.1% 3.9% 1.6%
Convertible notes payable at 12/31/20	\$ 9,767,461	Risky Put + Stock Payoff	Probability weighting assigned to automatic and optional conversion scenarios Applied discount rate Common share class volatility Preferred stock class volatility Negotiation discount	90%/10% 30.0% 68.5% 40.5% 5.5%

There were no transfers into or out of level 3 during the years ended December 31, 2021, and 2020, respectively. The Company issued a total of \$3.3 million and \$1.5 million in convertible notes during for the years ended December 31, 2021, and 2020, respectively, which are included in level 3 liabilities. The following table summarizes the fair values of convertible note payables and the change in fair value at each measurement date:

Fair value of convertible notes payable at December 31, 2019	\$ 4,011,005
Convertible notes payable issued	1,475,952
Change in fair value of convertible notes payable	4,280,504
Fair value of convertible notes payable at December 31, 2020	\$ 9,767,461
Convertible notes payable issued	3,295,000
Debt discount for warrants issued	(1,665,956)
Accretion of debt issuance costs	480,574
Change in fair value of convertible notes payable	(724,928)
Fair value of convertible notes payable at December 31, 2021	\$ 11,152,151

Note 8. CONVERTIBLE NOTES PAYABLE

From August 2018 through July 2020, the Company has issued a total of \$5.0 million in notes payable, including \$2.7 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price was initially determined as seventy percent (70%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing had occurred, and the note was still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of \$6.62 per share. The convertible notes payable had a maturity date of December 31, 2020, and bear interest at 8% annually, and are secured by the intellectual property of the Company. In November 2021, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to May 31, 2022.

From October 2020 through June 2021, the Company has issued a total of \$0.9 million in notes payable, including \$0.5 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price was determined as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing has occurred, and the note is still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of \$6.62 per share. The convertible notes payable bear interest at 8% annually and had a maturity date in October 2021. In December 2021, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to May 31, 2022.

In the second and third quarters of 2021, the Company issued a total of approximately \$0.9 million in additional notes payable, including \$0.1 million to related parties, convertible into the next class of equity securities in which the Company issues and sells equity securities with aggregate gross proceeds of at least \$5.0 million. The conversion price was initially determined as eighty percent (80%) multiplied by the per share purchase price for the next equity financing. Additionally, provided no equity financing has occurred, and the note is still outstanding, the noteholder may elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of \$6.62 per share. As a result of the completion of a bridge financing sufficient to provide working capital to complete an initial public offering, the notes are now convertible into the Company's equity securities on same terms as the conversion feature established in the bridge financing. The convertible notes payable have a maturity date in December 2022, bear interest at eight percent (8%) annually.

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

In the fourth quarter 2021, the Company obtained the necessary noteholder approvals to amend certain terms of the convertible notes that provide for conversion into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. Additionally, each noteholder shall receive a warrant to purchase one share of Common Stock based on the investor's Convertible Note principal balance investment. The warrants have a five-year term at an exercise price equal to the Company's IPO price or \$0.75 per share if the Company does not complete an IPO by the maturity date. The maturity date of the notes was extended to May 31, 2022 (See Note 12).

Bridge Notes

In the fourth quarter of 2021, the Company issued a total of \$2.0 million in bridge notes convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bear interest at 6% and have a maturity date of May 31, 2022. Additionally, each noteholder shall receive a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to the Company's IPO price or \$5.25 per share if the Company does not complete an IPO by the maturity date. In connection with the offering, we paid commissions of nine (9) percent and issued our placement agent Common Stock purchase warrants equal to ten (10) percent of the Common Stock issuable by the Company. For noteholders that were not introduced to the Company by the placement agent, we paid commissions of four and one-half (4.5) percent and issued our placement agent Common Stock purchase warrants equal to five (5.0) percent of the Common Stock issuable by the Company. The warrants have substantially the same terms as the warrants issued to our noteholders. Convertible notes payable consisted of the following:

	December 31,	
	2021	2020
Secured convertible notes payable	\$ 5,041,957	\$ 5,041,957
Unsecured convertible notes payable	3,740,000	445,000
Principal amount of convertible notes payable	8,781,957	5,486,957
Debt issuance costs	(1,185,382)	—
Fair value adjustments on convertible notes payable	3,555,576	4,280,504
Total convertible notes payable	\$ 11,152,151	\$ 9,767,461

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the consolidated statements of operations until the convertible notes are settled. The fair value of the convertible notes was determined with the assistance of a third party specialist, considering the value of the notes payable that would be received by converting into Common Stock in each scenario, plus a put option.

Note 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its corporate offices under a month-to-month agreement, and lab space under an operating lease that is renewable annually and expires in February 2023. Rent expense for office and lab space amounted to approximately \$52,000 and \$61,000 for the years ended December 31, 2021 and 2020, respectively.

Legal Matters

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

bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

Note 10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

Convertible Preferred Stock

The Company has authorized a total of 20,000,000 shares of \$0.001 per share par value preferred stock. The Company has issued 756,558 shares of preferred stock, designated as Series A. In July 2017, the Company completed a private placement of securities in which 0.2 million shares of Series A preferred stock were sold, resulting in net proceeds of \$1.5 million. As part of the closing, the Company issued 0.6 million shares in exchange for \$2.6 million of the Company's convertible notes payable and related accrued interest.

The Company classifies convertible preferred stock outside of stockholders' deficit because the shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of the Company. The holders of the Series A preferred stock have various rights, preferences and privileges as follows:

Voting Rights

Each share of Series A preferred stock shall be entitled to the number of votes equal to the number of shares of Common Stock into which each share of Series A preferred stock could be converted at the record date for determination of the stockholders entitled to vote. The voting rights and powers are equal to the voting rights and powers of the Common Stock. For so long as 30% or more of the shares of Series A preferred stock remain outstanding, the holders of the Series A preferred stock, voting together as a single class, shall be entitled to elect one director of the Company.

Dividends

The holders of shares of Series A preferred stock shall be entitled to receive dividends, when, as and if declared by the Company's board of directors, out of any assets legally available therefor, prior and in preference to any declaration of payment of any dividend on the Company's Common Stock at the rate of 8% per share. The right to receive dividends shall not be cumulative, and no right to such dividends shall accrue to the holders of Series A preferred stock by reason of the fact that dividends on such shares are not declared or paid in any year.

Optional Conversion Rights

Each share of Series A preferred stock shall be convertible, at the option of the holder, at any time after the date of issuance of such share into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series A original issuance price by the conversion price in effect at the time of conversion. As of December 31, 2021, and 2020, each of the 756,558 shares of Series A preferred stock is convertible into one share of Common Stock. The respective applicable conversion prices for the Series A preferred stock is subject to adjustment upon any future stock split, stock dividend, combination, reclassification or similar event affecting the convertible preferred stock or any series thereof.

Mandatory Conversion Rights

Each share of Series A preferred stock automatically converts into the number of shares of Common Stock determined in accordance with the conversion rate upon the earlier of: (a) the closing of a public offering of Common Stock at a price of at least \$3.00 per share resulting in at least \$10,000,000 of gross proceeds, or (b) written consent of a

majority of the holders of the then outstanding shares of Series A preferred stock.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A preferred stock shall be entitled to receive an amount equal to \$7.70 per share (subsequent to the reverse-stock-split calculation) plus an additional amount equal to any dividends declared or accrued but unpaid on each share. If, upon such liquidation event, the assets and funds distributed are insufficient to permit the payment to each holder of the Series A preferred stock of the full preferential amount, the entire assets and funds legally available for distribution to the holders of Series A preferred stock shall be distributed ratably among the holders of the Series A preferred stock based on the number of shares held. Deemed liquidation events include the sale of the Company or grant of an unlimited exclusive license to the Company's technology or intellectual property rights.

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Common Stock

The Company has authorized a total of 14,285,714 shares of \$0.007 per share par value Common Stock. Holders of Common Stock are entitled to cast one vote for each share held of record on all matters presented to the stockholders and have no cumulative voting rights. As of December 31, 2021, the Company has issued 2,677,139 shares of Common Stock.

In November 2021, the Company received shareholder approval to increase the number of authorized shares from 7,142,857 to a total of 14,285,714 shares of \$0.007 per share par value Common Stock.

Note 11. STOCK-BASED COMPENSATION

The Company grants options under its 2014 Equity Incentive Plan (the "Plan"). The Plan is authorized to grant Incentive Stock Options, Non-statutory Stock Options, or Restricted Stock for up to 1.1 million shares of Common Stock, or twenty percent (20%) of the total issued and outstanding Common Stock, whichever is greater. The Company has reserved 1.1 million shares to be under the plan. Options may be granted to employees, the Company's board of directors and external consultants who provide service to the Company and have vesting schedules with terms of one to four years and become fully exercisable based on specific terms imposed at the date of grant. The requisite service period for employees or consultants begins on the grant date and ends when the employee or consultant cease to be employed or provide service, unless a longer period is provided in the option agreement. The requisite service period for directors begins on the grant date and ends on the option term provided in the option agreement. Options are exercisable for a period of up to ten (10) years from grant date. The Plan will terminate according to the respective terms of the Plan in September 2026.

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

	2021	2020
Research and development	\$ 25,262	\$ 69,300
General and administrative	17,750	206,432
Total stock-based compensation expense	<u>\$ 43,012</u>	<u>\$ 275,732</u>

The following table summarizes stock option activity under the Plan:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2019	735,546	\$ 3.66		
Granted	88,558	7.70		
Exercised	—	—		
Forfeited	—	—		
Outstanding at December 31, 2020	824,104	\$ 4.10		
Granted	79,273	5.49		
Exercised	—	—		
Forfeited	(24,997)	7.70		
Outstanding at December 31, 2021	<u>878,380</u>	<u>\$ 4.12</u>	<u>4.8</u>	<u>\$ 1,324,740</u>
Vested and exercisable at December 31, 2021	<u>809,302</u>	<u>\$ 4.03</u>	<u>2.3</u>	<u>\$ 1,324,740</u>

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

As of December 31, 2021, there was approximately \$150,000 of total unrecognized compensation cost related to non-vested stock options which vest over time. That cost is expected to be recognized over a weighted-average period of 1.0 year.

During the year ended December 31, 2021, the Company issued options to purchase 79,273 shares of Common Stock to employees and non-employees. The per share weighted-average fair value of the options granted during 2021 was estimated at \$2.23 on the date of grant.

During the year ended December 31, 2021, the Company issued restricted stock units (RSUs) for 7,856 shares of Common Stock to employees. The shares vest in equal monthly installments over terms of between one to three years, subject to the employee providing continuous service through the vesting date. The approximately 6,000 unissued shares vest over a weighted-average period of 1.7 years.

During the year ended December 31, 2020, the Company issued options to purchase 88,558 shares of Common Stock to employees. The per share weighted-average fair value of the options granted during 2020 was estimated at \$3.47 on the date of grant. During the years ended December 31, 2021, and 2020, no options were exercised.

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during the years ended December 31, 2021, and 2020, respectively:

	2021	2020
Fair value of Common Stock	\$ 3.79	\$ 6.44
Volatility	72.8%	64%
Expected term (years)	6.1	6.0
Risk-free interest rate	1.14%	0.78%
Dividend yield	0%	0%

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Fair value of Common Stock—Historically, because there has been no public market for the Company's Common Stock, the fair value of the Company's Common Stock underlying stock-based awards was estimated on each grant date by the Company's board of directors. In order to determine the fair value of the Company's Common Stock underlying stock-based awards, the Company's board of directors considered, among other things, a valuation of the Company's Common Stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

Expected volatility—Since the Company is a privately held company and does not have any trading history for its Common Stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

Expected dividend—The Company has never paid dividends on its Common Stock and has no plans to pay dividends on its Common Stock. Therefore, the Company used an expected dividend yield of zero.

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

Note 12. WARRANTS

We account for Common Stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Warrants are accounted for as derivative liabilities if the warrants allow for cash settlement or provide for modification of the warrant exercise price in the event subsequent sales of Common Stock by the Company are at a lower price per share than the then-current warrant exercise price. We classify derivative warrant liabilities on the balance sheet at fair value, and changes in fair value during the periods presented in the statement of operations, which is revalued at each balance sheet date subsequent to the initial issuance of the stock warrant.

During the year ended December 31, 2021 and 2020, no warrants were exercised into an equivalent number of common shares.

In March 2017, the Company issued an aggregate of 6,428 Common Stock purchase warrants, which are classified as equity. The warrants were issued with an exercise price of \$7.00 per share and expire on the tenth anniversary of the issuance date.

From October through December 2021, the Company issued \$1,950,000 in convertible promissory notes, or Bridge Notes, that accrue interest at a rate of 6% per year and all principal and unpaid interest is due, if not settle prior, on May 31, 2022. All principal and unpaid interest will automatically convert into Common Stock and at \$4.20 per share upon completion of a qualified IPO. In the event of default all principal and unpaid interest are due on demand. In the event the notes mature prior to completion of an IPO, the holders may, at their option, elect to convert all outstanding principal and unpaid interest into Common Stock and at \$4.20 per share. Each Bridge Note was issued with an accompanying warrant to purchase one share of the Company's Common Stock for each conversion share based on the principal balance of each Bridge Note at an exercise price equal to the Company's IPO price or \$5.25 per share if the IPO is not completed by the maturity date.

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

The Company issued an aggregate of 464,272 equity-classified Common Stock warrants. Proceeds from the Bridge Notes were allocated to the notes and warrants on a relative fair value basis resulting in a beneficial conversion feature ("BCF") of \$0.7 million and equal to the excess fair value of the Company's Common Stock over the effective conversion price of the Bridge Notes. The BCF was recorded as a debt discount and is being amortized over the life of the Bridge Notes using the effective interest method. For the year ended December 31, 2021, the Company recognized interest \$0.5 million in interest expense including the amortization of the debt discount.

In connection with the issuance of the Bridge Notes, the Company amended the 2018 and 2020 Notes whereby upon completion of an IPO, all outstanding principal and interest will convert into shares of the Company's Common Stock and at \$4.20 per share. As an inducement to amending the notes, the Company issued 1,419,483 Common Stock warrants with the same terms and conditions as the warrants issued to the Bridge Note holders. The estimated fair value of the warrants was \$4.1 million and immediately expensed within the accompanying statement of operations.

The following table summarizes the calculated aggregate fair values for the warrant derivative liability using the Black-Scholes method based on the following assumptions at December 31, 2021:

Exercise price per share of warrant	\$ 5.25
Fair market closing price per share of Common Stock	\$ 4.20
Volatility	109-118%
Expected term (years)	5.0
Risk-free interest rate	1.05-1.33%
Dividend yield	0%

Note 13. INCOME TAXES**Deferred tax assets and valuation allowance**

The Company had, subject to limitation, approximately \$15.7 million of net operating loss carryforwards at December 31, 2021, of which approximately \$6.0 million will begin expiring in 2034. The remaining balance of approximately \$9.7 million will carryforward 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 \$0.5 million and \$0.6 million for the years ended December 31, 2021, and 2020, respectively.

Significant components of deferred tax assets are as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryover	\$ 3,302,836	2,902,915
Stock compensation	434,645	425,612
Depreciation and amortization	1,099	5,241
Other	3,974	20,881
Tax credits	484,778	363,835
Total deferred tax assets	4,227,332	3,718,484
Less: valuation allowance	(4,227,332)	(3,718,484)
Net deferred tax assets	\$ —	—

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bioAffinity Technologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended December 31, 2021 and 2020

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2021, and 2020 was as follows:

	Year Ended December 31,	
	2021	2020
Tax at federal statutory rate	(21.0)%	(21.0)%
Permanent differences	14.8	13.8
Research and development credits	(1.9)	(1.4)
Change in valuation allowance	8.1	8.6
Effective income tax rate	—%	—%

Unrecognized tax benefits

As of December 31, 2021, and 2020, the Company has unrecognized tax benefits related to tax credits of \$49,646, and \$70,893, respectively. None of the unrecognized tax benefits as of December 31, 2021, 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,	
	2021	2020
Beginning balance	\$ 70,893	\$ 42,042
Deductions based on tax positions related to the prior year	(21,247)	—
Additions based on tax positions related to the current year	—	28,851
Ending balance	\$ 49,646	\$ 70,893

The Company is not under audit with any taxing jurisdiction at this time. The Company's tax returns for the previous three years remain open for audit by the respective tax jurisdictions.

Note 14. RELATED PARTY TRANSACTIONS

From August 2018 through July 2020, the Company has issued a total of \$5.0 million in notes payable to various investors, of which \$3.1 million were sold to related parties. See Note 8, Convertible Notes Payable, for further information. From October 2020 through June 2021, the Company has issued a total of \$0.9 million in notes payable, including \$0.5 million to related parties. From June 2021 through September 2021, the Company issued a total of approximately \$0.9 million in additional notes payable, including \$0.1 million to related parties.

All of these notes bear interest at 8% per annum. The unpaid principal and accrued interest under the notes may be converted into shares of the Company's Common Stock at a conversion price of \$4.20 per share. The notes will automatically convert into shares of the Company's Common Stock upon the completion of an IPO.

Note 15. SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2021, up through the date the consolidated financial statements were available to be issued (April 22, 2022). During this period, the Company did not have any material subsequent events required to be disclosed as of and for the period ended December 31, 2021, except for the following:

Bridge Notes

In 2022, the Company issued a total of \$0.5 million in bridge notes convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at \$4.20 per share, adjusted to reflect any stock split, stock dividend or other similar change in the Common Stock. The bridge notes bear interest at 6% and have a maturity date of May 31, 2022. Additionally, each noteholder shall receive a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The

warrants have a five-year term at an exercise price equal to the Company's IPO price or \$5.25 per share if the Company does not complete an IPO by the maturity date. In connection with the offering, we paid commissions of nine (9) percent and issued our placement agent Common Stock purchase warrants equal to ten (10) percent of the Common Stock issuable by the Company. For noteholders that were not introduced to the Company by the placement agent, we paid commissions of four and one-half (4.5) percent and issued our placement agent Common Stock purchase warrants equal to five (5.0) percent of the Common Stock issuable by the Company. The warrants have substantially the same terms as the warrants issued to our noteholders.

In the first quarter of 2022, the Company increased the number of shares reserved under its 2014 Equity Incentive Plan (the "Plan") to 1.1 million shares of Common Stock.

In March 2021, the Company received a second PPP Loan for \$0.2 million bearing interest at a one percent (1%) fixed annual rate, and will mature in two years, and is eligible for forgiveness under certain conditions. In April 2022, the Company received notice the loan was forgiven by the SBA.

NOTE 16. REVERSE STOCK SPLIT

The 1-for-7 reverse stock split became effective with the State of Delaware on June 23, 2022. All share and per share amounts have been adjusted on a retroactive basis in these consolidated financial statements to reflect the effect of the reverse stock split. The Company will make a cash payment to stockholders for all fractional shares which would otherwise be required to be issued as a result of the stock split. In addition, the par value of the Company's common stock has now increased to \$0.007 per share.

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PRELIMINARY PROSPECTUS

bioAffinity Technologies, Inc.



1,285,325 Units
Each Unit Consisting of
One Share of Common Stock,
One Tradeable Warrant to Purchase One Share of Common Stock, and
One Non-tradeable Warrant to Purchase One Share of Common Stock
(and the shares of Common Stock underlying such Warrants)

WallachBeth Capital, LLC
Craft Capital Management LLC
WestPark Capital, Inc.

August [], 2022

Until [], 2022 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade the securities, whether or not participating in this Offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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 amounts shown are estimates except for the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority (FINRA) filing fee and the exchange listing fee:

	Amount to be Paid	
Securities and Exchange Commission registration fee	\$	3,008
FINRA filing fee		5,368
Nasdaq Capital Market listing fee		55,000
Printing and engraving expenses		5,995
Legal fees and expenses		350,000
Accounting fees and expenses		245,000
Transfer agent and registrar fees		598
Miscellaneous		234,547
Total	\$	900,000

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.

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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 or not the corporation would have the power to indemnify the person against such liability under Section 145 of the DGCL.

We expect that the A&R Charter adopted by us prior to the completion of this Offering will provide that no director of our Company shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (1) for any breach of the director's duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) in respect of unlawful dividend payments or stock redemptions or repurchases or other distributions pursuant to Section 174 of the DGCL, or (4) for any transaction from which the director derived an improper personal benefit. In addition, our A&R Charter will provide that if the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of our Company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

We also expect that our A&R Charter will provide 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.

We expect that our A&R Charter will provide that we shall indemnify each of our directors and executive officers, and shall have power to indemnify our other 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 expenses, judgments, penalties, fines and amounts reasonably paid in settlement that are 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. We expect the A&R Charter will further provide for the advancement of expenses to each of our directors and, in the discretion of the board of directors, to certain officers and employees, in advance of the final disposition of such action, suit or proceeding only upon receipt of an undertaking by such person to repay all amounts advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such person is not entitled to be indemnified for such expenses.

In addition, we expect that the A&R Charter will provide that the right of each of our directors and officers 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 bylaws, agreement, vote of stockholders or otherwise. Furthermore, our A&R Charter will authorize us to provide insurance for our directors, officers, employees and agents against any liability, whether or not 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.

In any underwriting agreement we will enter into in connection with the sale of the Common Stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

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Item 15. Recent Sales of Unregistered Securities

In the three years preceding the filing of this Registration Statement, we have issued the following securities that were not registered under the Securities Act:

Between January 14, 2019 and July 27, 2020, we issued and sold secured, convertible promissory notes to 25 investors pursuant to a note purchase agreement with an aggregate principal amount of \$3,451,326. These notes bear interest at 8% per annum and originally had a maturity date of May 31, 2022. Except as to one note with a principal amount of \$100,000 that has been repaid in full, these notes have been amended and currently have a maturity date of October 31, 2022. The principal and accrued interest under these notes will automatically convert into shares of the equity security sold by the Company in its next equity financing involving the receipt by the Company of at least \$5,000,000 at a price per share equal to 80% of the lowest per share price paid for such securities by the investors in such offering. Holders of these notes may also, at their option, convert 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.

Between October 22, 2020 and June 8, 2021, we issued and sold unsecured, convertible promissory notes to 10 investors with an aggregate principal amount of \$937,957. These notes bear interest at 8% per annum and had a maturity date of May 31, 2022. These notes have been amended and currently have a maturity date of October 31, 2022. The principal and accrued interest under these notes will automatically convert into shares of the equity security sold by the Company in its next equity financing involving the receipt by the Company of at least \$5,000,000 at a price per share equal to 80% of the lowest per share price paid for such securities by the investors in such offering. Holders of these notes may also, at their option, convert 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.

Between June 30, 2021 and August 28, 2021, we issued and sold unsecured, convertible promissory notes to 6 investors with an aggregate principal amount of \$870,000. These notes bear interest at 8% per annum and have a maturity date of December 31, 2022. The principal and accrued interest under these notes will automatically convert into shares of the Company's Common Stock upon completion of this Offering at the price in this Offering. Holders of these notes may also, at their option, convert 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.

Between October 7, 2021 and January 20, 2022, we issued and sold unsecured, convertible promissory notes to 23 investors pursuant to a note purchase agreement with an aggregate principal amount of \$2,425,000. These notes bear interest at 6% per annum and had a maturity date of May 31, 2022. These notes have been amended and currently have a maturity date of October 31, 2022. The principal and accrued interest under these notes will automatically convert into shares of the Company's Common Stock upon completion of this Offering at the price in this Offering. Holders of these notes may also, at their option, convert 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 577,380 shares of the Company's Common Stock were issued to the noteholders. These warrants have an exercise price equal to the price in this Offering. However, if this Offering is not completed by May 31, 2022, the warrants will have an exercise price of \$5.25 per share. The warrants have a term of 5 years. In addition, we issued a warrant to the placement agent in the convertible note offering exercisable for 29,464 shares of our Common Stock at an exercise price equal to 120% of the anticipated price in this Offering.

Between November and December of 2021, we issued warrants to the holders of our convertible promissory notes issued prior to June 30, 2021 as consideration for their agreement to extend the maturity date of such notes to May 31, 2022. We issued warrants to purchase that number of shares of Common Stock equal to the original principal amount of the notes divided by 4.20. Accordingly, we issued warrants to purchase 1,419,509 shares of the Company's Common Stock to these noteholders. These warrants have an exercise price equal to the price in this Offering. However, if this Offering is not completed by May 31, 2022, the warrants will have an exercise price of \$5.25 per share. The warrants have a term of 5 years.

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.

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In connection with the sale of the convertible bridge notes and issuance of the warrants in the fourth quarter of 2021 and the first quarter of 2022 (none of which were purchased by the Placement Agent), we have agreed to issue to WallachBeth Capital, LLC, the exclusive placement agent for the convertible bridge notes and the associated warrants, the Placement Agent's Warrant to purchase one share of Common Stock based on the investors' bridge note principal balance investment, or a total of 29,464 shares of our Common Stock (based on the assumed initial Offering Price of \$6.125 per Unit, which is the midpoint of the Price Range set forth on the cover of this prospectus). The exercise price of one share of our Common Stock pursuant to the Placement Agent's Warrant will be equal to 120% of the assumed initial Offering Price of one Unit offered hereby. The Placement Agent's Warrant will expire on a date that is not more than five (5) years from the date of the commencement of the sale of our Common Stock in this Offering in compliance with FINRA Rule 5110(e)(1)(A). The Placement Agent's Warrant has been deemed compensation by FINRA and is therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(e)(1). The Placement Agent (or its respective permitted assignees under Rule 5110(e)(2)(B)) will not sell, transfer, assign, pledge, or hypothecate the Placement Agent's Warrant or the securities underlying such warrant, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such warrant or the underlying securities for a period of 180 days following the date of commencement of sales pursuant to the offering. The Placement Agent's Warrant contains the same adjustment provisions as the warrants issued to the investors in the bridge notes. In addition, we have granted the underwriters the ability to exercise them in a "cashless" manner. The Placement Agent's Warrant and the underlying shares of Common Stock that may be issued upon exercise are being registered in the Registration Statement of which this prospectus is a part. The Placement Agent's Warrant is non-exercisable for 180 days following the commencement of the sales of the public securities in this Offering. The shares of Common Stock underlying the Placement Agent's Warrant are being registered in this Registration Statement.

The foregoing transactions were exempt from registration under the Securities Act pursuant to Rule 506 of Regulation D promulgated under the Securities Act.

Between April 2014 and March 2022, we issued non-statutory stock options under our 2014 Stock Incentive Plan to certain of our employees, directors and consultants to purchase up to 969,645 shares of our Common Stock. Some of those options were exercised, resulting in the issuance of 34,456 shares of our Common Stock. Options to purchase 55,380 shares of our Common Stock were forfeited when the recipients' service to the Company was terminated. Options to purchase 876,952 shares of our Common Stock at a weighted average exercise price of approximately \$4.13 per share remain outstanding as of the date of this registration statement. The options generally have a term of 10 years from the date of grant. Our stock option grants and stock issuances upon exercise of such options were exempt from registration under Securities Act pursuant to Rule 701.

Between August 2015 and January 2022, we issued 41,417 shares of our Common Stock as restricted stock grants under our 2014 Stock Incentive Plan to certain of our employees and consultants. These restricted stock grants were exempt from registration under Securities Act pursuant to Rule 701.

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 to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, (the 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the 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, the 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 Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Act, 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.
- (2) For the purpose of determining any liability under the 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 thereof.

EXHIBIT INDEX

Exhibit Number	Description
1.1**	<u>Form of Underwriting Agreement.</u>
3.1*	<u>Amended and Restated Certificate of Incorporation of Registrant, as currently in effect.</u>
3.2*	<u>Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 in order to effectuate the 1-for-7 reverse stock split prior to the completion of this Offering.</u>
3.3*	<u>Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately prior to the completion of this Offering.</u>
3.4*	<u>Certificate of Designation of Series A Convertible Preferred Stock of the Registrant dated July 13, 2017, as currently in effect.</u>
3.5*	<u>Bylaws of the Registrant, as currently in effect.</u>
3.6*	<u>Form of Amended and Restated Bylaws of Registrant, to be in effect immediately prior to completion of the Offering.</u>
4.1*	<u>Form of Registrant's Common Stock Certificate.</u>
4.2*	<u>Common Stock Purchase Warrant issued to San Antonio Economic Development Corporation dated March 17, 2017.</u>
4.3*	<u>Form of Common Stock Purchase Warrant issued to Holders of the Registrant's Convertible Promissory Notes.</u>
4.4**	<u>Form of Placement Agent's Warrant to be issued to WallachBeth Capital, LLC.</u>
4.5*	<u>Form of Representative's Warrant to be issued to WallachBeth Capital, LLC pursuant to the Underwriting Agreement.</u>
4.6*	<u>Form of (Tradeable) Common Stock Purchase Warrant to be issued as part of the Units to be sold in the Offering pursuant to the Underwriting Agreement.</u>
4.7**	<u>Form of Warrant Agent Agreement for the Warrants to be issued as part of the Units to be sold in the Offering.</u>
4.8*	<u>Secured Convertible Note Purchase Agreement dated December 21, 2018, as amended to date.</u>
4.9*	<u>Form of Secured Convertible Promissory Note of Registrant used in private offerings from December 2018 to July 2020.</u>
4.10*	<u>Form of Unsecured Convertible Promissory Note of the Registrant used in private offerings from October 2020 to August 2021.</u>
4.11*	<u>Form of Convertible Promissory Note of the Registrant used in private offerings from October 2021 to January 2022.</u>
4.12*	<u>Form of Amendment to Unsecured Convertible Promissory Note of the Registrant to extend the maturity date to October 31, 2022.</u>
4.13*	<u>Form of Amendment to Convertible Promissory Note of the Registrant to extend the maturity date to October 31, 2022.</u>
4.14*	<u>Form of Note Extension Common Stock Purchase Warrant issued to holders of the Registrant's Convertible Promissory Notes as consideration to extend the maturity date to October 31, 2022.</u>
4.15*	<u>Form of (Non-tradeable) Common Stock Purchase Warrant to be issued as part of the Units to be sold in the Offering pursuant to the Underwriting Agreement.</u>
5.1**	<u>Opinion of Dykema Gossett, PLLC.</u>
10.1*	<u>2014 Equity Incentive Plan of Registrant, as amended.</u>
10.2+*	<u>Executive Chairman Employment Agreement dated January 1, 2020, by and between Registrant and Steven Girgenti, as amended.</u>
10.3+*	<u>Employment Agreement dated February 1, 2015, by and between Registrant and Maria Zannes.</u>
10.4+*	<u>Employment Agreement dated April 4, 2016, by and between Registrant and Vivienne Rebel, as amended.</u>
10.5+*	<u>Employment Agreement dated February 1, 2015, by and between Registrant and Timothy Zannes.</u>
10.6+*	<u>Consulting Agreement dated May 25, 2017, by and between Registrant and Michael Edwards, as amended.</u>
10.7*	<u>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.</u>
10.8*	<u>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.</u>
10.9*	<u>Agreement dated October 17, 2020, by and between Registrant and GO2 Partners.</u>

- 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.](#)
- 14.1* [Code of Business Conduct of the Registrant.](#)
- 16.1** [Letter re Change in Certifying Accountant from Ernst & Young dated August 4, 2022.](#)
- 21.1* [List of Subsidiaries of the Registrant.](#)
- 23.1** [Consent of Dykema Gossett, PLLC \(included in Exhibit 5.1\).](#)
- 23.2** [Consent of Ernst & Young, independent registered public accounting firm.](#)
- 23.3** [Consent of WithumSmith+Brown, PC, independent registered public accounting firm.](#)
- 24.1* [Power of Attorney \(filed as an exhibit to the Company's Registration Statement on Form S-1 filed on April 25, 2022, and incorporated by reference herein\).](#)
- 107** [Amended and Restated Filing Fee Table.](#)
- * Previously filed.
 ** Filed herewith.
 + Indicates management contract or compensatory plan.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of San Antonio, Texas, on August 4, 2022.

bioAffinity Technologies, Inc.

By: /s/ Maria Zannes

Maria Zannes

Chief Executive Officer, President, Founder, and Director

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
<u>/s/ Maria Zannes</u> Maria Zannes	Founder, President, Chief Executive Officer, and Director (Principal Executive Officer)	August 4, 2022
<u>/s/ Michael Edwards</u> Michael Edwards	Chief Financial Officer	August 4, 2022
<u>/s/ Steven Girgenti*</u> Steven Girgenti	Founder, Executive Chairman, and Director	August 4, 2022
<u>/s/ Robert Anderson*</u> Robert Anderson	Director	August 4, 2022
<u>/s/ Stuart Diamond*</u> Stuart Diamond	Director	August 4, 2022
<u>/s/ Peter S. Knight*</u> Peter S. Knight	Director	August 4, 2022
<u>/s/ Mohsin Meghji*</u> Mohsin Meghji	Director	August 4, 2022
<u>/s/ Gary Rubin*</u> Gary Rubin	Director	August 4, 2022

*By: /s/ Maria Zannes
Attorney-in-Fact

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BIOAFFINITY TECHNOLOGIES, INC.

UNDERWRITING AGREEMENT

**1,285,325 UNITS,
EACH UNIT CONSISTING OF ONE SHARE OF COMMON STOCK AND TWO WARRANTS;
EACH WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK**

[*], 2022

WallachBeth Capital, LLC
Harborside Financial Plaza 5
185 Hudson St., Suite 1410
Jersey City, NJ 07311
*As Representative of the
Several Underwriters Named on Schedule I hereto*

Ladies and Gentlemen:

BIOAFFINITY TECHNOLOGIES, INC., a Delaware corporation (the “Company”), proposes, subject to the terms and conditions stated herein, to issue and sell to the underwriters named in Schedule I hereto (the “Underwriters,” or each, an “Underwriter”), for whom WallachBeth Capital, LLC is acting as representative (the “Representative”), an aggregate of 1,285,325 units (“Units”) at an estimated initial public offering price between \$6.00 and \$6.25 per Unit (the “Price Range”). Each Unit will consist of: (i) one share of the Company’s common stock, \$0.007 par value per share (the “Common Stock”); (ii) one five year tradeable warrant (“Tradeable Warrant”) to purchase one share of Common Stock at an exercise price equal to 120% of the assumed per-Unit Offering Price (defined below) of \$6.125, which is the midpoint of the Price Range; and one five year non-tradeable warrant (“Non-Tradeable Warrant”) to purchase one share of Common Stock (“Warrant Shares”) at an exercise price equal to 125% of the Unit Offering Price (defined below). The Tradeable Warrant and the Non-Tradeable Warrant are referred to herein together as the “Warrants” and the shares of Common Stock for which the Warrants are exercisable are referred to herein as the “Warrant Shares.” The said 1,285,325 Units referred to herein are hereinafter referred to as the “Firm Units.” The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock and the Warrants comprising the Units will be immediately separable and will be issued separately in this offering. The Company also proposes to sell to the Underwriters, upon the terms and conditions set forth in Section 4 hereof, an option (the “Over-Allotment Option”) to purchase up to an additional 192,799 shares of Common Stock (the “Option Shares”) and/or up to an additional 192,799 Non-Tradeable Warrants and/or 192,799 Tradeable Warrants (the “Option Warrants”), representing, in total, up to fifteen percent (15%) of the number of Firm Units sold in the offering for the purpose of covering over-allotments of such securities, if any. The exercise of the Over-Allotment Option is at the Underwriters’ sole discretion. The Representative’s Warrant (defined in Section 4(f)) and the shares of Common Stock issuable upon exercise thereof (“Representative’s Warrant Shares”) are referred to herein as the “Representative’s Securities.” The Firm Units, the Common Stock, the Warrants, the Option Shares, the Option Warrants, the shares of Common Stock underlying the Warrants and the Option Warrants and the Representative’s Securities are collectively referred to herein as the “Securities.” The Securities shall be issued directly by the Company and shall have the rights and privileges described in the Registration Statement, the Preliminary Prospectus and the Pricing Prospectus (as defined below). The offering and sale of the Securities is herein referred to as the “Offering.”

The Company and the several Underwriters hereby confirm their agreement as follows:

1. Registration Statement and Prospectus.

The Company has prepared and filed with the Securities and Exchange Commission (the “Commission”) a registration statement covering the Securities on Form S-1 (File No. 333-264463) under the Securities Act of 1933, as amended (the “Securities Act”), and the rules and regulations (the “Rules and Regulations”) of the Commission thereunder, including a preliminary prospectus relating to the Securities and such amendments to such registration statement (including post effective amendments) as may have been required to the date of this Agreement. Such registration statement, as amended (including any post effective amendments), has been declared effective by the Commission. Such registration statement, including amendments thereto (including post effective amendments thereto) and all documents and information deemed to be a part of the Registration Statement through incorporation by reference or otherwise at the time of effectiveness thereof (the “Effective Time”), the exhibits and any schedules thereto at the Effective Time or thereafter during the period of effectiveness and the documents and information otherwise deemed to be a part thereof or included therein by the Securities Act or otherwise pursuant to the Rules and Regulations at the Effective Time or thereafter during the period of effectiveness, is herein called the “Registration Statement.” If the Company has filed or files an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the “Rule 462 Registration Statement”), then any reference herein to the term Registration Statement shall include such Rule 462 Registration Statement. Any preliminary prospectus included in the Registration Statement or filed with the Commission pursuant to Rule 424(a) under the Securities Act is hereinafter called a “Preliminary Prospectus.” The Preliminary Prospectus relating to the Securities that was included in the Registration Statement immediately prior to the pricing of the offering contemplated hereby is hereinafter called the “Pricing Prospectus.”

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The Company is filing with the Commission pursuant to Rule 424 under the Securities Act a final prospectus covering the Securities, which includes the information permitted to be omitted therefrom at the Effective Time by Rule 430A under the Securities Act. Such final prospectus, as so filed, is hereinafter called the “Final Prospectus.” The Final Prospectus, the Pricing Prospectus and any Preliminary Prospectus in the form in which they were included in the Registration Statement or filed with the Commission pursuant to Rule 424 under the Securities Act is hereinafter called a “Prospectus.” Reference made herein to any Preliminary Prospectus, the Pricing Prospectus or to the Prospectus shall be deemed to refer to and include any documents incorporated by reference therein.

2. Representations and Warranties of the Company Regarding the Offering.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date (as defined in Section 4(d) below) and as of each Option Closing Date (as defined in Section 4(b) below), as follows:

(i) **No Material Misstatements or Omissions.** At each time of effectiveness, at the date hereof, at the Closing Date, and at each Option Closing Date, if any, the Registration Statement and any post-effective amendment thereto complied or will comply in all material respects with the requirements of the Securities Act and the Rules and Regulations and did not, does not, and will not, as the case may be, contain any 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 not misleading. The Time of Sale Disclosure Package (as defined below) as of the date hereof and at the Closing Date and on each Option Closing Date, any roadshow or investor presentations delivered to and approved by the Underwriter for use in connection with the marketing of the offering of the Securities (the “Marketing Materials”), if any, and the Final Prospectus, as amended or supplemented, as of its date, at the time of filing pursuant to Rule 424(b) under the Securities Act, at the Closing Date, and at each Option Closing Date, if any, did not, does not and will not contain any 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. The representations and warranties set forth in the two immediately preceding sentences shall not apply to statements in or omissions from the Registration Statement, the Time of Sale Disclosure Package or any Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f). The Registration Statement contains all exhibits and schedules required to be filed by the Securities Act or the Rules and Regulations. No order preventing or suspending the effectiveness

or use of the Registration Statement or any Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission. For purposes of this Agreement, the term “knowledge of the Company” (or its correlatives) means the knowledge of the senior executive officers, or what such persons should have known if they had made due inquiry with respect to the matter being represented.

(ii) **Marketing Materials.** The Company has not distributed any prospectus or other offering material in connection with the offering and sale of the Securities other than the Time of Sale Disclosure Package and the roadshow or investor presentations delivered to and approved by the Representative for use in connection with the marketing of the offering of the Securities (the “Marketing Materials”).

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(iii) **Accurate Disclosure.**

(A) “Time of Sale Disclosure Package” means the Prospectus most recently filed with the Commission before the time of this Agreement, including any preliminary prospectus supplement deemed to be a part thereof.

(B) The Time of Sale Disclosure Package, at the time of filing with the Commission did not, does not and will not contain any 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.

(C) At the time of filing of the Registration Statement and at the date hereof, the Company is not an “ineligible issuer,” as defined in Rule 405 under the Securities Act.

(iv) **Financial Statements.** The financial statements of the Company, together with the related notes and schedules, included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the rules and regulations of the Commission thereunder, and fairly present in all material respects the financial condition of the Company as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with U.S. generally accepted accounting principles (“GAAP”) consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP). No other financial statements, pro forma financial information or schedules are required under the Securities Act, the Exchange Act, or the Rules and Regulations to be included in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus.

(v) **Independent Accountants.** To the Company’s knowledge, Ernst & Young LLP and WithumSmith+Brown, PC, which have expressed their opinions with respect to the audited financial statements and schedules included as a part of the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, are both independent public accounting firms with respect to the Company within the meaning of the Securities Act and the Rules and Regulations.

(vi) **Accounting Controls.** The Company will maintain a system of “internal control over financial reporting” (as defined under Rules 13a-15 and 15d-15 under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by, or under the supervision of, its principal executive and principal financial officer, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, 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.

(vii) **Forward-Looking Statements.** The Company had a reasonable basis for, and made in good faith, each “forward-looking statement” (within the meaning of Section 27A of the Securities Act or Section 21E of the Exchange Act) contained or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package, the Final Prospectus or the Marketing Materials.

(viii) **Statistical and Marketing-Related Data.** All statistical or market-related data included or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, or included in the Marketing Materials, are based on or derived from sources that the Company reasonably believes to be reliable and accurate, and the Company has obtained the written consent to the use of such data from such sources, to the extent required.

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(ix) **Pursuant to the Exchange Act.** The Company has filed with the Commission a Form 8-A (File Number 001-[*]) providing for the registration pursuant to Section 12(b) under the Exchange Act of the shares of Common Stock. The registration of the shares of Common Stock and the Representative’s Warrant under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to terminate the registration of the shares of Common Stock or the Representative’s Warrant under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

(x) **Stock Exchange Listing.** The shares of Common Stock and the Tradeable Warrants have been approved for listing on The Nasdaq Capital Market (“Nasdaq”), and the Company has taken no action designed to delist the shares of Common Stock from Nasdaq, nor has the Company received any written notification that Nasdaq is contemplating terminating such listing.

(xi) **Absence of Manipulation.** The Company has not taken, directly or indirectly, any action that is designed to or that has constituted or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xii) **Investment Company Act.** The Company is not and, after giving effect to the offering and sale of the Securities and the application of the net proceeds thereof, will not be an “investment company,” as such term is defined in the Investment Company Act of 1940, as amended.

(b) Any certificate signed by any officer of the Company and delivered to the Underwriters or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

3. Representations and Warranties Regarding the Company.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date and as of each Option Closing Date, if any, as follows:

(i) **Good Standing.**

(A) The Company has been duly organized and is validly existing as a corporation or other entity in good standing under the laws of its

jurisdiction of incorporation or organization. The Company has the power and authority (corporate or otherwise) to own its properties and conduct its business as currently being carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation or other entity in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary, except where the failure to so qualify would not have a material adverse effect upon the business, prospects, properties, operations, condition (financial or otherwise) or results of operations of the Company and its subsidiaries, considered as one entity, or in the Company's ability to perform its obligations under this Agreement or the Representative's Warrant (as defined in Section 4(f)) ("Material Adverse Effect").

(B) All of the Subsidiaries of the Company are set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. 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 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. Each Subsidiary has been duly organized and is validly existing as a corporation or other entity in good standing under the laws of its jurisdiction of incorporation or organization and is duly qualified to do business as a foreign corporation or other entity in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary, except where the failure to so qualify would not have, or be reasonably likely to result in, a Material Adverse Effect.

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(ii) **Validity and Binding Effect of Agreements.** The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement, the Representative's Warrant and each of the other documents relating to the transactions contemplated hereby (the "Transaction Documents") to which it is a party 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 stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and the Representative's Warrant, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(iii) **Contracts.** The execution, delivery and performance of this Agreement and the Representative's Warrant and the consummation of the transactions herein and therein contemplated will not (A) result in a breach or violation of any of the terms and provisions of, or constitute a default under, any law, order, rule or regulation to which the Company is subject, or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, breach or default would not result in a Material Adverse Effect, (B) conflict with, result in any violation or breach of, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) (a "Default Acceleration Event") of, any agreement, lease, credit facility, debt, note, bond, mortgage, indenture or other instrument (the "Contracts") or obligation or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, default, or Default Acceleration Event would not result in a Material Adverse Effect, or (C) result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Company's current Amended and Restated Certificate of Incorporation, as amended ("Certificate of Incorporation"), or Amended and Restated Bylaws ("Bylaws").

(iv) **No Violations of Governing Documents.** The Company is not in violation, breach or default under its Certificate of Incorporation, Bylaws or other equivalent organizational or governing documents or any Contract, except where the breach of any such Contract would not have a Material Adverse Effect.

(v) **Consents.** No consents, approvals, orders, authorizations or filings are required on the part of the Company in connection with the execution, delivery or performance of this Agreement and the Representative's Warrant and the issue and sale of the Securities and the Representative's Securities, except (A) the registration under the Securities Act of the Securities and Representative's Securities, which has been effected, (B) the necessary filings and approvals from Nasdaq to list the Securities and the shares of Common Stock underlying the Representative's Warrant, (C) such consents, approvals, authorizations, registrations or qualifications as may be required under state or foreign securities or Blue Sky laws and the rules of the Financial Industry Regulatory Authority, Inc. ("FINRA") in connection with the purchase and distribution of the Securities by the several Underwriters, (D) such consents and approvals as have been obtained and are in full force and effect, and (E) such consents, approvals, orders, authorizations and filings the failure of which to make or obtain would not result in a Material Adverse Effect.

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(vi) **Capitalization.** The Company has an authorized capitalization as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. All of the issued and outstanding shares of capital stock of the Company are duly authorized and validly issued, fully paid and nonassessable, and have been issued in compliance with all applicable securities laws, and conform to the description thereof in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. The Company has not issued any capital stock since December 31, 2021, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Share Equivalents (defined below) outstanding as of the date of the Registration Statement. No Person other than the Representative 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 such rights which have been waived prior to the date hereof. Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, 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 Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements ("Common Share Equivalents") by which the Company or any Subsidiary is or may become bound to issue additional Common Stock or Common Share Equivalents or the capital stock of any Subsidiary. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue Common Stock or other securities to any Person (other than the Underwriters). Other than what is disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, 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 as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, 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, state and foreign securities and other laws or the applicable statute of limitations has expired, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable foreign and state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements or the applicable statute of limitations has expired. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. Other than what is disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, 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.

(vii) **Taxes.** The Company has (a) filed all foreign, federal, state and local tax returns (as hereinafter defined) required to be filed with taxing

authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof (except where the failure to file would not, individually or in the aggregate, have a Material Adverse Effect) and (b) paid all taxes (as hereinafter defined) shown as due and payable on such returns that were filed and has paid all taxes imposed on or assessed against the Company (except where the failure to pay would not, individually or in the aggregate, have a Material Adverse Effect). The provisions for taxes payable, if any, shown on the financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. To the knowledge of the Company, no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company, and no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company. The term “taxes” mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term “returns” means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(viii) **Material Change.** Since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, and except as disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, (a) the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock; (c) there has not been any change in the capital stock of the Company (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants, upon the conversion of outstanding shares of preferred stock or other convertible securities, due to the vesting of outstanding stock grants or the issuance of restricted stock awards or restricted stock units under the Company’s existing stock awards plan, or any new grants thereof in the ordinary course of business), (d) there has not been any material change in the Company’s long-term or short-term debt, other than periodic accruals in the ordinary course pursuant to the terms of the Company’s outstanding debt, and (e) there has not been the occurrence of any Material Adverse Effect. Unless otherwise disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(ix) **Absence of Proceedings.** There has not been, and to the knowledge of the Company there is not pending or contemplated, any 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 adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities. Neither the Company nor any Subsidiary, nor, to the Company’s knowledge, any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under United States or foreign federal or state securities laws or a claim of breach of fiduciary duty. To the knowledge of the Company, there has not been, and there is not pending or contemplated, any investigation by the Commission or any Foreign governmental authority involving the Company or any current or former director or officer of the Company.

(x) **Regulatory.** The Company is and at all times has been in compliance with all statutes, rules, or regulations applicable to the Company, including, without limitation, all statutes, rules, or regulations relating to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company, including the Federal Food, Drug, and Cosmetic Act and foreign equivalent laws regulate the research, development, testing, manufacture, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, quality control, labeling, and export and import of pharmaceutical products, laws relating to the conduct of business in the internet and the Federal Hazardous Substances Act, state and foreign laws relating to the same, and licensing and certification Laws covering any material aspect of the business of the Company (“Applicable Laws”), except in each case as would not, individually or in the aggregate, have a Material Adverse Effect. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus: (i) the Company has not received notice from any Governmental Entity (as defined below) alleging or asserting noncompliance with any Applicable Regulations (as defined below) or Authorizations (as defined below); (ii) the Company possesses all licenses, certificates, approvals, clearances, consents, authorizations, qualifications, registrations, permits, and supplements or amendments thereto required by any such Applicable Regulations and/or to carry on its businesses as now conducted (“Authorizations”) and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iii) the Company has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Regulations or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, has there been any material noncompliance with or violation of any Applicable Regulations by the Company requiring the issuance of any such communication or result in an investigation, corrective action, or enforcement action by any Governmental Entity; and (iv) the Company has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action. Neither the Company nor, to the Company’s knowledge, any of its directors, officers, employees or agents has been convicted of any crime under any Applicable Regulations. “Governmental Entity” shall be defined as any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency (whether foreign or domestic) having jurisdiction over the Company or any of its properties, assets or operations.

(xi) **Good Title.** The Company has good and marketable title to all property (whether real or personal) described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as being owned by it that are material to the business of the Company, in each case free and clear of all liens, claims, security interests, other encumbrances or defects, except those that are disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus and those that would not result, or would not be reasonably likely to result, in a Material Adverse Effect. The property held under lease by the Company is held by it under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company.

(xii) **Intellectual Property.** The Company owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights (“Intellectual Property Rights”) necessary for the conduct of the business of the Company as currently carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. To the knowledge of the Company, no action or use by the Company necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Final Prospectus will involve or give rise to any infringement of, or license or similar fees for, any Intellectual Property Rights of others. The Company has not received any notice alleging any such infringement, fee or conflict with asserted Intellectual Property Rights of others. Except as would not result or would not be reasonably likely to result, individually or in the aggregate, in a Material Adverse Effect (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), result in a Material Adverse Effect; (C) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii) result in a Material Adverse Effect; (D) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or

claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), result in a Material Adverse Effect; and (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company, or actions undertaken by the employee while employed with the Company and would result, individually or in the aggregate, in a Material Adverse Effect. To the Company's knowledge, all material technical information developed by and belonging to the Company which has not been patented has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus and are not described therein. The Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons. To the Company's knowledge, there is no prior art or public or commercial activity that may render any patent included in the Intellectual Property Rights invalid or that would preclude the issuance of any patent on any patent application included in the Intellectual Property which has not been disclosed to the U.S. Patent and Trademark Office or the relevant foreign patent authority, as the case may be. The Company has not, and to the Company's knowledge, no third party has, committed any act or omitted to undertake any act the effect of such commission or omission resulting, or would reasonably be expected to result, in a legal determination that any item of Intellectual Property Rights thereby was rendered invalid or unenforceable in whole or in part. The manufacture, use and sale of the products or product candidates described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as under development by the Company fall within the scope of one or more claims of the patents or patent applications included in the Intellectual Property Rights. Other than information disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property Rights that are owned or purported to be owned by the Company that would confer upon any governmental agency or body, university, college, other educational institution or research center any claim or right in or to any such Intellectual Property Rights.

(xiii) **Employment Matters.** There is (A) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relation board or any foreign labor relations board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (B) no labor disturbance by the employees of the Company exists or, to the Company's knowledge, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, resulting singularly or in the aggregate, in a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

(xiv) **ERISA Compliance.** No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred with respect to any employee benefit plan of the Company resulting, or would reasonably be likely to result, singularly or in the aggregate, in a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and, to the Company's knowledge, nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, cause the loss of such qualification.

(xv) **Environmental Matters.** The Company is in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses ("Environmental Laws"), except where the failure to comply has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability, except for any violation or liability which has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company has knowledge.

(xvi) **SOX Compliance.** The Company has taken all actions it deems reasonably necessary or advisable to take on or prior to the date of this Agreement to assure that, upon and at all times after the Effective Date, it will be in compliance in all material respects with all applicable provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof. (the "Sarbanes-Oxley Act") that are then in effect and will take all action it deems reasonably necessary or advisable to assure that it will be in compliance in all material respects with other applicable provisions of the Sarbanes-Oxley Act not currently in effect upon it and at all times after the effectiveness of such provisions.

(xvii) **Money Laundering Laws.** The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xviii) **Foreign Corrupt Practices Act.** Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent, affiliate of the Company or any other person acting on behalf of the Company, is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure continued compliance therewith.

(xix) **OFAC.** Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent or affiliate of the Company or any other person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering of the Securities contemplated hereby, or lend,

contribute or otherwise make available such proceeds to any person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(xx) **Insurance.** Following the closing of the offering contemplated hereby, the Company will carry insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries.

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(xxi) **Books and Records.** The minute books of the Company have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a complete summary of all meetings and actions of the board of directors (including each board committee) and stockholders of the Company (or analogous governing bodies and interest holders, as applicable), since the time of its incorporation or organization through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all transactions referred to in such minutes.

(xxii) **No Violation.** 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 United States or foreign 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 has not resulted, and would not reasonably be expected to result, in a Material Adverse Effect.

(xxiii) **Continued Business.** No supplier, customer, distributor or sales agent of the Company has notified the Company that it intends to discontinue or decrease the rate of business done with the Company, except where such discontinuation or decrease has not resulted in a Material Adverse Effect.

(xxiv) **No Finder's Fee.** There are no claims, payments, issuances, arrangements or understandings for services in the nature of a finder's, consulting or origination fee with respect to the introduction of the Company to any Underwriter or the sale of the Securities hereunder or any other arrangements, agreements, understandings, payments or issuances with respect to the Company that may affect the Underwriters' compensation, as determined by FINRA.

(xxv) **No Fees.** Except as disclosed to the Representative in writing, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to (i) any person, as a finder's fee, investing fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who provided capital to the Company, (ii) any FINRA member, or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member within the twelve (12) month period prior to the date on which the Registration Statement was filed with the Commission ("Filing Date") or thereafter.

(xxvi) **Proceeds.** None of the net proceeds of the offering will be paid by the Company to any participating FINRA member or any affiliate or associate of any participating FINRA member, except as specifically authorized herein.

(xxvii) **No FINRA Affiliations.** To the Company's knowledge and except as disclosed to the Representative in writing, no (i) officer or director of the Company or (ii) owner of 5% or more of any class of the Company's securities or (iii) owner of any amount of the Company's unregistered securities acquired within the 180-day period prior to the Filing Date, has any direct or indirect affiliation or association with any FINRA member. The Company will advise the Representative and counsel to the Underwriters if it becomes aware that any officer, director of the Company or any owner of 5% or more of any class of the Company's securities is or becomes an affiliate or associated person of a FINRA member participating in the offering.

(xxviii) **No Financial Advisor.** Other than the Underwriters no person has the right to act as an underwriter or as a financial advisor to the Company in connection with the transactions contemplated hereby.

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(xxix) **Data Privacy and Security Laws.** The Company is, and at all prior times was, in material compliance with all applicable state and federal data privacy and security laws and regulations in the United States, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act, and the Company has taken commercially reasonable actions to prepare to comply with, and have been and currently are in compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). To ensure compliance with the Privacy Laws, the Company has in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) Protected Health Information as defined by HIPAA; (iv) "personal data" as defined by GDPR; and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. The Company has at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies: (i) it has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would result in any such notice; (ii) it is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(xxx) **No Registration Rights.** There are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights which have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.

(xxxi) **Prior Sales of Securities.** Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, stock option plans or other employee compensation plans, pursuant to outstanding preferred stock, options, rights or warrants or other outstanding convertible securities or in connection with the vesting of any outstanding stock grants.

(xxxii) **Compliance with Laws.** The Company, (A) to the best of its knowledge, is and at all times has been in compliance with, to the extent applicable, (i) the Federal Food, Drug, and Cosmetic Act (the "FDCA"), (ii) the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and Laws applicable to hazardous or regulated substances and radioactive or biologic materials, (iii) the federal Anti-Kickback Statute, (iv) the False Claims Act, (v) the Civil Monetary Penalties Law, (vi) the Physicians Payments Sunshine Act; (vii) the criminal False Claims Law, (viii) the HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act, (xi) licensing and certification laws covering any aspect of the business of the Company

and (ix) all other statutes, rules or regulations applicable to the Company (“Applicable Laws”), except as would not, or would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; (B) has not received any warning letter, untitled letter or other correspondence or notice from any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its business as now conducted (“Applicable Authorizations”); (C) possesses all material Application Authorizations and such material Applicable Authorizations are valid and in full force and effect and are not in material violation of any term of any such Applicable Authorizations; (D) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product operation or activity is in violation of any Applicable Laws or Applicable Authorizations and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding nor, to the Company’s knowledge, has there been any material noncompliance with or violation of any Applicable Laws by the Company that requires the issuance of any such communication or would reasonably be expected to result in an investigation, corrective action, or enforcement action by any Governmental Entity; (E) has not received written notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Applicable Authorizations and has no knowledge that any such Governmental Entity has threatened or is considering such action; (F) to its knowledge, has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Applicable Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, “dear doctor” letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company’s knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

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(xxxiii) **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 Time of Sale Disclosure Package and the Final 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 Time of Sale Disclosure Package and the Final 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 Time of Sale Disclosure Package and the Final 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 Time of Sale Disclosure Package or the Prospectus, the Company has not received any written notices or correspondence from the FDA 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.

(xxxiv) **Loans to Directors or Officers.** There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective family members, except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(xxxv) **Transactions With Affiliates and Employees.** Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final or Prospectus, 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 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. There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus that have not been described as required.

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(xxxvi) **Stock Option Plans.** As of the date of this Agreement, there are no outstanding stock options under the Company’s stock incentive plans, other than what is disclosed Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(xxxvii) **D&O Questionnaires.** To the Company’s knowledge, all information contained in the questionnaires completed by each of the Company’s directors and officers immediately prior to the Offering is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires to become inaccurate and incorrect.

(xxxviii) **Board of Directors.** The Board of Directors is comprised of the persons set forth under the heading of “Management” in the Registration Statement, Time of Sale Disclosure Package and the Final Prospectus. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Nasdaq Capital Market. At least one member of the Board of Directors qualifies as a “financial expert” as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Nasdaq Capital Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as “independent” as defined under the rules of the Nasdaq Capital Market.

(xxxix) **IT Systems.** Except as would not, individually or in the aggregate, have a Material Adverse Effect, the Company reasonably believes that (A) the Company and the Subsidiaries own or have a valid right to access and use all computer systems, networks, hardware, software, databases, websites, and equipment used to process, store, maintain and operate data, information, and functions used in connection with the business of the Company and the Subsidiaries (the “Company IT Systems”), (B) the Company IT Systems are adequate for, and operate and perform as required in connection with, the operation of the business of the Company and the Subsidiaries as currently conducted and (C) the Company and the Subsidiaries have implemented reasonable backup, security and disaster recovery technology consistent with applicable regulatory standards.

(xl) **Industry Data.** The statistical and market-related data included in each of the Registration Statement, Time of Sale Disclosure Package and the Final Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company’s good faith estimates that are made on the basis of data derived from such sources.

(xli) **Contracts Affecting Capital.** There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Rules and Regulations) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that materially affect the Company’s or its Subsidiaries’ liquidity or the availability of or requirements for their capital resources required to be described or incorporated by reference in the Registration Statement and the Prospectus which have not been described or incorporated by reference as required.

(xlii) **Diligence Materials.** The Company has provided to the Representative and Representative Counsel all materials required or necessary to respond in all material respects to the diligence request submitted to the Company or Company Counsel by the Representative.

4. Purchase, Sale and Delivery of Shares.

(a) On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell the Firm Units to the several Underwriters, and the several Underwriters agree, severally and not jointly, to purchase the Firm Units set forth opposite the names of the Underwriters in Schedule I hereto. The purchase price for each Firm Unit shall be \$[*] per Firm Unit (or 91% of the public offering price) (the Unit Offering Price), provided however, that if more than twenty-five percent (25.0%) of the Firm Units offered hereby are sold to existing investors in the Company as agreed by the Representative, then the purchase price for the Firm Units sold to those investors will be reduced to \$[*] per share (or 96% of the public offering price). The prices of the Units shall be set forth in Schedule II hereof.

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(b) The Company hereby grants to the Underwriters the option to purchase some or all of the Option Shares and Option Warrants or Option Warrants, or any combination of Option Shares and Option Warrants, and, upon the basis of the warranties and representations and subject to the terms and conditions herein set forth, the Underwriter shall have the right, severally and not jointly, to purchase all or any portion of the Option Shares and/or Option Warrants as may be necessary to cover over-allotments made in connection with the transactions contemplated hereby. The purchase price to be paid per Option Share shall be equal to the product of the Unit Offering Price minus \$0.01 multiplied by 0.91 and the purchase price to be paid per Option Warrant shall be equal to \$0.0091. The Underwriters shall not be under any obligation to purchase any of the Option Shares or Option Warrants prior to the exercise of the Over-Allotment Option. This Over-Allotment Option may be exercised by the Underwriters at any time and from time to time on or before the forty-fifth (45th) day following the date hereof, by written notice to the Company (the "Option Notice"). The Option Notice shall set forth the aggregate number of Option Shares and/or Option Warrants as to which the Over-Allotment Option is being exercised, and the date and time when the Option Shares and/or Option Warrants are to be delivered (such date and time being herein referred to as the "Option Closing Date"); provided, however, that the Option Closing Date shall not be earlier than the Closing Date (as defined below) nor earlier than the first Business Day after the date on which the Over-Allotment Option shall have been exercised nor later than the fifth Business Day after the date on which the Over-Allotment Option shall have been exercised unless the Company and the Representative otherwise agree. Upon exercise of the Over-Allotment Option with respect to all or any portion of the Option Shares or Option Warrants subject to the terms and conditions set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Shares and/or Option Warrants specified in such notice; and (ii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Shares and/or Option Warrants then being purchased as set forth in Schedule I opposite the name of such Underwriter, subject to such adjustments as the Representative, in its sole discretion, shall determine. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company (except to the extent the Representative has exercised the Over-Allotment Option in accordance herewith). "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 that banks shall not be deemed to be authorized or obligated to be closed due to a "shelter in place," "non-essential employee" or similar closure of physical branch locations at the direction of any governmental authority if such banks' electronic funds transfer systems (including for wire transfers) are open for use by customers on such day. Any action that is to take place hereunder on a day that is not a Business Day shall take place on the next succeeding Business Day.

(c) Payment of the purchase price for and delivery of the Option Shares and/or Option Warrants shall be made on an Option Closing Date in the same manner and at the same office as the payment for the Firm Units as set forth in subparagraph (d) below.

(d) The Firm Units will be delivered by the Company to the Representative, for the respective accounts of the several Underwriters against payment of the aggregate Unit Offering Price therefor by wire transfer of same day funds payable to the order of the Company at the offices of WallachBeth Capital, LLC, Harborside Financial Plaza 5, 185 Hudson Street, Suite 1410, Jersey City, New Jersey 07311, or such other location as may be mutually acceptable, at 10:00 a.m. Eastern Time, on the second (or if the Firm Units are priced, as contemplated by Rule 15c6-1(c) under the Exchange Act, after 4:30 p.m. Eastern time, the third) full Business Day following the date hereof, or at such other time and date as the Representative and the Company determine pursuant to Rule 15c6-1(a) under the Exchange Act, or, in the case of the Option Shares and/or Option Warrants, at such date and time set forth in the Option Notice. The time and date of delivery of the Firm Units is referred to herein as the "Closing Date." On the Closing Date, the Company shall deliver the Common Stock and the Warrants which shall be registered in the name or names and shall be in such denominations as the Representative may request on behalf of the Underwriters at least one (1) Business Day before the Closing Date, to the respective accounts of the several Underwriters, which delivery shall with respect to the Common Stock and the Warrants, be made through the facilities of The Depository Trust Company's Deposit or Withdrawal at Custodian ("DWAC") system.

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(e) It is understood that the Representative has been authorized, for its own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Units and any Option Shares and/or Option Warrants the Underwriters have agreed to purchase. The Representative, individually and not as the Representative of the Underwriters, may (but shall not be obligated to) make payment for any Securities to be purchased by any Underwriter whose funds shall not have been received by the Representative by the Closing Date or any Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) The Company hereby agrees to issue to the Underwriters (and/or its designees) on the Closing Date a five-year warrant (the "Representative's Warrant") for the purchase of an aggregate of up to 25,507 shares of Common Stock, representing up to two percent (2.0%) of the Firm Units plus two percent (2.0%) of any Option Shares purchased in the Offering, provided that if more than twenty five percent (25%) of the Firm Units or Option Shares offered hereby are sold to existing investors in the Company as agreed by the Representative, then the number of shares subject to the Representative's Warrant relating to the Firm Units and Option Shares sold to existing investors shall cover only two-and-one-half percent (2.5%) of the number of shares of Firm Units and Option Shares purchased by the existing investors. The Representative's Warrant, in the form attached hereto as Exhibit A, shall be exercisable, in whole or in part, commencing on a date which is six (6) months after the date of the commencement of sales of the Firm Units in the public Offering after the effective date of the Registration Statement (the "Effective Date") and expiring on the five-year anniversary of the Effective Date at an initial exercise price per share of Common Stock equal to 115% of the Unit Offering Price (subject to adjustment as set forth therein). The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant and the underlying shares of Common Stock during the one hundred eighty (180) days after the commencement of sales of the Firm Units in the public Offering after the Effective Date and by its acceptance thereof shall agree that it will not sell, transfer, assign, pledge or hypothecate the Representative's Warrant, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of one hundred eighty (180) days following the commencement of sales of the Firm Units in the public Offering after the Effective Date to anyone other than (i) an Underwriter or a selected dealer in connection with the Offering of the Securities or (ii) a bona fide officer or partner of the Representative or of any such Underwriter or selected dealer; and only if any such transferee agrees to the foregoing lock-up restrictions. Delivery of the Representative's Warrant shall be made on the Closing Date and shall be issued in the name or names and in such authorized denominations as the Representative may request.

5. Covenants.

(a) The Company covenants and agrees with the Underwriters as follows:

(i) The Company shall prepare the Final Prospectus in a form approved by the Representative and file such Final Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if

applicable, such earlier time as may be required by the Rules and Regulations.

(ii) During the period beginning on the date hereof and ending on the later of the Closing Date or such date as determined by the Representative the Final Prospectus is no longer required by law to be delivered in connection with sales by an underwriter or dealer (the "Prospectus Delivery Period"), prior to amending or supplementing the Registration Statement, including any Rule 462 Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company shall furnish to the Representative for review and comment a copy of each such proposed amendment or supplement, and the Company shall not file any such proposed amendment or supplement to which the Representative reasonably objects.

(iii) From the date of this Agreement until the end of the Prospectus Delivery Period, the Company shall promptly advise the Representative in writing (A) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (B) of the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, (C) of the time and date that any post-effective amendment to the Registration Statement becomes effective and (D) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending its use or the use of the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Stock or the Tradeable Warrants from any securities exchange upon which either is listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time during the Prospectus Delivery Period, the Company will use its reasonable efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rules 424(b), 430A, 430B or 430C as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission (without reliance on Rule 424(b)(8) or 164(b) of the Securities Act).

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(iv) During the Prospectus Delivery Period, the Company will comply with all requirements imposed upon it by the Securities Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, and by the Exchange Act, as now and hereafter amended, so far as necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the Time of Sale Disclosure Package, the Registration Statement and the Final Prospectus. If during the Prospectus Delivery Period any event occurs the result of which would cause the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary or appropriate in the opinion of the Company or its counsel or the Representative or counsel to the Underwriters to amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to comply with the Securities Act, the Company will promptly notify the Representative, allow the Representative the opportunity to provide reasonable comments on such amendment, prospectus supplement or document, and will amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) or file such document (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(v) The Company shall take or cause to be taken all necessary action to qualify the Securities and Representative's Securities for sale under the securities laws of such jurisdictions as the Representative reasonably designates and to continue such qualifications in effect so long as required, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified, to execute a general consent to service of process in any state or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise subject.

(vi) The Company will furnish to the Underwriters and counsel to the Underwriters copies of the Registration Statement, each Prospectus, and all amendments and supplements to such documents, in each case as soon as available and in such quantities as the Underwriters may from time to time reasonably request.

(vii) The Company will make generally available (which includes filings pursuant to the Exchange Act made publicly through the Electronic Data Gathering, Analysis and Retrieval ("EDGAR") system) to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement (which need not be audited) covering a 12-month period that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 of the Rules and Regulations.

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(viii) The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid all expenses relating to the Offering, including, without limitation, (a) all filing fees and communication expenses relating to the registration of the Securities and the Representative's Securities to be sold in the Offering with the Commission; (b) all actual Public Offering Filing System filing fees associated with the review of the Offering by FINRA; (c) all fees and expenses relating to the listing of the Common Stock and the Tradeable Warrants on the Nasdaq Capital Market; (d) all fees, expenses and disbursements, if any, relating to the registration or qualification of the Securities and the Representative's Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representatives may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable and documented fees and disbursements of "blue sky" counsel); (e) all actual fees, expenses and disbursements relating to the registration, qualification or exemption of the Securities and the Representative's Securities under the securities laws of such foreign jurisdictions as the Representatives may reasonably designate; (f) the costs of all mailing and printing of the Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and Final Prospectuses as the Representatives may reasonably deem necessary; (g) the costs of preparing, printing and delivering certificates representing the Securities and the Representative's Securities; (h) fees and expenses of the transfer agent for the Common Stock; (i) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (j) the fees and expenses of the Company's accountants; (k) the fees and expenses of the Company's legal counsel and other agents and representatives; (l) all reasonable and documented "road show" expenses for the Offering; and (m) the due diligence fees and expenses of the Underwriters, including, without limitation, legal fees and expenses of the Underwriters and other diligence expenses. The Representatives may deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or any Option Closing Date, if any, the expenses set forth herein to be paid by the Company to the Underwriters, provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the reasonable and documented out-of-pocket expenses incurred in connection with the Offering and any advance paid by the Company to the Representative but not utilized against accountable expenses will be returned to the Company to the extent not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

(ix) The Company intends to apply the net proceeds from the sale of the Securities to be sold by it hereunder for the purposes set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus under the heading "Use of Proceeds."

(x) The Company has not taken and will not take, directly or indirectly, during the Prospectus Delivery Period, any action designed to cause or result in, or that has constituted, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xi) The Company represents and agrees that, unless it obtains the prior written consent of the Representative, and each Underwriter, severally, and not jointly, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the free writing prospectuses included in Schedule III. Any such free writing prospectus consented to by the Company and the Representative is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as

defined in Rule 433, and has complied or will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record-keeping.

(xii) The Company hereby agrees that, without the prior written consent of the Representative, it and any successors will not, during the period ending one hundred and eighty (180) days after the date hereof (“Lock-Up Period”), (a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, (b) file or caused to be filed any registration statement with the Commission relating to the offering of any shares of capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock or (c) enter into any swap or other arrangement that transfers to another in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (a), (b) or (c) above is to be settled by delivery of shares of capital stock of the Company or any successors or such other securities, in cash or otherwise. The restrictions contained in the preceding sentence shall not apply to (i) the shares of Common Stock to be sold hereunder, (ii) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the terms of which option, warrant or other outstanding convertible security are not thereafter amended, (iii) the issuance by the Company of shares of Common Stock upon the vesting of outstanding stock grants, (iv) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock (whether upon the exercise of stock options or otherwise) to the Company’s employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the Closing Date and described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, provided that if the grantee of any such equity award set forth in this Section is an executive officer or director of the Company, such person enters into a Lock-Up Agreement (as defined below) in the form attached hereto as Exhibit B in connection with any such grant, provided further that such securities issued to advisors or consultants of the Company are issued as “restricted securities” (as defined in Rule 144 of the Securities Act) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the Lock-Up Period, and (v) the filing by the Company of any registration statement on Form S-8 or a successor form thereto relating to an equity compensation plan described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

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(xiii) From the date hereof until the 181st day after the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of shares of capital stock of the Company or any of its subsidiaries or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company or any of its subsidiaries (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. Any Underwriter 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.

(xiv) To engage and maintain, at its expense, a registrar and transfer agent for the Common Stock (if other than the Company) for a period of at least three (3) years after the Effective Date.

(xv) To use its commercially reasonable best efforts to maintain the listing of the Common Stock and the Tradeable Warrants on the Nasdaq Capital Market for a period of at least three (3) years after the Effective Date.

(xvi) To not take, directly or indirectly, any action designed to cause or result in, or that has constituted or will constitute, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Securities.

(xvii) As of the Closing Date, the Company shall have retained an investor relations advisory firm reasonably acceptable to the Representative and the Company and shall retain such firm or another firm reasonably acceptable to the Representative for a period of not less than one (1) year after the Closing Date.

(xviii) Within 120 days from the closing date of the Offering, the Company will have appropriate Directors’ & Officers’ (“D&O”) and Errors & Omissions (“E&O”) insurance with appropriate liability levels as reasonably determined by the Company. The Company acknowledges and agrees that the Representative and their principal officers shall be named additional insureds of the Company’s D&O and E&O insurance policies.

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(b) Right of First Refusal: Tail.

(i) For a period of sixteen (16) months from the closing of the Offering, the Company hereby grants a right of first refusal to the Representative to act as lead underwriter or book-running manager or placement agent for each and every future public and private equity, equity-linked, convertible or debt (excluding commercial bank debt) offerings of the Company, or any successor to or any subsidiary of the Company during such sixteen (16) month period. If the Representative fails to accept an offer within ten (10) Business Days after the receipt of a notice containing the material terms of a proposed financing by registered mail or overnight courier service addressed to the Representative, then the Representative shall have no further claim or right with respect to the financing proposal contained in such notice. If, however, the terms of such financing proposal are subsequently modified in any material respect, the preferential right referred to herein shall apply to such modified proposal as if the original proposal had not been made. The Representative’s failure to exercise its preferential right with respect to any particular proposal shall not affect its preferential rights relative to future proposals.

(ii) For a period of 12 months after the closing of the Offering, the Representative will receive a cash fee equal to the underwriting discount and the Representative’s Warrant set forth herein with respect to any sale, merger, acquisition or other similar transactions (each, a “Transaction”) occurring with a party introduced to the Company by the Representative in connection with the Offering.

The term “Transaction” shall include, without limitation, any investment in (whether in one or a series of transactions) the assets or the capital stock of the Company, through any proposed merger, consolidation, joint venture or other business/strategic combination with or involving the Company or any event which results in the transfer of control of or a material interest in the Company or of all or a substantial amount of the assets thereof, as well as any recapitalization or restructuring of the Company by the current owners, a third party or any combination thereof, or any other form of transaction which results in the effective acquisition of the principal business and operations of the Company.

6. Conditions of the Underwriter’s Obligations. The respective obligations of the several Underwriters hereunder to purchase the Securities are subject to the accuracy, as of the date hereof and at all times through the Closing Date, and on each Option Closing Date (as if made on the Closing Date or such Option Closing Date, as applicable), of and compliance with all representations, warranties and agreements of the Company contained herein, the performance by the Company of its obligations

hereunder and the following additional conditions:

(a) If filing of the Final Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, is required under the Securities Act or the Rules and Regulations, the Company shall have filed the Final Prospectus (or such amendment or supplement) or such Issuer Free Writing Prospectus with the Commission in the manner and within the time period so required (without reliance on Rule 424(b)(8) or 164(b) under the Securities Act); the Registration Statement shall remain effective; no stop order suspending the effectiveness of the Registration Statement or any part thereof, any Rule 462 Registration Statement, or any amendment thereof, nor suspending or preventing the use of the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened by the Commission; any request of the Commission or the Representative for additional information (to be included in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, any Issuer Free Writing Prospectus or otherwise) shall have been complied with to the satisfaction of the Representative.

(b) At the Closing Date and at each Option Closing Date, the Common Stock and Warrant and, as to each Option Closing Date, if any, the applicable Option Shares and Option Warrants, shall be delivered in book-entry form unless physical certificates are requested by the Underwriters in their discretion (in form and substance satisfactory to the Underwriters) representing the Common Stock and Warrants and Option Shares and/or Option Warrants (or through the full fast transfer facilities of The Depository Trust Company (the “DTC”)) for the account of the Underwriters.

(c) At the Closing Date and at each Option Closing Date, if any, the duly executed and delivered legal opinion as set forth in Exhibit C hereto and negative assurance letter of Dykema Gossett PLLC (“Company Counsel”) as set forth in Exhibit D hereto, all dated as of the Closing Date, and dated as of each Option Closing Date, if any, in form and substance satisfactory to counsel to the Underwriters.

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(d) At the Closing Date and at each Option Closing Date, if any, the duly executed and delivered opinion of Peacock Law P.C. (“Special Intellectual Property Counsel”) for the Company as set forth in Exhibit E hereto, with respect to certain intellectual property matters, addressed to the Underwriters, dated as of the Closing Date and each Option Closing Date, if any, in form and substance satisfactory to counsel to the Underwriters;

(e) At the Closing Date and at each Option Closing Date, if any, the duly executed and delivered opinion of Hyman, Phelps & McNamara, P.C. (“FDA Counsel”) for the Company as set forth in Exhibit F hereto, with respect to certain matters relating to the U.S. Food and Drug Administration, addressed to the Underwriters, dated as of the Closing Date and each Option Closing Date, if any, in form and substance satisfactory to counsel to the Underwriters;

(f) At the Closing Date and at each Option Closing Date, if any, the duly executed and delivered negative assurance letter of Timothy P. Zannes, Esq., General Counsel (“General Counsel”) for the Company as set forth in Exhibit G hereto, with respect to certain matters relating to the U.S. Food and Drug Administration, addressed to the Underwriters, dated as of the Closing Date and each Option Closing Date, if any, in form and substance satisfactory to counsel to the Underwriters;

(g) The Common Stock and the Tradeable Warrants shall be approved for listing on the Nasdaq Capital Market, and satisfactory evidence thereof shall have been provided to the Representative and its counsel.

(h) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(i) The Representative shall not have reasonably determined, and advised the Company, that the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment thereof or supplement thereto, or any Issuer Free Writing Prospectus, contains an untrue statement of fact which, in the reasonable opinion of the Representative, is material, or omits to state a fact which, in the reasonable opinion of the Representative, is material and is required to be stated therein or necessary to make the statements therein not misleading.

(j) The Underwriters shall have received a letter from WithumSmith+Brown and Ernst & Young, LLP, on the date hereof and on the Closing Date and on each Option Closing Date, addressed to the Underwriters, confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualifications of accountants under Rule 2-01 of Regulation S-X of the Commission, and confirming, as of the date of each such letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, as of a date not prior to the date hereof or more than three (3) days prior to the date of such letter), the conclusions and findings of said firm with respect to the financial information and other matters required by the Underwriters.

(k) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Underwriters a certificate, dated the Closing Date and on each Option Closing Date and addressed to the Underwriters, signed by the chief executive officer and the chief financial officer of the Company, in their capacity as officers of the Company, substantially in the form required by Exhibit H attached hereto.

(l) On the Closing Date and on each Option Closing Date, if any, the duly executed and delivered Secretary’s Certificate, substantially in the form required by Exhibit I attached hereto.

(m) On the Closing Date and on each Option Closing Date, if any, a certificate of good standing from the Secretary of State of Delaware dated as of such Closing Date or each Option Closing Date.

(n) On or before the date hereof, the Representative shall have received duly executed lock-up agreement, substantially in the form of Exhibit B hereto (each a “Lock-Up Agreement”), by and between the Representative and each of the parties specified in Schedule IV.

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(o) On the Closing Date, the Company shall have delivered to the Representative executed copies of the Representative’s Warrant in the form of Exhibit A hereto and the Placement Agent’s Warrant in the form as filed as Exhibit 4.4 to the Registration Statement.

(p) The Company shall have furnished to the Representative and its counsel such additional documents, certificates and evidence as the Representative and its counsel may have reasonably requested.

If any condition specified in this Section 6 shall not have been fulfilled when and as required to be fulfilled, this Agreement may be terminated by the Representative by notice to the Company at any time at or prior to the Closing Date or on the Option Closing Date, as applicable, and such termination shall be without liability of any party to any other party, except that Section 5(a)(viii), Sections 7, 8, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

7. Indemnification and Contribution.

(a) The Company agrees to indemnify, defend and hold harmless each Underwriter, its affiliates, and their respective directors and officers, employees, agents, counsel and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (each, an “Underwriter Indemnified Party”), from and against any losses, claims, damages or liabilities to which such Underwriter or such person may become subject, under the

Securities Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Rules and Regulations, or arise out of or are based upon the omission from the Registration Statement, or alleged omission to state therein, a material fact required to be stated therein or necessary to make the statements therein not misleading (ii) an untrue statement or alleged untrue statement of a material fact contained in the Time of Sale Disclosure Package, any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act (Written Testing-the-Waters Communications), any Prospectus, the Final Prospectus, or any amendment or supplement thereto, or the Marketing Materials or in any other materials used in connection with the offering of the Securities, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, (iii) in whole or in part, any inaccuracy in the representations and warranties of the Company contained herein, or (iv) in whole or in part, any failure of the Company to perform its obligations hereunder or under law, and will reimburse each Underwriter Indemnified Party for any reasonable and documented legal or other expenses incurred by it in connection with evaluating, investigating or defending against such loss, claim, damage, liability or action; *provided, however*, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Time of Sale Disclosure Package, any Written Testing-the-Waters Communications, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus, in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f).

(b) Each Underwriter, severally and not jointly, will indemnify, defend and hold harmless the Company, its affiliates, directors, officers and employees, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f), and will reimburse the Company for any reasonable and documented legal or other expenses incurred by the Company in connection with evaluating, investigating, and defending against any such loss, claim, damage, liability or action. The obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount equal to the Underwriting discount applicable to the Firm Units actually received by such Underwriter hereunder.

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(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof, but the failure to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure. In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof; *provided, however*, that if (i) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (ii) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party), or (iii) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, the indemnified party shall have the right to employ a single counsel to represent it in any claim in respect of which indemnity may be sought under subsection (a) or (b) of this Section 7, in which event the reasonable and documented fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the indemnified party as incurred.

The indemnifying party under this Section 7 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld), effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is a party or could be named and indemnity was or would be sought hereunder by such indemnified party, unless such settlement, compromise or consent (a) includes an unconditional release of such indemnified party from all liability for claims that are the subject matter of such action, suit or proceeding and (b) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 7 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering and sale of the Securities, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discount received by the Underwriters, in each case as set forth in the table on the cover page of the Final Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relevant intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in the first sentence of this subsection (d). The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim that is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount of the underwriting discount applicable to the Securities to be purchased by such Underwriter hereunder actually received by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' respective obligations to contribute as provided in this Section 7 are several in proportion to their respective underwriting commitments and not joint.

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(e) The obligations of the Company under this Section 7 shall be in addition to any liability that the Company may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or

Section 20 of the Exchange Act; and the obligations of each Underwriter under this Section 7 shall be in addition to any liability that each Underwriter may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to the Company and its officers, directors and each person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act.

(f) For purposes of this Agreement, each Underwriter severally confirms, and the Company acknowledges, that there is no information concerning such Underwriter furnished in writing to the Company by such Underwriter specifically for preparation of or inclusion in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus, other than the statements set forth in the “Underwriting – Electronic Offer, Sale and Distribution of Units” and “Underwriting – Price Stabilization, Short Positions and Penalty Bids” sections of the Registration Statement, the Time of Sale Disclosure Package, and the Final Prospectus only insofar as such statements relate to stabilization and related activities that may be undertaken by such Underwriter.

8. Representations and Agreements to Survive Delivery. All representations, warranties, and agreements of the Company contained herein or in certificates delivered pursuant hereto, including, but not limited to, the agreements of the several Underwriters and the Company contained in Section 5(a)(viii) and Section 7 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of the several Underwriters or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Securities to and by the Underwriters hereunder.

9. Termination of this Agreement.

(a) The Representative shall have the right to terminate this Agreement by giving notice to the Company as hereinafter specified at any time at or prior to the Closing Date or any Option Closing Date (as to the Option Shares and/ or Option Warrants to be purchased on such Option Closing Date only), if in the reasonable discretion of the Representative, (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Representative, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States as such as to make it, in the reasonable judgment of the Representative, inadvisable or impracticable to market the Securities or enforce contracts for the sale of the Securities (ii) trading in securities generally on the Nasdaq Stock Market, the NYSE or the NYSE American shall have been suspended, (iii) minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on the Nasdaq Stock Market, the NYSE or NYSE American, by such exchange or by order of the Commission or any other governmental authority having jurisdiction, (iv) a banking moratorium shall have been declared by federal or state authorities, (v) there shall have occurred any attack on, outbreak or escalation of hostilities or act of terrorism involving the United States any declaration by the United States of a national emergency or war, any substantial change or development involving a prospective substantial change in United States or other international political, financial or economic conditions or any other calamity or crisis, including a pandemic, general order to shut down businesses by any federal or state authority, (vi) the Company suffers any material loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, or (vii) in the judgment of the Representative, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business. Any such termination shall be without liability of any party to any other party except that the provisions of Section 5(a)(viii) and Section 7 hereof shall at all times be effective and shall survive such termination.

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(b) If the Representative elects to terminate this Agreement as provided in this Section 9, the Company and the other Underwriters shall be notified promptly by the Representative by telephone, confirmed in writing which may be via electronic mail.

(c) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (y) the Company will reimburse the Representative only for all actual, accountable out-of-pocket expenses (including the reasonable fees and disbursements of its counsel) reasonably incurred by the Representative in connection with the proposed purchase and sale of the Securities or in contemplation of performing their obligations hereunder and (z) no Underwriter who shall have failed or refused to purchase the Securities agreed to be purchased by it under this Agreement on the Closing Date or Option Closing Date, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company, or to the other Underwriters for damages occasioned by its failure or refusal.

10. Substitution of Underwriters. If any Underwriter or Underwriters shall default in its or their obligations to purchase Firm Units hereunder on the Closing Date or the Option Shares or Option Warrants on any Option Closing Date and the aggregate number of Firm Units or Option Shares or Option Warrants which such defaulting Underwriter or Underwriters agreed but failed to purchase does not exceed ten percent (10%) of the total number of Firm Units or Option Shares or Option Warrants to be purchased by all Underwriters on such Closing Date or Option Closing Date, the other Underwriters shall be obligated severally, in proportion to their respective commitments hereunder, to purchase the Firm Units or Option Shares or Option Warrants, respectively, which such defaulting Underwriter or Underwriters agreed but failed to purchase on such Closing Date or Option Closing Date. If any Underwriter or Underwriters shall so default and the aggregate number of Firm Units with respect to which such default or defaults occur is more than ten percent (10%) of the total number of Firm Units to be purchased by all Underwriters on such Closing Date or is more than ten percent (10%) of the total number of Option Shares or Option Warrants on such Option Closing Date and arrangements satisfactory to the remaining Underwriters and the Company for the purchase of such Firm Units or Option Shares or Option Warrants by other persons are not made within forty-eight (48) hours after such default, this Agreement shall terminate.

If the remaining Underwriters or substituted Underwriters are required hereby or agree to take up all or part of the Firm Units or Option Shares or Option Warrants of a defaulting Underwriter or Underwriters on such Closing Date or Option Closing Date as provided in this Section 10, (i) the Company shall have the right to postpone such Closing Date or Option Closing Date for a period of not more than five (5) full Business Days in order to permit the Company to effect whatever changes in the Registration Statement, the Final Prospectus, or in any other documents or arrangements, which may thereby be made necessary, and the Company agrees to promptly file any amendments to the Registration Statement or the final Prospectus which may thereby be made necessary, and (ii) the respective numbers of Firm Units or Option Shares or Option Warrants to be purchased by the remaining Underwriters or substituted Underwriters shall be taken as the basis of their underwriting obligation for all purposes of this Agreement. Nothing herein contained shall relieve any defaulting Underwriter of its liability to the Company or any other Underwriter for damages occasioned by its default hereunder. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of any non-defaulting Underwriters or the Company, except that the obligations with respect to expenses to be paid or reimbursed pursuant to Section 5(a)(viii) and Section 7 and Sections 9 through 17, inclusive, shall not terminate and shall remain in full force and effect.

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11. Notices. All notices and communications hereunder shall be in writing and mailed or delivered or by telephone, electronic mail or telegraph if subsequently confirmed in writing, (a) if to the Representative, WallachBeth Capital, LLC Harborside Financial Center Plaza 5, 185 Hudson Street, Suite 1410 Jersey City, New Jersey 07311, Attention: Kenneth Bantum, with a copy (which shall not constitute notice) to Carmel, Milazzo & Feil LLP, 55 West 39th Street, 18th Floor, New York, NY 10018, Attention: Ross Carmel, and (b) if to the Company, to bioAffinity Technologies, Inc., 22211 W Interstate 10, Suite 1206, San Antonio, Texas 78257, Attention Ms. Maria Zannes, Chief Executive Officer, with a copy (which shall not constitute notice) to Wilhelm E. Liebmann, Esq. Dykema Gossett PLLC, 112 E. Pecan Street, Suite 1800, San Antonio, Texas 78205.

12. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 7. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term “successors and assigns” as herein used shall not include any purchaser, as such purchaser, of any of the Securities from any Underwriters.

13. Absence of Fiduciary Relationship. The Company acknowledges and agrees that: (a) each Underwriter has been retained solely to act as underwriter in connection with the sale of the Securities and that no fiduciary, advisory or agency relationship between the Company and any Underwriter has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Underwriter has advised or is advising the Company on other matters; (b) the price and other terms of the Securities set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Underwriters and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Underwriters and their affiliates are engaged in a broad range of transactions that may involve interests that differ from those of the Company and that no Underwriter has any obligation to disclose such interest and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and (d) it has been advised that each Underwriter is acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of such Underwriter, and not on behalf of the Company.

14. Amendments and Waivers. No supplement, modification or waiver of this Agreement shall be binding unless executed in writing by the party to be bound thereby. The failure of a party to exercise any right or remedy shall not be deemed or constitute a waiver of such right or remedy in the future. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (regardless of whether similar), nor shall any such waiver be deemed or constitute a continuing waiver unless otherwise expressly provided.

15. Partial Unenforceability. The invalidity or unenforceability of any section, paragraph, clause or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph, clause or provision.

16. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to the State's conflicts of laws statutes or rules.

17. Submission to Jurisdiction. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. EACH OF THE COMPANY (ON BEHALF OF ITSELF AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS) AND THE UNDERWRITER HEREBY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, THE REGISTRATION STATEMENT, THE TIME OF SALE DISCLOSURE PACKAGE, ANY PROSPECTUS AND THE FINAL PROSPECTUS.

18. Counterparts. This Agreement may be executed and delivered (including by facsimile transmission or electronic mail) in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

[Signature Page Follows]

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Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the several Underwriters in accordance with its terms.

Very truly yours,

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: Chief Executive Officer

Confirmed as of the date first above-mentioned by the Representative of the several Underwriters.

WALLACHBETH CAPITAL, LLC

By: _____
Name: Eric Schweitzer
Title: Chief Compliance Officer

[Signature page to Underwriting Agreement]

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SCHEDULE I

Underwriter	Number of Firm Shares to be Purchased	Number of Option Shares to be Purchased
WallachBeth Capital, LLC		
Craft Capital Management LLC		
WestPark Capital, Inc.		
Total		

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SCHEDULE II

Pricing Information

Number of Firm Units: [*]
Number of Option Shares: [*]
Number of Option Warrants: [*]
Public Offering Price per Firm Unit: \$[*]
Public Offering Price per Option Share: \$[*]
Public Offering Price per Option Warrant: \$0.01
Underwriting Discount per Firm Unit: \$[*] (9.0% per Firm Unit)
Underwriting Discount per Option Share: \$[*] (9.0% per Option Share)
Underwriting Discount per Option Warrant: \$0.0009

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SCHEDULE III

Free Writing Prospectus

Free Writing Prospectus (File No. 333-264463) filed pursuant to Rule 433 with the Securities and Exchange Commission on May 26, 2022.

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SCHEDULE IV

List of Lock-Up Parties

- Maria Zannes
- Vivienne Rebel
- Michael Edwards
- Timothy P. Zannes
- Steven Girgenti
- Robert Anderson
- Stuart Diamond
- Peter Knight
- Mohsin Meghji
- Gary Rubin
- Madeleine Lemieux
- The Harvey Sandler Revocable Trust

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EXHIBIT A

Form of Representative's Warrant

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY (180) DAYS FOLLOWING THE LATER OF THE EFFECTIVE DATE (DEFINED BELOW) OR THE COMMENCEMENT OF SALES OF THE OFFERING TO WHICH THIS PURCHASE WARRANT RELATES TO ANYONE OTHER THAN WALLACHBETH CAPITAL, LLC OR AN UNDERWRITER OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING, OR (II) A BONA FIDE OFFICER OR PARTNER OF WALLACHBETH CAPITAL, LLC OR OF ANY SUCH UNDERWRITER OR SELECTED DEALER.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO [DATE THAT IS 180 DAYS FROM THE DATE OF THE COMMENCEMENT OF SALE OF THE COMMON STOCK IN THE OFFERING].

VOID AFTER 5:00 P.M., EASTERN TIME, [DATE THAT IS FIVE YEARS FROM THE EFFECTIVE DATE OF THE OFFERING].

WARRANT TO PURCHASE COMMON STOCK

BIOAFFINITY TECHNOLOGIES, INC.

Warrant Shares: [*]¹

Initial Exercise Date: [DATE THAT IS 180 DAYS FROM THE COMMENCEMENT OF THE SALE OF THE FIRM UNITS IN THE OFFERING]

1. Purchase Warrant. THIS CERTIFIES THAT, pursuant to that certain Underwriting Agreement by and between BIOAFFINITY TECHNOLOGIES, INC., a Delaware corporation (the "Company") and WallachBeth Capital, LLC dated [*], 2022, as amended (the "Underwriting Agreement"), WallachBeth Capital, LLC ("Holder") and its assignees, as registered holders of this Purchase Warrant, is entitled, at any time or from time to time from [*], 2022 (the "Effective Date"), the date that is one hundred and eighty (180) days after the date of the commencement of the sales of the Company's units (each unit ("Unit") consisting of one share of the Company's common stock, \$0.007 par value per share ("Common Stock"), one tradeable warrant to purchase one share of Common Stock, and one non-tradeable warrant to purchase one share of Common Stock) in the Company's initial public offering, and at or before 5:00 p.m., Eastern time, on [*], 2027 (five (5) years from the Effective Date) (the "Expiration Date"), but not thereafter, to subscribe for, purchase and receive, in whole or in part, up to [*] shares of Common Stock of the Company (equal to two (2.0%) percent of the Common Stock sold in the Offering including any exercise of the overallotment option), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this purchase warrant ("Purchase Warrant"). This Purchase Warrant is initially exercisable at \$[*] per share of Common Stock (115% of the price of the Common Stock sold in the Offering); *provided, however*, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per share and the number of shares of Common Stock to be received upon such exercise, shall be adjusted as therein specified. The term "Exercise Price" shall mean the initial exercise price as set forth above or the adjusted exercise price as a result of the events set forth in Section 6 below, depending on the context.

Capitalized terms not defined herein shall have the meaning ascribed to them in the Underwriting Agreement.

¹ (2.0%) of the number of shares of Common Stock sold in the Offering.

2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto as Exhibit A must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Common Stock being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire.

2.2 Cashless Exercise. At any time after the Exercise Date and until the Expiration Date, Holder may elect to receive the number of shares of Common Stock equal to the value of this Purchase Warrant (or the portion thereof being exercised), by surrender of this Purchase Warrant to the Company, together with the exercise form attached hereto, in which event the Company shall issue to Holder, Shares in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

X=The number of shares of Common Stock to be issued to Holder;

Y=The number of shares of Common Stock for which the Purchase Warrant is being exercised;

A=The fair market value of one share of Common Stock; and

B=The Exercise Price.

For purposes of this Section 2.2, the “fair market value” of a share of Common Stock is defined as follows:

- (i) if the Common Stock is traded on a national securities exchange or the OTCQB Market (or similar quotation system), the value shall be deemed to be the closing price on such exchange or quotation system the trading day immediately prior to the exercise form being submitted in connection with the exercise of this Purchase Warrant; or
- (ii) if there is no market for the Common Stock, the value shall be the fair market value thereof, as determined in good faith by the Company’s Board of Directors.

2.3 Legend. Each certificate for the Common Stock purchased under this Purchase Warrant shall bear a legend as follows unless such Common Stock has been registered under the Securities Act of 1933, as amended (the “Act”), or are exempt from registration under the Act:

“The Common Stock represented by this certificate have not been registered under the Securities Act of 1933, as amended (the “Act”), or applicable state law. Neither the Common Stock nor any interest therein may be offered for sale, sold or otherwise transferred except pursuant to an effective registration statement under the Act, or pursuant to an exemption from registration under the Act and applicable state law which, in the opinion of counsel to the Company, is available.”

3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Purchase Warrant for a period of one hundred eighty (180) days following the Effective Date to anyone other than: (i) the Underwriter or a representative or a selected dealer participating in the Offering, or (ii) a bona fide officer or partner of the Underwriter or of any such selected dealer, in each case in accordance with FINRA Conduct Rule 5110(g)(1), or (b) cause this Purchase Warrant or the securities issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities hereunder, except as provided for in FINRA Rule 5110(g)(2). On and after that date that is one hundred eighty (180) days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto as Exhibit B duly executed and completed, together with this Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of shares of Common Stock purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3.2 Restrictions Imposed by the Act. The securities evidenced by this Purchase Warrant shall not be transferred unless and until: (i) the Company has received the opinion of counsel for the Company that the securities may be transferred pursuant to an exemption from registration under the Act and applicable state securities laws, the availability of which is established to the reasonable satisfaction of the Company, (ii) a registration statement or a post-effective amendment to the Registration Statement relating to the offer and sale of such securities that has been declared effective by the U.S. Securities and Exchange Commission (the “Commission”) and includes a current prospectus or (iii) a registration statement, pursuant to which the Holder has exercised its registration rights pursuant to Sections 4.1 and 4.2 herein, relating to the offer and sale of such securities has been filed and declared effective by the Commission and compliance with applicable state securities law has been established.

4. Registration Rights.

4.1 Demand Registration.

4.1.1 Grant of Right. The Company, upon written demand (a “Demand Notice”) of the Holders of at least 51% of the Purchase Warrants and/or the underlying Common Shares, agrees to register, on one (1) occasion, all or any portion of the Common Shares underlying the Purchase Warrants (collectively, the “Registrable Securities”). On such occasion, the Company will file a registration statement with the Commission covering the Registrable Securities within sixty (60) days after receipt of a Demand Notice and use its reasonable best efforts to have the registration statement declared effective promptly thereafter, subject to compliance with review by the Commission; provided, however, that the Company shall not be required to comply with a Demand Notice if the Company has filed a registration statement with respect to which the Holder is entitled to piggyback registration rights pursuant to Section 4.2 hereof and either: (i) the Holder has elected to participate in the offering covered by such registration statement or (ii) if such registration statement relates to an underwritten primary offering of securities of the Company, until the offering covered by such registration statement has been withdrawn or until thirty (30) days after such offering is consummated. The Company covenants and agrees to give written notice of its receipt of any Demand Notice by any Holders to all other registered Holders of the Purchase Warrants and/or the Registrable Securities within ten (10) days after the date of the receipt of any such Demand Notice. Notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 4.1 shall not be applicable so long as the Company’s Registration Statement on Form S-1 (File No. 333-264463) covering the Registrable Securities remains effective.

4.1.2 Terms. The Company shall bear all fees and expenses attendant to the registration of the Registrable Securities pursuant to Section 4.1.1, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. The Company agrees to use its reasonable best efforts to cause the filing required herein to become effective promptly and to qualify or register the Registrable

Securities in such states as are reasonably requested by the Holders; provided, however, that in no event shall the Company be required to register the Registrable Securities in a State in which such registration would cause: (i) the Company to be obligated to register or license to do business in such State or submit to general service of process in such State, or (ii) the principal shareholders of the Company to be obligated to escrow their shares of capital stock of the Company. The Company shall cause any registration statement filed pursuant to the demand right granted under Section 4.1.1 to remain effective for a period of at least twelve (12) consecutive months after the date that the Holders of the Registrable Securities covered by such registration statement are first given the opportunity to sell all of such securities. The Holders shall only use the prospectuses provided by the Company to sell the shares covered by such registration statement, and will immediately cease to use any prospectus furnished by the Company if the Company advises the Holder that such prospectus may no longer be used due to a material misstatement or omission. Notwithstanding the provisions of this Section 4.1.2, the Holder shall be entitled to a demand registration under this Section 4.1.2 on only one (1) occasion and such demand registration right shall terminate on the fifth anniversary of the Effective Date in accordance with FINRA Rule 5110(g)(8)(C).

4.2 “Piggy-Back” Registration.

4.2.1 Grant of Rights. In addition to the demand right of registration described in Section 4.1 hereof, the Holder shall have the right, for a period of no more than seven (7) years from the Effective Date in accordance with FINRA Rule 5110(g)(8)(D), to include the Registrable Securities as part of any other registration of securities filed by the Company (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to Form S-8 or Form S-4 or any equivalent form); provided, however, that if, solely in connection with any primary underwritten public offering for the account of the Company, the managing underwriter(s) thereof shall, in its reasonable discretion, impose a limitation on the number of Common Shares which may be included in the Registration Statement because, in such underwriter(s)’ judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such Registration Statement only such limited portion of the Registrable Securities with respect to which the Holder requested inclusion hereunder as the underwriter shall reasonably permit. Any exclusion of Registrable Securities shall be made pro rata among the Holders seeking to include Registrable Securities in proportion to the number of Registrable Securities sought to be included by such Holders; provided, however, that the Company shall not exclude any Registrable Securities unless the Company has first excluded all outstanding securities, the holders of which are not entitled to inclusion of such securities in such Registration Statement or are not entitled to pro rata inclusion with the Registrable Securities. Notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 4.2 shall not be applicable so long as the Company’s Registration Statement on Form S-1 (File No. 333-264463) covering the Registrable Securities remains effective.

4.2.2 Terms. The Company shall bear all fees and expenses attendant to registering the Registrable Securities pursuant to Section 4.2.1 hereof, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. In the event of such a proposed registration, the Company shall furnish the then Holders of outstanding Registrable Securities with not less than thirty (30) days’ written notice prior to the proposed date of filing of such registration statement. Such notice to the Holders shall continue to be given for each registration statement filed by the Company until such time as all of the Registrable Securities have been sold by the Holder. The holders of the Registrable Securities shall exercise the “piggy-back” rights provided for herein by giving written notice within ten (10) days of the receipt of the Company’s notice of its intention to file a registration statement. Except as otherwise provided in this Purchase Warrant, there shall be no limit on the number of times the Holder may request registration under this Section 4.2.2; provided, however, that such registration rights shall terminate on a date that is seven (7) years from the Effective Date.

4.3 General Terms.

4.3.1 Indemnification. The Company shall indemnify the Holders of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Securities Act or Section 20(a) of the Securities Exchange Act of 1934, as amended (“Exchange Act”), against all loss, claim, damage, expense or liability (including all reasonable attorneys’ fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Securities Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify the Underwriters contained in Section 5.1 of the Underwriting Agreement between the Underwriters and the Company, dated as of [*], 2022. The Holders of the Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense, or liability (including all reasonable attorneys’ fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Securities Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in Section 5.2 of the Underwriting Agreement pursuant to which the Underwriters have agreed to indemnify the Company.

4.3.2 Exercise of Purchase Warrants. Nothing contained in this Purchase Warrant shall be construed as requiring the Holders to exercise their Purchase Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

4.3.3 Documents Delivered to Holders. The Company shall furnish to each Holder participating in any of the foregoing offerings and to each underwriter of any such offering, if any, a signed counterpart, addressed to such Holder or underwriter, of: (i) an opinion of counsel to the Company, dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, an opinion dated the date of the closing under any underwriting agreement related thereto), and (ii) a “cold comfort” letter dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, a letter dated the date of the closing under the underwriting agreement) signed by the independent registered public accounting firm which has issued a report on the Company’s financial statements included in such registration statement, in each case covering substantially the same matters with respect to such registration statement (and the prospectus included therein) and, in the case of such accountants’ letter, with respect to events subsequent to the date of such financial statements, as are customarily covered in opinions of issuer’s counsel and in accountants’ letters delivered to underwriters in underwritten public offerings of securities. The Company shall also deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below and to the managing underwriter, if any, copies of all correspondence between the Commission and the Company, its counsel or auditor, and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to the information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records, and properties, and opportunities to discuss the business of the Company with its officers and independent auditor, all to such reasonable extent and at such reasonable times as any such Holder shall reasonably request.

4.3.4 Underwriting Agreement. The Company shall enter into an underwriting agreement with the managing underwriter(s), if any, selected by any Holders whose Registrable Securities are being registered pursuant to this Section 4, which managing underwriter shall be reasonably satisfactory to the Company. Such agreement shall be reasonably satisfactory in form and substance to the Company, each Holder, and such managing underwriters, and shall contain such representations, warranties, and covenants by the Company and such other terms as are customarily contained in agreements of that type used by the managing underwriter. The Holders shall be parties to any underwriting agreement relating to an underwritten sale of their Registrable Securities and may, at their option, require that any or all the representations, warranties, and covenants of the Company to or for the benefit of such underwriters shall also be made to and for the benefit of such Holders. Such Holders shall not be required to make any representations or warranties to or agreements with the Company or the underwriters except as they may relate to such Holders, their Shares, and their intended methods of distribution.

4.3.5 Documents to be Delivered by Holders. Each of the Holders participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

4.3.6 Damages. Should the registration or the effectiveness thereof required by Sections 4.1 and 4.2 hereof be delayed by the Company or the Company otherwise fails to comply with such provisions, the Holders shall, in addition to any other legal or other relief available to the Holders, be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

4.4 Termination of Registration Rights. The registration rights afforded to the Holders under this Section 4 shall terminate on the earliest date when all Registrable Securities of such Holder either: (i) have been publicly sold by such Holder pursuant to a Registration Statement, (ii) have been covered by an effective Registration Statement on Form S-1 or Form S-3 (or successor form), which may be kept effective as an evergreen Registration Statement, or (iii) may be sold by the Holder (including on a cashless basis) within a 90 day period without registration pursuant to Rule 144 or consistent with applicable SEC interpretive guidance (including C&DI No. 201.04 (April 2, 2007) or similar interpretive guidance).

5. New Purchase Warrants to be Issued

5.1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form and funds sufficient to pay any Exercise Price and/or transfer tax if exercised pursuant to Section 2.1 hereof, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of shares of Common Stock purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5.2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments

6.1 Adjustments to Exercise Price and Number of Shares of Common Stock. The Exercise Price and the number of shares of Common Stock underlying this Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6.1.1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Common Stock is increased by a stock dividend payable in Common Stock or by a split up of the Common Stock or other similar event, then, on the effective day thereof, the number of shares of Common Stock purchasable hereunder shall be increased in proportion to such increase in outstanding shares of Common Stock, and the Exercise Price shall be proportionately decreased.

6.1.2 Subsequent Equity Sales. If the Company or any Subsidiary thereof, as applicable, at any time while this Warrant is outstanding, shall sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the “Base Share Price” and such issuances collectively, a “Dilutive Issuance”) (it being understood and agreed that if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price on such date of the Dilutive Issuance at such effective price), then simultaneously with the consummation (or, if earlier, the announcement) of each Dilutive Issuance the Exercise Price shall be reduced and only reduced to equal the Base Share Price provided that the Base Share Price shall not be less than \$[*] (subject to adjustment for reverse and forward stock splits, recapitalizations and similar transactions following the Initial Issuance Date). Notwithstanding the foregoing, no adjustments shall be made, paid or issued under this Section 3(b) in respect of an Exempt Issuance. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any shares of Common Stock or Common Stock Equivalents subject to this Section 3(b), indicating therein the applicable issuance price, or applicable reset price, exchange price, conversion price and other pricing terms (such notice, the “Dilutive Issuance Notice”). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise. If the Company enters into a Variable Rate Transaction, the Company shall be deemed to have issued shares of Common Stock or Common Stock Equivalents at the lowest possible price, conversion price or exercise price at which such securities may be issued, converted or exercised. An “Exempt Issuance” means the issuance of (a) shares of Common Stock or options to employees, officers, 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 the Common Stock to be 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 Warrant, provided that such securities have not been amended since the date of this Warrant 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 dividends, stock splits or combinations) or to extend the term of such securities, (c) securities in connection with an underwritten public offering, and (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a person or entity (“Person”) (or to the equity holders 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.

6.1.3 Aggregation of Shares of Common Stock. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding shares of Common Stock is decreased by a consolidation, combination or reclassification of the Common Stock or other similar event, then, on the effective date thereof, the number of shares of Common Stock purchasable hereunder shall be decreased in proportion to such decrease in outstanding shares, and the Exercise Price shall be proportionately increased.

6.1.4 Replacement of Common Stock upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Common Stock other than a change covered by Section 6.1.1, 6.1.2 or Section 6.1.3 hereof or that solely affects the par value of such Common Stock, or in the case of any share reconstruction or amalgamation or consolidation of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Common Stock), or in the case of any sale or conveyance to another corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of Common Stock or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of shares of Common Stock of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Common Stock covered by Section 6.1.1, 6.1.2 or Section 6.1.3, then such adjustment shall be made pursuant to Section 6.1.1, Section 6.1.2, 6.1.3 and this

Section 6.1.34 The provisions of this Section 6.1.4 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.5 Fundamental Transaction. If, at any time while this Purchase 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, 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, (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 the 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, (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, 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, spinoff or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding Common Stock (not including any Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with, the other Persons making or party to such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Purchase Warrant, the Holder shall have the right to receive, for each Purchase Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, the number Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional or alternative consideration (the “Alternative Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Purchase Warrant is exercisable immediately prior to such Fundamental Transaction. For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternative Consideration based on the amount of Alternative Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternative Consideration in a reasonable manner reflecting the relative value of any different components of the Alternative Consideration. If holders of the 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 Alternative Consideration it receives upon any exercise of this Purchase 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 Purchase Warrant, and to deliver to the Holder in exchange for this Purchase Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Purchase Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the Common Stock acquirable and receivable upon exercise of this Purchase 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 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 Purchase Warrant immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Purchase Warrant and the other Transaction Documents referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of, the Company and shall assume all of the obligations of the Company, under this Purchase Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

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6.1.6 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of shares of Common Stock as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the date hereof or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation which does not result in any reclassification or change of the outstanding Common Stock), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares of Common Stock and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of shares of Common Stock of the Company for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section 6 shall similarly apply to successive consolidations or share reconstructions or amalgamations.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of a share of Common Stock upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up to the nearest whole number of shares of Common Stock or other securities, properties or rights.

7. Reservation and Listing. The Company shall at all times reserve and keep available out of its authorized Common Stock, solely for the purpose of issuance upon exercise of this Purchase Warrant, such number of shares of Common Stock or other securities, properties or rights as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of this Purchase Warrant and payment of the Exercise Price therefor, in accordance with the terms hereby, all Common Stock and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any shareholder. As long as this Purchase Warrant shall be outstanding, the Company shall use its commercially reasonable efforts to cause this Purchase Warrant and all Common Stock issuable upon exercise of this Purchase Warrant to be listed (subject to official notice of issuance) on all national securities exchanges (or, if applicable, on the OTCQB Market or any successor quotation system) on which the Common Stock issued to the public in the Offering may then be listed and/or quoted (if at all).

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8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a shareholder for the election of directors or any other matter, or as having any rights whatsoever as a shareholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall give written notice of such event at least fifteen days prior to the date fixed as a record date or the date of closing the transfer books (the “Notice Date”) for the determination of the shareholders entitled to such dividend, distribution, conversion or exchange of securities or subscription rights, or entitled to vote on such proposed dissolution, liquidation, winding up or sale. Such notice shall specify such record date or the date of the closing of the transfer books, as the case may be. Notwithstanding the foregoing, the Company shall deliver to each Holder a copy of each notice given to the other shareholders of the Company at the same time and in the same manner that such notice is given to the shareholders.

8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Common Stock for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company, (ii) the Company shall offer to all the holders of its Common Stock any additional shares of the Company or securities convertible into or exchangeable for shares of the Company, or any option, right or warrant to subscribe therefor, or (iii) a dissolution, liquidation or winding up of the Company (other than in connection with a consolidation or share reconstruction or amalgamation) or a sale of all or substantially all of its property, assets and business shall be proposed.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change ("Price Notice"). The Price Notice shall describe the event causing the change and the method of calculating same and shall be certified as being true and accurate by the Company's Chief Financial Officer.

8.4 Transmittal of Notices. All notices and communications hereunder shall be in writing and mailed or delivered or by telephone, electronic mail or telegraph if subsequently confirmed in writing, (a) if to the Representative, WallachBeth Capital, LLC Harborside Financial Center Plaza 5, 185 Hudson Street, Suite 1410 Jersey City, New Jersey 07311, Attention: Kenneth Bantum, with a copy (which shall not constitute notice) to Carmel, Milazzo & Feil LLP, 55 West 39th Street, 18th Floor, New York, NY 10018, Attention: Ross Carmel, and (b) if to the Company, to bioAffinity Technologies, Inc., 22211 W Interstate 10, Suite 1206, San Antonio, Texas 78257, Attention Ms. Maria Zannes, Chief Executive Officer, with a copy (which shall not constitute notice) to Wilhelm E. Liebmann, Esq. Dykema Gossett PLLC, 112 E. Pecan Street, Suite 1800, San Antonio, Texas 78205.

9. Miscellaneous.

9.1 Amendments. The Company and the Underwriter may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and the Underwriter may deem necessary or desirable and that the Company and the Underwriter deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by the party against whom enforcement of the modification or amendment is sought.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3 Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

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9.4 Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5 Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6 Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

9.7 Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and the Underwriter enter into an agreement ("Exchange Agreement") pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

9.8 Execution in Counterparts. This Purchase Warrant may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Such counterparts may be delivered by facsimile transmission or other electronic transmission.

[Signature Page to Follow]

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IN WITNESS WHEREOF, the Company has caused this Purchase Warrant to be signed by its duly authorized officer as of the[*] day of [*], 2022.

BIOAFFINITY TECHNOLOGIES, INC.

By:

Name: Maria Zannes

Title: Chief Executive Officer

[Signature page to Representative's Warrant]

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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, 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 register and 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 or by physical delivery of a certificate to:

(4) Accredited Investor. If the Warrant is being exercised via cash exercise, the undersigned is an “accredited investor” as defined in Regulation D promulgated under the Securities Act of 1933, as amended

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

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ASSIGNMENT FORM

(To assign the foregoing warrant, execute this form and supply required information. Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [*] all of or [*] shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

whose address is

Dated: _____,

Holder's Signature: _____

Holder's Address: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

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EXHIBIT B

Form of Lock-Up Agreement

[*], 2022

WallachBeth Capital, LLC
Harborside Financial Plaza 5
185 Hudson St., Suite 1410
Jersey City, NJ 07311

As Representative of the several Underwriters named on Schedule 1 to the Underwriting Agreement referenced below

Ladies and Gentlemen:

The undersigned understands that WallachBeth Capital, LLC (the “Representative”), proposes to enter into an Underwriting Agreement (the “Underwriting Agreement”) with bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), providing for the public offering (the “Public Offering”) of shares of common stock, par value \$0.007 per share, of the Company (the “Common Stock”). Terms not defined herein shall have the meaning given to them in the Underwriting Agreement.

To induce the Representative to continue its efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representative, the undersigned will not, during the period commencing on the date hereof and ending one hundred eighty (180) days after the effective date of the Registration

Statement on Form S-1 relating to the Public Offering (the “Lock-Up Period”), (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the “Lock-Up Securities”); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities. Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer Lock-Up Securities without the prior written consent of the Representative in connection with (a) transactions relating to Lock-Up Securities acquired in open market transactions after the completion of the Public Offering; provided that no filing under Section 13 or Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or other public announcement shall be required or shall be voluntarily made in connection with subsequent sales of Lock-Up Securities acquired in such open market transactions; (b) transfers of Lock-Up Securities as a *bona fide* gift, by will or intestacy or to a family member or trust for the benefit of the undersigned (for purposes of this lock-up agreement, “family member” means any relationship by blood, marriage or adoption, not more remote than first cousin); (c) transfers of Lock-Up Securities to a charity or educational institution; (d) if the undersigned is a corporation, partnership, limited liability company or other business entity, (i) any transfers of Lock-Up Securities to another corporation, partnership or other business entity that controls, is controlled by or is under common control with the undersigned or (ii) distributions of Lock-Up Securities to members, partners, stockholders, subsidiaries or affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned; (e) if the undersigned is a trust, to a trustee or beneficiary of the trust; provided that in the case of any transfer pursuant to the foregoing clauses (b), (c) (d) or (e), (i) any such transfer shall not involve a disposition for value, (ii) each transferee shall sign and deliver to the Representative a lock-up agreement substantially in the form of this lock-up agreement and (iii) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made during the Lock-Up Period; (f) the receipt by the undersigned from the Company of Common Stock upon the vesting of restricted stock awards or stock units or upon the exercise of options to purchase the Company’s Common Stock issued under an equity incentive plan of the Company or an employment arrangement described in the Pricing Prospectus (as defined in the Underwriting Agreement) (the “Plan Shares”) or the transfer or withholding of Common Stock or any securities convertible into Common Stock to the Company upon a vesting event of the Company’s securities or upon the exercise of options to purchase the Company’s securities, in each case on a “cashless” or “net exercise” basis or to cover tax obligations of the undersigned in connection with such vesting or exercise, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Stock during the Lock-Up Period, the undersigned shall include a statement in such schedule or report to the effect that the purpose of such transfer was to cover tax withholding obligations of the undersigned in connection with such vesting or exercise and, provided further, that the Plan Shares shall be subject to the terms of this lock-up agreement; (g) the transfer of Lock-Up Securities pursuant to agreements described in the Pricing Prospectus under which the Company has the option to repurchase such securities or a right of first refusal with respect to the transfer of such securities, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Stock during the Lock-Up Period, the undersigned shall include a statement in such schedule or report describing the purpose of the transaction; (h) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Lock-Up Securities, provided that (i) such plan does not provide for the transfer of Lock-Up Securities during the Lock-Up Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such public announcement or filing shall include a statement to the effect that no transfer of Lock-Up Securities may be made under such plan during the Lock-Up Period; (i) the transfer of Lock-Up Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period, and provided further, that any filing under Section 13 or Section 16(a) of the Exchange Act that is required to be made during the Lock-Up Period as a result of such transfer shall include a statement that such transfer has occurred by operation of law; and (j) the transfer of Lock-Up Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the Common Stock involving a change of control (as defined below) of the Company after the closing of the Public Offering and approved by the Company’s board of directors; provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Securities owned by the undersigned shall remain subject to the restrictions contained in this lock-up agreement. For purposes of clause (j) above, “change of control” shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any “person” (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company’s transfer agent and registrar against the transfer of the undersigned’s Lock-Up Securities except in compliance with this lock-up agreement.

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If the undersigned is an officer or director of the Company, (i) the Representative agrees that, at least three (3) Business Days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Lock-Up Securities, the Representative will notify the Company of the impending release or waiver; and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two (2) Business Days before the effective date of the release or waiver. Any release or waiver granted by the Representative hereunder to any such officer or director shall only be effective two (2) Business Days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer of Lock-Up Securities not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of such transfer.

The undersigned understands that the Company and the Representative are relying upon this lock-up agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this lock-up agreement is irrevocable and shall be binding upon the undersigned’s heirs, legal representatives, successors and assigns.

The undersigned understands that, if the Underwriting Agreement is not executed by July 31, 2022 or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, then this lock-up agreement shall be void and of no further force or effect.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Representative.

Very truly yours,

(Name - Please Print)

(Signature)

(Name of Signatory, in the case of entities - Please Print)

(Title of Signatory, in the case of entities - Please Print)

Address: _____

EXHIBIT C

Opinion of Dykema Gossett PLLC



Dykema Gossett PLLC
Weston Centre
112 E. Pecan Street, Suite 1800
San Antonio, TX 78205
www.dykema.com
Tel: (210) 554-5500
Fax: (210) 226-8395

July [*], 2022

WallachBeth Capital, LLC
Harborside Financial Plaza 5
185 Hudson St., Suite 1410
Jersey City, New Jersey 07311

Gentlepersons:

We have acted as counsel to bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act") of: (i) 1,285,325 Units (the "Firm Units") at an estimated initial public offering price between \$6.00 and \$6.25 per Firm Unit (the "Price Range"), each Firm Unit consisting of (1) one share of the Company's common stock, par value \$0.007 per share (the "Common Stock"), (2) one five-year tradeable warrant (a "Tradeable Warrant") to purchase one share of Common Stock at an exercise price equal to 120% of the assumed public offering price of \$6.125 per Firm Unit (the "Unit Offering Price"), which is the midpoint of the Price Range, and (3) one five-year non-tradeable warrant (a "Non-tradeable Warrant"; together with each Tradeable Warrant, the "Warrants") to purchase one share of Common Stock at an exercise price equal to 125% of the Unit Offering Price; (ii) up to an additional 192,799 shares of Common Stock (the "Option Shares") and/or 192,799 Non-tradeable Warrants and/or 192,799 Tradeable Warrants (such additional Non-tradeable Warrants or Tradeable Warrants, the "Option Warrants"), pursuant to an option granted by the Company to the underwriters listed on Schedule I hereto (the "Underwriters"); (iii) the warrant to be issued to WallachBeth Capital, LLC as representative of the Underwriters (the "Representative"; such warrant, the "Representative's Warrant"); and (iv) the shares of Common Stock underlying the Warrants (the "Warrant Shares"), the Option Warrants (the "Option Warrant Shares"), and the Representative's Warrant (the "Representative's Warrant Shares"; together with the Firm Units, the Common Stock issued as part of the Firm Units, the Option Shares, the Warrant Shares, the Option Warrant Shares, the Warrants, the Option Warrants, and the Representative's Warrant, the "Securities"), and the public offering thereof pursuant to that certain Underwriting Agreement dated [*], 2022 (the "Underwriting Agreement"), by and between the Company and the Representative of the Underwriters, pursuant to which the Company has agreed to sell and the Underwriters have agreed to purchase the Firm Units, the Option Shares and/or the Option Warrants. This opinion is given to you pursuant to Section 6(c) of the Underwriting Agreement. Unless defined herein, capitalized terms have the meanings given to them in the Underwriting Agreement.

I. In our capacity as counsel to the Company and in connection with this opinion letter, we have examined and relied upon the following:

1. executed counterparts of the Underwriting Agreement;
2. executed counterparts of the Tradeable Warrant to be issued as a part of each Firm Unit;
3. executed counterparts of the Non-Tradeable Warrant to be issued as a part of each Firm Unit;
4. the Warrant Agent Agreement between the Company and VStock Transfer, LLC (the "Warrant Agent");
5. executed counterparts of the Representative's Warrant issued to the Representative dated [*], 2022;
6. the Company's Certificate of Incorporation, as amended, certified by the Secretary of State of the State of Delaware as of June 23, 2022 (the "Certificate of Incorporation"), and the Amended and Restated Bylaws of the Company, adopted March 17, 2022, as currently in effect, certified by the Secretary of the Company as of the date hereof (the "Bylaws");

7. those records of the proceedings and actions of the stockholders and the Board of Directors of the Company as we have deemed necessary or appropriate to render the opinions expressed herein, as well as a copy of the stock transfer ledger of the Company, certified in each case by the Secretary of the Company as of the date hereof;
8. a certificate of the Secretary of State of the State of Delaware dated June 21, 2022, to the effect that the Company is duly incorporated and validly existing and in good standing under the laws of the State of Delaware;
9. a certificate of the Secretary of State of Texas dated June 21, 2022, to the effect that the Company holds a certificate of authority to transact business in Texas and is in existence;
10. a signed copy of the pre-effective Amendment No. [3] to the Registration Statement on Form S-1 (Registration No. 333-264463) with respect to the Firm Units declared effective by the Securities and Exchange Commission (the "Commission") under the Securities Act on [*], 2022, and signed copies of the Registration Statement as initially filed with the Commission on April 25, 2022 and pre-effective Amendments Nos. 1 and 2 to the Registration Statement filed with the Commission on May 25, 2022 and June 16, 2022, respectively (collectively, the "Registration Statement");
11. written confirmation from the staff of the Commission on [*], 2022, as to the issuance of an order declaring the Registration Statement effective at [4:30] p.m. Eastern Daylight Time on [*], 2022, and the absence of any order suspending the effectiveness of the Registration Statement or of any proceedings for that purpose;
12. the Preliminary Prospectus dated [*], 2022, and the Pricing Prospectus dated [*], 2022;
13. a specimen certificate for the Common Stock and the forms of the Tradeable Warrant and the Non-tradeable Warrant;
14. a certificate of the President of the Company as to certain factual matters dated as of the date hereof;
15. a certificate of the Secretary of the Company as to certain factual matters dated as of the date hereof;

16. certain agreements and instruments to which the Company is a party as identified on Schedule II hereto (the “Listed Agreements”); and
17. such other certificates, documents and records as we have deemed necessary or appropriate to express the opinions set forth herein.

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- II. In basing the opinions and other matters set forth herein on “our knowledge” or information “known to us,” or “of which we are aware” the words “our knowledge,” “known to us” and “aware” signify that, in the course of our representation of the Company in matters with respect to which we have been engaged by the Company as counsel, no information has come to our attention that would give us actual knowledge or actual notice that any such opinions or other matters are not accurate. Except as otherwise stated herein, we have undertaken no independent investigation or verification of such matters, whether or not such investigation or verification might otherwise be reasonable or prudent. Although we act as counsel to the Company with respect to specific matters on a regular basis, we do not act as counsel to the Company as to all matters and, therefore, we may be unaware of certain of its business dealings. Our knowledge of factual matters regarding the Company is based upon those matters with respect to which we have rendered advice and matters which the Company has disclosed to us, upon inquiry or otherwise. The words “our knowledge,” “known to us,” “of which we are aware,” and similar language used herein are limited to the knowledge of the lawyers within our firm who have provided substantive legal attention to matters on behalf of the Company in the form of legal consultations or legal representation in connection with the Registration Statement, Time of Sale Disclosure Package and Pricing Prospectus, which knowledge has been obtained by such lawyers in their capacities as such.
- III. In reaching the opinions set forth below, we have assumed, and to our knowledge there are no facts inconsistent with, the following:
1. the genuineness of all signatures and the accuracy, completeness and authenticity of all instruments, documents and agreements submitted to us as originals;
 2. the conformity to original documents (and the accuracy, completeness and authenticity of such original documents) of all instruments, documents and agreements submitted to us as certified, facsimile, or photostatic copies;
 3. the accuracy, completeness and authenticity of certifications of public officials and corporate officials and of the statements of facts contained in certifications thereby upon which we are relying for purposes of this opinion;
 4. that each of the parties thereto (other than the Company) has duly authorized, executed and delivered the Underwriting Agreement, and each such party’s (other than the Company) obligations as set forth therein are its legal, valid, and binding obligations, enforceable in accordance with their respective terms;
 5. that each party executing the Underwriting Agreement (other than the Company) has all requisite corporate or other power to execute and deliver the Underwriting Agreement and to perform such party’s obligations thereunder;
 6. that each natural person executing any such instrument, document, or agreement is legally competent to do so at the time of execution;
 7. that there are no oral or written waivers, modifications of or amendments to the Underwriting Agreement or any of the Listed Agreements, by actions or conduct of the parties thereto or otherwise, and
 8. that there are no records of any proceedings or actions of the stockholders or the Board of Directors of the Company which have not been provided to us.

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- IV. Based upon and subject to the foregoing and the qualifications and limitations, it is our opinion that:
1. The Company is a corporation duly incorporated, validly existing as a corporation in good standing under the laws of the State of Delaware. The Company has the corporate power and authority to own, lease and operate its properties and assets and to carry on its business as described in the Registration Statement, the Time of Sale Disclosure Package, and the Pricing Prospectus.
 2. Based solely on our review of the Certificate of Incorporation, as amended to date, Bylaws, as amended to date, and the Company’s stock records, the authorized capital stock of the Company is as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus under the caption “Description of Capital Stock.” The Firm Units, Common Stock, Warrants and Warrant Shares delivered by the Company on the date hereof have been duly authorized and, when issued and paid for as applicable and in accordance with the Underwriting Agreement, will be validly issued, fully paid and nonassessable. The Representative’s Warrant and the Representative’s Warrant Shares have been duly authorized, and upon proper exercise and payment therefor, assuming (i) that there is a sufficient number of authorized and unissued shares of Common Stock at the time of the Representative’s Warrant exercise, (ii) no change has occurred in the applicable law or the pertinent facts, and (iii) the pertinent provisions of such “blue-sky” and securities laws as may be applicable have been complied with by the Company, when and if issued, the Representative’s Warrant Shares will be validly issued, fully paid and nonassessable. The issuance and sale of the Securities by the Company pursuant to the Underwriting Agreement are not subject to any written preemptive rights, written right of first offer or written right of first refusal in each case, pursuant to the Company’s Certificate of Incorporation and Bylaws, or the laws of the State of Delaware that have not otherwise been waived or satisfied.
 3. The Underwriting Agreement, the Warrants and the Representative’s Warrant have been duly authorized, executed and delivered by the Company. The Company has all the requisite corporate power and authority to enter into the Underwriting Agreement, the Warrants and the Representative’s Warrant and to perform its obligations thereunder.
 4. The Underwriting Agreement, the Warrants and the Representative’s Warrant constitute the valid and legally binding obligation of the Company, enforceable against the Company in accordance with its respective terms.
 5. The execution, delivery and performance of the Underwriting Agreement, the Warrants and the Representative’s Warrant and compliance by the Company with the terms and provisions thereof and the consummation of the transactions contemplated thereby, and the issuance and sale of the Securities do not and will not, with or without the giving of notice or the lapse of time, or both, (a) conflict with, or result in a breach of, any of the terms or provisions of, or constitute a default under, or result in the creation or modification of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company pursuant to the terms of any agreement filed as an exhibit to the Registration Statement, or (b) result in any violation of the provisions of the Company’s Certificate of Incorporation or Bylaws, as amended, or (c) result in any violation of any Federal or State law or regulation, or (d) result in any violation of any Listed Agreement.

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6. The execution and delivery by the Company of the Underwriting Agreement, the Warrants and the Representative's Warrant, the performance by the Company of its obligations under the Underwriting Agreement and the Securities does not violate any judgment or order of any Federal or State governmental authority of which we are aware.
7. To our knowledge after due inquiry, other than as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus, there are no legal or governmental proceedings pending to which the Company or any director or officer or controlling shareholder is a party or of which any property of the Company is or the subject which, if determined adversely to the Company, a director, officer or controlling shareholder would have a material adverse effect on the general affairs, business, management, financial position, shareholders' equity or results of operations of the Company or would prevent or impair the consummation of the transactions contemplated by the Underwriting Agreement, or which are required to be described in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus.
8. The information in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus under the headings "Business – Legal Proceedings," "Description of Capital Stock," and in Part II of the Registration Statement under Items 14 and 15, in each case insofar as such statements purport to constitute summaries of legal matters or specific provisions of documents referred to therein, fairly summarize in all material respects the matters referred to therein.
9. The Securities will be issued in compliance with applicable United States securities laws, rules and regulations and will conform in all material respects to the descriptions thereof contained in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus.
10. No consent, approval, authorization or other order of, or registration or filing with, any Federal or State governmental or regulatory authority or agency is required for the execution, delivery and performance by the Company of the Underwriting Agreement, and the issuance and sale of the Securities except for (i) the registration of the offer and sale of the Securities under the Securities Act of 1933, as amended, which has been effected, and (ii) such consents, approvals, authorizations, orders and registrations or filings as may be required (A) under applicable State securities laws, as to which we express no opinion, (B) from the Financial Industry Regulatory Authority, Inc. as to which we express no opinion, and (C) from The Nasdaq Capital Market in connection with the purchase and distribution of the Firm Units by the Underwriters, which has been obtained.
11. Other than the Listed Agreements, no other contracts of which we are aware are required to be described or referred to in or filed as exhibits to the Registration Statement or the Final Prospectus.
12. Other than the Representative's Warrant, none of the Listed Agreements grant any holders of securities of the Company rights to require the registration under the Securities Act of resales of such securities in the Registration Statement or otherwise.

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13. The Company is not and, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Registration Statement, the Time of Sale Disclosure Package and the Pricing Prospectus, will not be an "investment company" as defined in the Investment Company Act of 1940, as amended.
14. The Registration Statement was declared effective by the Commission on [*], 2022. No stop order suspending the effectiveness of the Registration Statement has been issued by the Commission and to our knowledge, no proceeding for that purpose has been instituted by the Commission. The Prospectus was filed with the Commission pursuant to Rule 424(b) under the Securities Act in the manner and within the time period required by such Rule 424(b).
15. The Registration Statement and the Time of Sale Disclosure Package including any information deemed to be part of the Registration Statement pursuant to Rule 430A under the Securities Act, as of its effective date, and the Pricing Prospectus and as of its date (and, in each case, other than the Company financial statements and related schedules, and other financial and statistical data, contained therein or omitted therefrom, as to which we express no opinion or belief), appeared on their face to comply as to form in all material respects with the requirements of the Securities Act and the rules and regulations of the Commission promulgated thereunder.

We confirm to you that we are not representing the Company in any pending litigation in which the Company is a named defendant that challenges the validity or enforceability of the Underwriting Agreement or seeks to enjoin the performance of the Underwriting Agreement.

With respect to paragraph 4, we express no opinion herein as to the following: (i) the effects of bankruptcy, fraudulent transfer and conveyance, insolvency, reorganization, receivership, moratorium and other similar laws affecting the rights and remedies of creditors generally, including judicially developed doctrines in this area, such as substantive consolidation of entities and equitable subordination; (ii) the effects of general principles of equity, including, without limitation, concepts of reasonableness, good faith and fair dealing and the possible unavailability of specific performance, injunctive relief, or other equitable remedies, whether applied by a court of law or equity; (iii) the enforceability of provisions in any agreement referred to herein relating to delay or omission of enforcement of rights or remedies, or waivers of defenses, waivers of jury trials, or waivers of benefits of stay, extension, moratorium, statutes of limitation or other nonwaivable benefits bestowed by operation of law; (iv) the enforceability of any choice of law or consent to jurisdiction provision in any agreement referred to herein; (v) the enforceability of the indemnification or contribution provisions in any agreement referred to herein to the extent such provisions purport to indemnify any party against the consequences of its own negligence, gross negligence, recklessness, willful misconduct, fraud or similar illegal conduct; (vi) whether a court would grant any remedy sought with respect to immaterial breaches or to the extent any party has acted in bad faith in exercising remedies; or (vii) whether a court would grant a particular remedy provided for in the Underwriting Agreement as opposed to another remedy provided for in the Underwriting Agreement or at law or in equity. In addition, certain other provisions of the Underwriting Agreement otherwise addressed in our enforceability opinion might not be enforceable under the applicable law but, in our opinion (and subject to the other, assumptions, limitations, qualifications and exceptions of this opinion letter), those provisions, even if unenforceable, would not (individually or in the aggregate) render the Underwriting Agreement unenforceable as a whole or result in the intended beneficiaries having inadequate rights and remedies under the Underwriting Agreement and applicable law for the practical realization of the principal benefits intended by the Underwriting Agreement. In all cases, we assume that a court would sever an unenforceable provision from the Underwriting Agreement, even in the absence of a severability clause.

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We are members of the bar of the States of Texas and New York, and the opinions expressed herein are limited to the existing laws of the States of Texas and New York (not including the state securities or blue sky laws thereof), the General Corporation Law of the State of Delaware, and the federal laws of the United States of America, in each case excluding the principles of conflicts of laws thereof. We express no opinion as to the effect of the laws of any other jurisdiction, do not purport to be experts in the laws of any other jurisdiction, and disclaim any opinion as to the application or effect of any statute, rule, regulation, ordinance, order or other promulgation of any other jurisdiction.

We express no opinion as to the accuracy or completeness of any statements contained in the Registration Statement, the Time of Sale Disclosure Package, the Pricing Prospectus, or any document incorporated by reference therein relating to matters regulated by the U.S. Food and Drug Administration, the United States Federal Food, Drug, and Cosmetic Act, as amended, the Clinical Laboratory Improvement Amendments of 1988, as amended, the rules and regulations under any of the foregoing or the laws of any jurisdiction other than the laws of the jurisdictions set forth in the paragraph immediately above.

The opinions express herein are based upon the law and circumstances as they are in effect or exist on the date hereof, and we assume no obligation to revise or supplement this letter in the event of future changes in the law or interpretations thereof with respect to circumstances or events that may occur subsequent to the date hereof.

The opinions expressed in paragraph 1 above as to the good standing of the Company are (i) given solely on the basis of the certificate of the Secretary of State of the State of Delaware dated June 21, 2022, and the certificate of the Secretary of State of Texas dated June 21, 2022, and speak only as to the date of each such certificate and not as of the date hereof, and (ii) limited to the meaning ascribed to such certificates by such governmental authorities and applicable law.

This opinion letter is limited to the matters set forth herein, and no opinion is implied or may be inferred beyond the matters expressly stated herein.

The opinions expressed herein are solely for your benefit in connection with the closing of the transactions contemplated by the Underwriting Agreement and may not be used or relied upon by you or any other person for any other purpose whatsoever without, in each instance, our prior express written consent. This opinion may not be quoted or used in whole or in part for any purpose nor may copies be provided to any person without our prior express written consent.

Respectfully Submitted,

Dykema Gossett PLLC

Attachments

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SCHEDULE I
Underwriters

WallachBeth Capital, LLC
Craft Capital Management LLC
WestPark Capital, Inc.

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SCHEDULE II
Listed Agreements

Underwriting Agreement

Certificate of Incorporation, as amended to date

Amended and Restated Certificate of Incorporation of Registrant, to be in effect immediately prior to completion of the Offering

Certificate of Designation of Series A Convertible Preferred Stock

Amended and Restated Bylaws, as currently in effect

Code of Business Conduct

Company's Common Stock Certificate

Audit Committee Charter

Compensation Committee Charter

Nominating and Governance Committee Charter

Secured, Convertible Promissory Note of Company

Unsecured, Convertible Promissory Note of Company

Warrant Issued to San Antonio Economic Development Corporation dated March 17, 2017

Investor Warrants

Form of Note Extension Common Stock Purchase Warrant issued to holders of the Registrant's Convertible Promissory Notes as consideration to extend the maturity date to October 31, 2022

Form of (Unit) Tradeable Warrant

Form of (Unit) Non-tradeable Warrant

Placement Agent's Warrant

Convertible Bridge Promissory Notes

Form of Amendment to Convertible Promissory Note

2014 Equity Incentive Plan

Form of Stock Option Agreement under 2014 Equity Incentive Plan

Form of Restricted Stock Agreement 2014 Equity Incentive Plan

Executive Chairman Employment Agreement dated January 1, 2020 between Company and Steven Girgenti, as amended

Employment Agreement dated February 1, 2015 between Company and Maria Zannes

Employment Agreement dated April 4, 2016 between Company and Vivienne Rebel

Consulting Agreement with Michael Edwards

Note Purchase Agreement dated December 21, 2018, as amended

Note Purchase Agreements for Convertible Bridge Note Investors

Secured, Convertible Promissory Note

Unsecured, Convertible Promissory Note

Form of Amendment to Unsecured, Convertible Promissory Note

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

Agreement between Registrant and GO2 Partners dated October 17, 2020

Joint Development Agreement with Precision Pathology

EXHIBIT D

Negative Assurance Letter of Dykema Gossett PLLC



Dykema Gossett PLLC
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www.dykema.com
Tel: (210) 554-5500
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[*], 2022

WallachBeth Capital, LLC
Harborside Financial Plaza 5
185 Hudson St., Suite 1410
Jersey City, New Jersey 07311

Gentlepersons:

We have acted as legal counsel to bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act") of: (i) 1,285,325 Units (the "Units") with an estimated initial offering price between \$6.00 and \$6.25 per Unit (the "Price Range"), each Unit consisting of (1) one share of the Company's common stock, par value \$0.007 per share (the "Common Stock"), (2) one five-year tradeable warrant (a "Tradeable Warrant") to purchase one share of Common Stock at an exercise price equal to 120% of the assumed public offering price of \$6.125 per Unit (the "Unit Offering Price"), which is the midpoint of the Price Range, and (3) one five-year non-tradeable warrant (a "Non-tradeable Warrant"; together with each Tradeable Warrant, the "Warrants") to purchase one share of Common Stock at an exercise price equal to 125% of the Unit Offering Price; (ii) up to an additional 192,799 shares of Common Stock (the "Option Shares") and/or 192,799 Non-tradeable Warrants and/or 192,799 Tradeable Warrants (such additional Non-tradeable Warrants or Tradeable Warrants, the "Option Warrants"), pursuant to an option granted by the Company to the underwriters listed on Schedule I hereto (the "Underwriters"); (iii) the warrant to be issued to WallachBeth Capital, LLC as representative of the Underwriters (the "Representative"; such warrant, the "Representative's Warrant"); and (iv) the shares of Common Stock underlying the Warrants (the "Warrant Shares"), the Option Warrants (the "Option Warrant Shares"), and the Representative's Warrant (the "Representative's Warrant Shares"; together with the Units, the Common Stock issued as part of the Units, the Option Shares, the Warrant Shares, the Option Warrant Shares, the Representative's Warrant Shares, the Warrants, the Option Warrants, and the Representative's Warrant, the "Securities"), and the public offering thereof pursuant to that certain Underwriting Agreement dated [*], 2022 (the "Underwriting Agreement"), by and between the Company and the Representative of the Underwriters, pursuant to which the Company has agreed to sell and the Underwriters have agreed to purchase the Units, the Option Shares and/or the Option Warrants. This letter is furnished to you pursuant to Section 6(c) of the Underwriting Agreement. Unless defined herein, capitalized terms have the meanings given to them in the Underwriting Agreement.

During the course of the preparation of the Registration Statement on Form S-1 (File No. 333-264463), as amended by Amendments Nos. 1 and 2 thereto (the "Registration Statement") filed with the Securities and Exchange Commission (the "Commission"), as legal counsel to the Company, we reviewed the Registration Statement, the preliminary Prospectus dated [*], 2022, as filed with the Commission (the "Preliminary Prospectus"), and the preliminary Prospectus dated [*], 2022, as filed with the Commission (the "Pricing Prospectus"), and certain corporate records and documents furnished to us by the Company and participated in conferences with officers and other representatives of the Company, with representatives of the independent public accountants of the Company and with you and your representatives at which the contents of the Registration Statement, the Preliminary Prospectus, and the Pricing Prospectus and related matters were discussed. The purpose of our professional engagement was not to establish or confirm factual matters set forth in the Registration Statement, the Preliminary Prospectus, or the Pricing Prospectus. We have not undertaken any obligation to verify independently any of those factual matters, and have expressly relied on the Company management and others with respect to the adequacy of disclosure with respect to such matters. Accordingly, we do not assume any responsibility for the accuracy, completeness, or fairness of the statements in the Registration Statement, the Preliminary Prospectus or the Pricing Prospectus. Nothing herein shall be construed to cause us to be considered "experts" within the meaning of Section 11 of the Securities Act.

Subject to the foregoing and on our understanding of the United States federal securities laws and the experience we have gained in our practice thereunder, and relying as to certain factual matters on the representations and statements of the officers and other representatives of the Company and on the representations, warranties and covenants contained in the Underwriting Agreement no fact has come to our attention that causes us to believe (meaning, that those attorneys in our firm who have rendered legal services in connection with the offering of the Securities do not have actual knowledge) that the Registration Statement, at the time it became effective, the Preliminary Prospectus as of its date, or the Pricing Prospectus, as of its date or the date hereof, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

- (i) the financial statements, the accountants' reports, the supporting schedules, and notes or other financial or accounting data or forecasts or estimates, including, without limitation, with respect to assessments or reports on the effectiveness of internal controls over financial reporting;
- (ii) statistical data and other numerical information, including, without limitation (a) information about the Company's industry or its competitors; (b) information about industry sales; (c) market share information; (d) operating metrics; and (e) projections; or
- (iii) other information that is opined upon by the Company's Special Intellectual Property Counsel, Food and Drug Counsel, or general counsel;

in each case, included in or omitted from the Registration Statement, the Preliminary Prospectus or the Pricing Prospectus, or the statements contained in the exhibits to the Registration Statement, as to which we have not been requested to comment.

This letter is rendered solely to you for the benefit of the Underwriters pursuant to Section 6(c) of the Underwriting Agreement in connection with the offer and sale of the Securities pursuant to the Underwriting Agreement for purposes of assisting the Underwriters in establishing defenses under applicable securities laws. This letter may not be used, quoted, relied upon or otherwise referred to for any other purpose or by any person other than the Underwriters without our express prior written consent. This letter is rendered to you for the benefit of the Underwriters as of the date hereof and is not to be deemed to have been reissued by any subsequent delivery as permitted above, and we assume no obligation to advise you or any other person hereafter with regard to any change after the date hereof in the circumstances or the law that may bear on the matters set forth herein even though the change may affect the legal analysis or a legal conclusion or other matters in this letter.

Respectfully Submitted,

Dykema Gossett PLLC

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EXHIBIT E

Opinion of Peacock Law, P.C.

1. Attached Exhibit A lists all United States and international patent and trademark properties owned by the Company or a wholly-owned subsidiary under the Company's control (referred to as the "Company IP Portfolio"). To our knowledge, assignment documents have been recorded with the United States Patent and Trademark Office ("USPTO") showing ownership by the Company (or a wholly-owned subsidiary under the Company's control) for the United States patent properties. To our knowledge, assignment documents have been recorded with the European Patent Office ("EPO") and other foreign patent agencies or offices ("OPO") showing transfer of ownership to the Company (or a wholly-owned subsidiary under the Company's control) for the non-United States patent properties. Capitalized terms not defined herein are defined in the Underwriting Agreement by and between the Company and WallachBeth Capital, LLC dated [*], 2022, of which this opinion is an exhibit.

2. There are no pending or threatened legal or governmental proceedings, and there are no allegations on the part of any person or entity of infringement, to patent rights, trade secrets or other proprietary information or know-how of the Company with the sole exception of patent and trademark prosecution before the USPTO, EPO or the OPO or similar foreign entity, and no such proceedings are currently threatened or contemplated.

3. To our knowledge, the Company is not infringing or otherwise violating any patents of any person and, to our knowledge, no person is infringing or otherwise violating any of Company's patents in the Company IP Portfolio, trade secrets, trademarks, service marks, copyrights or other proprietary information or know-how of the Company.

4. The Company owns or possesses sufficient assignments, licenses, sub-licenses or other rights to use all patents, trade secrets or other proprietary information or know-how necessary to conduct the business now being or proposed to be conducted by Company as described in the Registration Statement.

5. All issued United States and Foreign patents and trademarks listed in the Company IP Portfolio and all of licenses and sub-licenses are in force and are valid, enforceable and all issued United States and Foreign patents and trademarks listed in the Company IP Portfolio are entitled to a statutory presumption of validity and of ownership by the recorded assignee in the United States and/or other Foreign country, as applicable. We are not aware of any facts that would form a reasonable basis for finding that any of the patents listed in the Company IP Portfolio are invalid or unenforceable.

6. There are no asserted or, to our knowledge, unasserted claims of any person or entity relating to the scope or ownership of the patents and patent applications listed in the Company IP Portfolio or the rights under any licenses or sub-licenses held by the Company.

7. To our knowledge, there are no liens which have been filed against any patent or patent application in the Company IP Portfolio other than as disclosed in the Registration Statement or the Prospectus.

8. There are no material defects of form in the preparation or filing of any patent or patent application in the Company IP Portfolio, the applications are being diligently prosecuted, and none of the applications are abandoned.

9. The Company's licenses and sub-licenses are duly executed, validly binding and enforceable in accordance with their terms and Company is not in default (declared or undeclared) of any material provision of such license. To our knowledge, the Offering will not materially adversely alter the scope of Company's rights in any aspect of the Company IP Portfolio or under any licenses or sub-licenses.

10. To our knowledge, all material information and pertinent prior art references known to us and to Company as material to the patentability of any pending claim, were disclosed to the USPTO, the EPO and the OPO during prosecution of patent applications, to the extent required under applicable law.

11. To our knowledge, none of prosecution counsel or the Company made any misrepresentation to, or concealed any material fact from, the USPTO, EPO or OPO during prosecution of any patent matter in violation of applicable law.

12. The statements relating to Company's patents and patent applications in the Registration Statement and the Prospectus, at the time such Registration Statement became effective, as of the date of the filing of the Prospectus and as of the date of this letter, appear on their face to fairly summarize the matters described therein in all material respects. We are unaware of any other facts that cause us to believe that the above-described statements as of the date of this letter, (i) contained an untrue statement of a material fact, or (ii) omitted to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

13. All maintenance fees (or their equivalents) are current for the patent properties in the Company IP Portfolio.

14. We are not aware of any inventorship disputes, formal or informal regarding any patent property in the Company IP Portfolio.

15. We are not aware of any threatened or pending claim or dispute relating to any license or sub-license.

16. To our knowledge, the Company has not sought outside counsel to perform any freedom-to-operate searches in the United States or the European Union.

17. To our knowledge, the Company has not obtained any form of IP opinion for any aspect of the Company IP Portfolio.

18. To our knowledge, the Registration Statement and the Prospectus do not contain any information that is either: (a) not already publicly available or (b) if not publicly available, then such information is the subject of an already-filed patent application by the Company.

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EXHIBIT F

Opinion of Hyman, Phelps & McNamara, P.C.

[TO BE PROVIDED]

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EXHIBIT G

Opinion of General Counsel

[bioAffinity Letterhead]

July [Closing Date], 2022

WallachBeth Capital, LLC
Harborside Financial Center Plaza 5
185 Hudson Street, Suite 1410
Jersey City, New Jersey 07311

Gentlemen and Ladies:

As the general counsel of bioAffinity Technologies, Inc. a Delaware corporation (the “Company”), I am writing to you in connection with the preparation and filing of the Company’s registration statement on Form S-1 (File No. 333-264463) (“Registration Statement”), as amended, for the offering of: (i) 1,285,325 units (“Firm Units”), each unit consisting of (1) one share of common stock, \$0.007 par value per share (“Common Stock”), (2) one five-year tradeable warrant to purchase one share of Common Stock (“Tradeable Warrants”), and (3) one five-year non-tradeable warrant to purchase one share of Common Stock (“Non-tradeable Warrants; together with the Tradeable Warrants, the “Warrants”), and at the election of the Representative (as defined below); (ii) up to an additional 192,799 shares of Common Stock (the “Option Shares”) and/or 192,799 Non-tradeable Warrants and/or 192,799 Tradeable Warrants¹ (the “Option Warrants”), pursuant to an option granted by the Company to the underwriters (the “Underwriters”) listed on Schedule I of that certain Underwriting Agreement, dated [*], 2022 (the “Underwriting Agreement”), by and between the Company and WallachBeth Capital, LLC as representative (the “Representative”) of the Underwriters ; (iii) the warrant to be issued to the Representative (the “Representative’s Warrant”); and (iv) the shares of Common Stock underlying the Warrants (“Warrant Shares”), the Option Warrants (“Option Warrant Shares”), and the Representative’s Warrant (“Representative’s Warrant Shares”) (the Units, the Common Stock issued as part of the Units, the Option Shares, the Warrant Shares, the Option Warrant Shares, the Representative’s Warrant Shares, the Warrants, the Option Warrants, and the Representative’s Warrant are collectively referred to herein as the “Securities”). This opinion is given to you pursuant to Section 6(f) of the Underwriting Agreement. Unless defined herein, capitalized terms have the meanings given to them in the Underwriting Agreement.

While acting as general counsel to the Company, I have participated in the preparation of the Registration Statement (including any documents filed as exhibits thereto), filed with the Securities and Exchange Commission (the “Commission”) on April 25, 2022 under the Securities Act of 1933, as amended (the “Securities Act”), the Preliminary Prospectus and the Pricing Prospectus dated [*], 2022, as filed by the Company with the Commission on [*], 2022 pursuant to Rule 424(b)(4)) under the Securities Act, and have participated in discussions with directors, officers and other representatives of the Company and its subsidiary and its outside counsel and independent auditors and with you and your representatives and your legal counsel at which the contents of the Registration Statement, Preliminary Prospectus and the Pricing Prospectus were discussed and have reviewed the Company’s corporate records and other relevant documents necessary to provide this opinion.

During the above related preparation and review of the Registration Statement, Preliminary Prospectus or the Pricing Prospectus in which I was involved, no fact has come to my attention that has caused me to believe that the Registration Statement at the time it became effective, the Preliminary Prospectus as of its date, or the Pricing Prospectus, as of its date and date hereof, contained any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

This letter is rendered solely to you for the benefit of the Underwriters pursuant to Section 6(f) of the Underwriting Agreement in connection with the offer and sale of the Common Stock pursuant to the Underwriting Agreement. This letter may not be relied upon by any person other than the Underwriters without my express prior written consent. This letter is rendered to you for the benefit of the Underwriters as of (add date here) and is not to be deemed to have been reissued by any subsequent delivery beyond this date. I assume no obligation to advise you or any other person hereafter with regard to any change after the date of this letter in the circumstances or the law that may bear on the matters set forth herein even though the change may affect the legal analysis or a legal conclusion or other matters in this letter.

Sincerely,

Timothy P. Zannes, J.D.

General Counsel

¹ Which shall equal 15% of the total shares of Common Stock underlying the Units sold in the offering.

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EXHIBIT H

**OFFICERS’ CERTIFICATE
OF
BIOAFFINITY TECHNOLOGIES, INC.
[*], 2022**

Reference is hereby made to the Underwriting Agreement, dated as of [*], 2022 (the “Underwriting Agreement”), by and between WallachBeth Capital LLC, as Representative of the several underwriters named on Schedule I to the Underwriting Agreement (the “Representative”), and bioAffinity, Inc., a Delaware corporation (the “Company”). Capitalized terms used herein and not defined have the meanings ascribed to them in the Underwriting Agreement.

The undersigned officers hereby certify, solely in their capacity as officers of the Company and not in their individual capacities, that they are the duly authorized Chief Executive Officer and Chief Financial Officer of the Company, and do hereby further certify that:

- i. the condition set forth in section 6 of the Underwriting Agreement has been satisfied;
- ii. as of the date hereof, the representations and warranties of the Company set forth in Sections 2 and 3 of the Underwriting Agreement are accurate;
- iii. as of the date hereof, all agreements, conditions and obligations of the Company to be performed or complied with pursuant to the Underwriting Agreement on or prior to the date hereof have been duly performed or complied with;
- iv. for the period from and including the date of the Underwriting Agreement through and including the date hereof, the Company has not: (i) sustained any material loss or interference with its respective businesses, whether or not covered by insurance, or from any labor dispute or any legal or governmental proceeding, or (ii) any change in the capital stock (other than the issuance of Common Stock, Warrants to purchase Common Stock, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement and the Prospectus) or long term debt of the Company, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock;
- v. no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereof has been issued and no proceedings therefor have been initiated or threatened by the Commission;
- vi. there are no pro forma or as adjusted financial statements that are required to be included or incorporated by reference in the Registration Statement and the Prospectus pursuant to the Rules and Regulations which are not so included or incorporated by reference;
- vii. such officers have examined the Registration Statement, the Preliminary Prospectus, any Issuer Free Writing Prospectus, the Time of Disclosure Package and the Pricing Prospectus and after reasonable investigation, the Registration Statement and each amendment thereto, the Preliminary Prospectus, any Issuer Free Writing Prospectus, the Time of Disclosure Package and the Pricing Prospectus, as of the effective date of the Registration Statement and as of the Closing Date, did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading;
- viii. the share numbers and percentages relating to the Company’s equity securities set forth in the Registration Statement, the Preliminary Prospectus, any Issuer Free Writing Prospectus, the Time of Disclosure Package and the Pricing Prospectus have been calculated by management and are true, accurate and correct as of the effective date of the Registration Statement;
- ix. 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 Certificate is provided to the Representative;
- x. there has been no action suit or proceeding, at law or in equity, pending or threatened against the Company or any affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement, Preliminary Prospectus, Time of Disclosure Package and Pricing Prospectus; and
- xi. subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus there has not been any Material Adverse Change or any development involving a prospective Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

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IN WITNESS WHEREOF, the undersigned have signed this certificate as of the date set forth above.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____

Maria Zannes, Chief Executive Officer

By: _____

Michael Edwards, Chief Financial Officer

[Signature Page of Officers’ Certificate to the Underwriting Agreement]

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EXHIBIT I

**SECRETARY’S CERTIFICATE
OF
BIOAFFINITY TECHNOLOGIES, INC.**

July [*], 2022

Reference is hereby made to the Underwriting Agreement, dated as of [*], 2022 (the “Underwriting Agreement”), between WallachBeth Capital, LLC, as Representative of the several underwriters named on Schedule I to the Underwriting Agreement (the “Representative”), and bioAffinity Technologies, Inc., a Delaware corporation (the “Company”). Capitalized terms used herein and not defined have the meanings ascribed to them in the Underwriting Agreement.

The undersigned hereby certifies, solely in his capacity as the Secretary of the Company and not in his individual capacity, that he is the duly authorized Secretary of the Company, and does hereby further certify that:

1. A true and correct copy of the Certificate of Incorporation of the Company, together with all amendments to date, is attached hereto as Exhibit A, and the bylaws of the Company, together with all amendments to date, are attached as Exhibit B. The Certificate of Incorporation, as amended, and the bylaws, as amended (collectively, the “Charter”

Documents”) are in full force and effect on the date hereof. No action has been taken by the Board of Directors or the stockholders of the Company for the purpose of effecting any further amendment to or modification of the Charter Documents.

2. No action or proceeding for the dissolution, merger, consolidation, liquidation or reorganization of the Company, or for the sale, lease or other transfer of all or substantially all of any of its assets, is pending, and to the best knowledge of the undersigned, no such action or proceeding is contemplated by the Company, its stockholders, directors or officers.

3. A true and correct copy of the resolutions of the Board of Directors of the Company, duly adopted and approved by the Board of Directors of the Company, is attached hereto as Exhibit C. Such resolutions have not been amended, modified or rescinded since their adoption and are in full force and effect as of the date hereof, and are the only resolutions relating to (a) the execution and delivery of the Underwriting Agreement, (b) the issuance and sale by the Company under the Underwriting Agreement of the Securities and the payment of the underwriters’ compensation, (c) the filing of the Company’s registration statement with the Commission, and (d) the authorization of all actions required to be taken, or other documents required to be executed and delivered, in connection with any of the foregoing. The resolutions were duly adopted and constitute all of the resolutions of the Board, with respect to the issuance, offering and sale of the Securities and the authorization of the actions to be taken in connection with the transactions described in the Registration Statement and the Pricing Prospectus.

4. Attached hereto as Exhibit D is a true, correct, and complete specimen of the certificate representing the Common Stock.

5. The Underwriting Agreement, as executed and delivered by the Company, is in substantially the form approved by the Board of Directors in the resolutions referred to in paragraph 3 above and has been duly executed and delivered on behalf of the Company by an appropriate officer of the Company.

6. After giving effect to the issuance and registration of the Common Stock described in the Underwriting Agreement, the Company has an aggregate of [] shares of Common Stock issued and outstanding as of the date hereof.

7. Each person who, as a director or officer of the Company, signed, and delivered by facsimile, portable document file (.pdf) or otherwise, (a) the Underwriting Agreement, (b) the Registration Statement, and (c) any and all other documents or instruments executed and delivered to the Representative in connection with the transactions contemplated by the Underwriting Agreement, was, at all times, duly elected or appointed, qualified and acting as such director or officer, and was duly authorized to execute and deliver such documents or other instruments at the respective times of such execution and delivery and, in the case of the certificates for the Common Stock, the Warrants, or the Representative’s Warrant, the making of true facsimiles or portable document files thereof, and, the signature of each such person (including any electronic signature covered by the U.S. Federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) appearing on each such document is the genuine signature of such director, officer or attorney-in-fact.

8. The minute books, records and other documents of the Company relating to all proceedings of the stockholders, the Board of Directors and the committees of the Board of Directors made available to Dykema Gossett PLLC and Carmel Milazzo & Feil LLP are the original minute books and records of the Company, or are true, correct and complete copies thereof in all material respects, with respect to all proceedings of said stockholders, Board of Directors and committees of the Board of Directors as of the date hereof, other than meetings for which minutes in draft form were provided. There have been no material changes, additions or alterations in said minute books, records and other documents that have not been provided to Dykema Gossett PLLC and Carmel Milazzo & Feil LLP.

9. VStock Transfer, LLC has been duly appointed by the Company to serve as the transfer agent and registrar for the Company’s Common Stock and as warrant agent for the Company’s Warrants and, as of the date hereof, serves in such capacity for the Company’s Common Stock and Warrants, respectively.

[Signature page follows.]

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IN WITNESS WHEREOF, the undersigned has signed this certificate as of the date set forth above.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____

Name: Timothy P. Zannes, J.D.

Title: Secretary

I, Maria Zannes, Chief Executive Officer of the Company, do hereby certify that Timothy J. Zannes is the duly elected, qualified and acting Secretary of the Company and that the signature set forth above her/his name is her/his genuine signature.

By: _____

Name: Maria Zannes

Title: Chief Executive Officer

[Signature Page of Secretary's Certificate to the Underwriting Agreement]

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Form of Placement Agent's Warrant

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING THE COMMENCEMENT OF THE SALE OF THE COMPANY'S UNITS IN ITS INITIAL PUBLIC OFFERING TO ANYONE OTHER THAN (I) WALLACHBETH CAPITAL, LLC OR AN UNDERWRITER OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING, OR (II) A BONA FIDE OFFICER OR PARTNER OF WALLACHBETH CAPITAL, LLC OR OF ANY SUCH UNDERWRITER OR SELECTED DEALER.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO [] [DATE THAT IS 180 DAYS AFTER THE COMMENCEMENT OF SALES OF THE COMPANY'S UNITS IN ITS INITIAL PUBLIC OFFERING]. VOID AFTER 5:00 P.M., EASTERN TIME, [] [DATE THAT IS FIVE YEARS FROM THE EFFECTIVE DATE OF THE OFFERING].

COMMON STOCK PURCHASE WARRANT

For the Purchase of [] Shares of Common Stock
of
BIOAFFINITY TECHNOLOGIES, INC.

1. Purchase Warrant. THIS CERTIFIES THAT, in consideration of services rendered by or on behalf WallachBeth Capital, LLC ("Holder"), as registered owner of this Purchase Warrant, bioAffinity Technologies, Inc., a Delaware corporation (the "Company"), Holder is entitled, from and after [], 2022 [DATE THAT IS 180 DAYS AFTER THE COMMENCEMENT OF SALES OF THE UNITS IN THE COMPANY'S INITIAL PUBLIC OFFERING] (the "Commencement Date"), and, in accordance with FINRA Rule 5110(g)(8)(A), at or before 5:00 p.m., Eastern time, [], 2027, which is the date that is five (5) years following the commencement of sales of the Company's units (each unit, "Unit") consisting of one share of the Company's common stock, \$0.007 par value per share ("Common Stock"), one tradeable warrant to purchase one share of Common Stock, and one non-tradeable warrant to purchase one share of Common Stock) in the Company's initial public offering (the "Expiration Date"), but not thereafter, to subscribe for, purchase and receive, in whole or in part, 29,464 shares of Common Stock of the Company (the "Shares"), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this Purchase Warrant. This Purchase Warrant is initially exercisable at the price equal to the product of 120% multiplied by the initial offering price of one Unit in the Company's initial public offering; provided, however, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per Share and the number of Shares to be received upon such exercise, shall be adjusted as therein specified. The term "Exercise Price" shall mean the initial exercise price or the adjusted exercise price, depending on the context. The term "Effective Date" shall mean [], 2022, the date on which the Company commenced sales of its Units in its initial public offering.

2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Shares being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check or official bank check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire.

2.2 Cashless Exercise. If at any time after the Commencement Date there is no effective registration statement registering, or no current prospectus available for, the resale of the Shares by the Holder, then in lieu of exercising this Purchase Warrant by payment of cash or check payable to the order of the Company pursuant to Section 2.1 above, Holder may elect to receive the number of Shares equal to the value of this Purchase Warrant (or the portion thereof being exercised), by surrender of this Purchase Warrant to the Company, together with the exercise form attached hereto, in which event the Company shall issue to Holder, Shares in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

- X = The number of Shares to be issued to Holder;
- Y = The number of Shares for which the Purchase Warrant is being exercised;
- A = The fair market value of one Share; and
- B = The Exercise Price.

For purposes of this Section 2.2, the fair market value of a Share is defined as follows:

- (i) if the Company's Common Stock is traded on a securities exchange, the value shall be deemed to be the closing price on such exchange on the trading day immediately prior to the exercise form being received by the Company in connection with the exercise of the Purchase Warrant; or
- (ii) if the Company's Common Stock is actively traded over-the-counter, the value shall be deemed to be the closing bid price on the trading day prior to the exercise form being received by the Company in connection with the exercise of the Purchase Warrant; if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's Board of Directors.

2.3 Legend. If at any time after the Commencement Date there is no effective registration statement registering, or no current prospectus available for, the resale of the Shares by the Holder, each certificate for the securities purchased under this Purchase Warrant shall bear a legend as follows unless such securities have been registered under the Securities Act of 1933, as amended (the "Securities Act"):

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR APPLICABLE STATE LAW. NEITHER THE SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED FOR SALE, SOLD OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT, OR PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT AND APPLICABLE STATE LAW WHICH, IN THE OPINION OF COUNSEL TO THE COMPANY, IS AVAILABLE."

3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Purchase Warrant for a period of one hundred eighty (180) days following the Effective Date to anyone other than: (i) WallachBeth Capital, LLC or

an underwriter or a selected dealer participating in the Offering, or (ii) a bona fide officer or partner of WallachBeth Capital, LLC or of any such underwriter or selected dealer, in each case in accordance with FINRA Rule 5110(e)(1), or (b) for a period of one hundred eighty (180) days following the Effective Date, cause this Purchase Warrant or the securities issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities hereunder, except as provided for in FINRA Rule 5110(e)(2). On and after 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) business days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3.2 Restrictions Imposed by the Securities Act. If at any time after the Commencement Date there is no effective registration statement registering, or no current prospectus available for, the resale of the Shares by the Holder, the securities evidenced by this Purchase Warrant shall not be transferred unless and until: the Company has respected the opinion of counsel for the Holder that the securities may be transferred pursuant to an exemption from registration under the Securities Act and applicable state securities laws, the availability of which is established to the reasonable satisfaction of the Company (the Company hereby agreeing that the opinion of Carmel, Milazzo & Feil LLP shall be deemed satisfactory evidence of the availability of an exemption), or (ii) a registration statement or a post-effective amendment to the Registration Statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the “**Commission**”) and compliance with applicable state securities law has been established.

4. RESERVED.

5. New Purchase Warrants to be Issued.

5.1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form and funds sufficient to pay any Exercise Price and/or transfer tax if exercised pursuant to Section 2.1 hereto, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of Shares purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5.2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments.

6.1 Adjustments to Exercise Price and Number of Securities. The Exercise Price and the number of Shares underlying the Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6.1.1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is increased by a stock dividend payable in Shares or by a split up of Shares or other similar event, then, on the effective day thereof, the number of Shares purchasable hereunder shall be increased in proportion to such increase in outstanding Shares, and the Exercise Price shall be proportionately decreased.

6.1.2 Aggregation of Shares. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is decreased by a consolidation, combination or reclassification of Shares or other similar event, then, on the effective date thereof, the number of Shares purchasable hereunder shall be decreased in proportion to such decrease in outstanding Shares, and the Exercise Price shall be proportionately increased.

6.1.3 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Shares other than a change covered by Section 6.1.1 or 6.1.2 hereof or that solely affects the par value of such Shares, or in the case of any share reconstruction or amalgamation or consolidation of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Shares), or in the case of any sale or conveyance to another corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of Shares of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Shares covered by Section 6.1.1 or 6.1.2, then such adjustment shall be made pursuant to Sections 6.1.1, 6.1.2 and this Section 6.1.3. The provisions of this Section 6.1.3 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.4 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of Shares as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the Commencement Date or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation which does not result in any reclassification or change of the outstanding Shares), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares of stock and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of Shares for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section shall similarly apply to successive consolidations or share reconstructions or amalgamations.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of Shares upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up or down, as the case may be, to the nearest whole number of Shares or other securities, properties or rights.

7. Reservation and Listing. The Company shall at all times reserve and keep available out of its authorized Shares, solely for the purpose of issuance upon exercise of the Purchase Warrants, such number of Shares or other securities, properties or rights as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon

exercise of the Purchase Warrants and payment of the Exercise Price therefor, in accordance with the terms hereby, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any stockholder. The Company further covenants and agrees that upon exercise of the Purchase Warrants and payment of the exercise price therefor, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any stockholder. As long as the Purchase Warrants shall be outstanding, the Company shall use its commercially reasonable efforts to cause all Shares issuable upon exercise of the Purchase Warrants to be listed (subject to official notice of issuance) on all national securities exchanges (or, if applicable, on the OTC Bulletin Board or any successor trading market) on which the Shares issued to the public in the Offering may then be listed and/or quoted.

8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a stockholder for the election of directors or any other matter, or as having any rights whatsoever as a stockholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall give written notice of such event at least fifteen (15) days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the stockholders entitled to such dividend, distribution, conversion or exchange of securities or subscription rights, or entitled to vote on such proposed dissolution, liquidation, winding up or sale. Such notice shall specify such record date or the date of the closing of the transfer books, as the case may be. Notwithstanding the foregoing, the Company shall deliver to each Holder a copy of each notice given to the other stockholders of the Company at the same time and in the same manner that such notice is given to the stockholders.

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8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Shares for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company; (ii) the Company shall offer to all the holders of its Shares any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor; or (iii) a dissolution, liquidation or winding up of the Company (other than in connection with a consolidation or share reconstruction or amalgamation) or a sale of all or substantially all of its property, assets and business shall be proposed.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change ("**Price Notice**"). The Price Notice shall describe the event causing the change and the method of calculating same and shall be certified as being true and accurate by the Company's Chief Financial Officer.

8.4 Transmittal of Notices. Any and all notices or other communications or deliveries to be provided by a party hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to the other party at the e-mail address or address of the party set forth below. 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 business 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 business day or later than 5:30 p.m. (New York City time) on any business day, (iii) the second business 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. For purposes of this Warrant, a "business day" is any day other than a Saturday, Sunday or Federal holiday.

If to the Representative:

WallachBeth Capital, LLC
Harborside Financial Center Plaza 5
185 Hudson Street, Suite 1410
Jersey City, New Jersey 07311
Attn: Eric Schweitzer, Chief Compliance Officer
Email: eschweitzer@wallachbeth.com

with a copy (which shall not constitute notice) to:

Carmel, Milazzo & Feil LLP
55 West 39th Street, 18th Floor
New York, NY 10018,
Attention: Ross Carmel, Esq.
Email: rcarmel@cmflp.com

If to the Company:

bioAffinity Technologies, Inc.
22211 W. Interstate 10, Suite 1206
San Antonio, Texas 78257
Attention Ms. Maria Zannes, Chief Executive Officer
Email: mz@bioaffinitytech.com

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with a copy (which shall not constitute notice) to:

Dykema Gossett PLLC
112 E. Pecan Street, Suite 1800
San Antonio, Texas 78205
Attention: Wilhelm E. Liebmann, Esq.
Email: wliebmann@dykema.com

9. Miscellaneous.

9.1 Amendments. The Company and WallachBeth Capital, LLC may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and WallachBeth Capital, LLC may deem necessary or desirable and that the Company and WallachBeth Capital, LLC deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by the party against whom enforcement of the modification or amendment is sought.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3 Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.4 Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5 Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the Supreme Court of the State of New York, sitting in the County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The parties Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6 Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

9.7 Execution in Counterparts. This Purchase Warrant may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Such counterparts may be delivered by facsimile transmission or other electronic transmission.

9.8 Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and WallachBeth Capital, LLC enter into an agreement ("Exchange Agreement") pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

[Signature Page Follows]

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BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: Chief Executive Officer

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[Form to be used to exercise Purchase Warrant]

Date: _____, 20____

The undersigned hereby elects irrevocably to exercise the Purchase Warrant for _____ shares of common stock, par value \$0.007 per share (the "**Shares**"), of bioAffinity Technologies, Inc., a Delaware corporation (the "**Company**"), and hereby makes payment of \$_____ (at the rate of \$_____ per Share) in payment of the Exercise Price pursuant thereto. Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been exercised.

or

The undersigned hereby elects irrevocably to convert its right to purchase _____ Shares of the Company under the Purchase Warrant for _____ Shares, as determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

- X = The number of Shares to be issued to Holder;
- Y = The number of Shares for which the Purchase Warrant is being exercised;
- A = The fair market value of one Share which is equal to \$_____; and
- B = The Exercise Price which is equal to \$_____ per share

The undersigned agrees and acknowledges that the calculation set forth above is subject to confirmation by the Company and any disagreement with respect to the calculation shall be resolved by the Company in its sole discretion.

Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been converted.

Signature _____

Signature Guaranteed _____

INSTRUCTIONS FOR REGISTRATION OF SECURITIES

Name: _____
(Print in Block Letters)

Address: _____

NOTICE: The signature to this form must correspond with the name as written upon the face of the Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

[Form to be used to assign Purchase Warrant]

ASSIGNMENT

(To be executed by the registered Holder to effect a transfer of the within Purchase Warrant):

FOR VALUE RECEIVED, _____ does hereby sell, assign and transfer unto the right to purchase shares of common stock, par value \$0.007 per share, of bioAffinity Technologies, Inc., a Delaware corporation (the “**Company**”), evidenced by the Purchase Warrant and does hereby authorize the Company to transfer such right on the books of the Company.

Dated: _____, 20__

Signature _____

Signature Guaranteed _____

NOTICE: The signature to this form must correspond with the name as written upon the face of the within Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

FORM OF WARRANT AGENT AGREEMENT

This WARRANT AGENT AGREEMENT (this “Warrant Agreement”) dated as of [●], 2022 (the “Issuance Date”) is between bioAffinity Technologies, Inc., a company incorporated under the laws of the State of Delaware (the “Company”), and VStock Transfer, LLC (the “Warrant Agent”).

WHEREAS, pursuant to the terms of that certain Underwriting Agreement (“Underwriting Agreement”), dated [●], 2022, by and among the Company and WallachBeth Capital, LLC, as representative of the underwriters set forth therein (the “Representative”), the Company is engaged in a public offering (the “Offering”) of up to 1,285,325 units at an estimated initial public offering price between \$6.00 and \$6.25 per Unit (the “Price Range”), each unit consisting of (i) one share (the “Shares”) of common stock, par value \$0.007 per share (the “Common Stock”) of the Company, (ii) one five-year tradeable warrant (each, a “Tradeable Warrant”) to purchase one share of Common Stock (“Tradeable Warrant Shares”) at an anticipated exercise price of \$7.35 per share, and (iii) one five-year non-tradeable warrant (a “Non-tradeable Warrant”; together with each Tradeable Warrant, the “Warrants”) to purchase one share of Common Stock (“Non-tradeable Warrant Shares; together with the Tradeable Warrant Shares, the “Warrant Shares”) at an anticipated exercise price of \$7.656 per share, which includes Shares and Warrants issuable pursuant to the underwriters’ over-allotment option and the warrant and 25,507 Warrant Shares subject to the warrant issued to the Representative (the “Representative’s Warrant”);

WHEREAS, the Company has filed with the Securities and Exchange Commission (the “Commission”) a Registration Statement, No. 333-264463, on Form S-1 (as the same may be amended from time to time, the “Registration Statement”), for the registration under the Securities Act of 1933, as amended (the “Securities Act”), of the units, Shares, Warrants, the Representative’s Warrant and the Warrant Shares, and such Registration Statement was declared effective on [●], 2022;

WHEREAS the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in accordance with the terms set forth in this Warrant Agreement in connection with the issuance, registration, transfer, exchange and exercise of the Warrants;

WHEREAS, the Company desires to provide for the provisions of the Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants; and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Warrant Agreement.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company with respect to the Warrants, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the express terms and conditions set forth in this Warrant Agreement (and no implied terms or conditions).

2. Warrants.

2.1. Form of Warrants. The Tradeable Warrants shall be registered securities and shall be evidenced by a global certificate (“Tradeable Global Certificate”) in the form of Exhibit A to this Warrant Agreement, which shall be deposited on behalf of the Company with a custodian for The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., a nominee of DTC. If DTC subsequently ceases to make its book-entry settlement system available for the Tradeable Warrants, the Company may instruct the Warrant Agent regarding making other arrangements for book-entry settlement. In the event that the Tradeable Warrants are not eligible for, or it is no longer necessary to have the Tradeable Warrants available in, book-entry form, the Company may instruct the Warrant Agent to provide written instructions to DTC to deliver to the Warrant Agent for cancellation of the Tradeable Global Certificate, and the Company shall instruct the Warrant Agent to deliver to DTC separate certificates evidencing the Tradeable Warrants (“Tradeable Definitive Certificates”) registered as requested through the DTC system. The Non-tradeable Warrants will be unregistered securities and will be evidenced by a global certificate (“Non-tradeable Global Certificate”; together with the Tradeable Global Certificate, the “Global Certificates”) in the form of Exhibit B to this Warrant Agreement, which shall be deposited on behalf of the Company with the Warrant Agent. If the Warrant Agent subsequently ceases to make its book-entry settlement system available for the Non-tradeable Warrants, the Company may instruct the Warrant Agent regarding making other arrangements for book-entry settlement. In the event that the Non-tradeable Warrants are not eligible for, or it is no longer necessary to have the Non-tradeable Warrants available in, book-entry form, the Company may instruct the Warrant Agent to cancel the Non-tradeable Global Certificate and to deliver separate certificates evidencing the Non-tradeable Warrants (“Non-tradeable Definitive Certificates”) and, together with the Global Certificates and the Tradeable Definitive Certificates, the “Warrant Certificates”).

2.2. Issuance and Registration of Warrants.

2.2.1. Warrant Register. The Warrant Agent shall maintain books (“Warrant Register”) for the registration of original issuance and the registration of transfer of the Warrants.

2.2.2. Issuance of Warrants. Upon the initial issuance of the Tradeable Warrants, the Warrant Agent shall issue the Tradeable Global Certificate and deliver the Tradeable Warrants in the DTC book-entry settlement system in accordance with written instructions delivered to the Warrant Agent by the Company. Upon the initial issuance of the Non-tradeable Warrants, the Warrant Agent shall issue the Non-tradeable Global Certificate and deliver the Non-tradeable Warrants in the Warrant Agent’s book-entry settlement system in accordance with the Company’s written instructions delivered to the Warrant Agent. Ownership of security entitlements in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained, (i) in the case of Tradeable Warrants (A) by DTC and (B) by institutions that have accounts with DTC (each, a “Participant”), and (ii) in the case of Non-tradeable Warrants, by the Warrant Agent.

2.2.3. Beneficial Owner; Holder. Prior to due presentment for registration of transfer of any Warrant, the Company and the Warrant Agent may deem and treat the Person in whose name that Warrant shall be registered on the Warrant Register (the “Holder”) as the absolute owner of such Warrant for purposes of any exercise thereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Company, the Warrant Agent or any agent of the Company or the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC governing the exercise of the rights of a Holder of a beneficial interest in any Tradeable Warrant. The rights of beneficial owners in a Warrant evidenced by the Global Certificates shall be exercised by the Holder or a Participant through (i) in the case of a Tradeable Warrant, the DTC system, or (ii) in the case of a Non-tradeable Warrant, the Warrant Agent’s system, except to the extent set forth herein or in the Global Certificates.

2.2.4. Execution. The Warrant Certificates shall be executed on behalf of the Company by any authorized officer of the Company (an “Authorized Officer”), which need not be the same authorized signatory for all of the Warrant Certificates, either manually or by facsimile signature. The Warrant Certificates shall be countersigned by an authorized signatory of the Warrant Agent, which need not be the same signatory for all of the Warrant Certificates, and no Warrant Certificate shall be valid for any purpose unless so countersigned. In case any Authorized Officer of the Company that signed any of the Warrant Certificates ceases to be an Authorized Officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent,

issued and delivered with the same force and effect as though the Person who signed such Warrant Certificates had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any Person who, at the actual date of the execution of such Warrant Certificate, shall be an Authorized Officer of the Company authorized to sign such Warrant Certificate, although at the date of the execution of this Warrant Agreement any such Person was not such an Authorized Officer.

2.2.5. Registration of Transfer. At any time at or prior to the Expiration Date (as defined below), a transfer of any Warrants may be registered and any Warrant Certificate or Warrant Certificates may be split up, combined or exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants as the Warrant Certificate or Warrant Certificates surrendered. Any Holder desiring to register the transfer of Warrants or to split up, combine or exchange any Warrant Certificate shall make such request in writing delivered to the Warrant Agent, and shall surrender to the Warrant Agent the Warrant Certificate or Warrant Certificates evidencing the Warrants the transfer of which is to be registered or that is or are to be split up, combined or exchanged and, in the case of registration of transfer, shall provide a signature guarantee. Thereupon, the Warrant Agent shall countersign and deliver to the Person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested. The Company and the Warrant Agent may require payment, by the Holder requesting a registration of transfer of Warrants or a split-up, combination or exchange of a Warrant Certificate (but, for purposes of clarity, not upon the exercise of the Warrants and issuance of Warrant Shares to the Holder), of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with such registration of transfer, split-up, combination or exchange, together with reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto.

2.2.6. Loss, Theft and Mutilation of Warrant Certificates. Upon receipt by the Company and the Warrant Agent of evidence reasonably satisfactory to them of the loss, theft, destruction or mutilation of a Warrant Certificate, and, in case of loss, theft or destruction, of indemnity or security in customary form and amount, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Warrant Agent shall, on behalf of the Company, countersign and deliver a new Warrant Certificate of like tenor to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated. The Warrant Agent may charge the Holder an administrative fee for processing the replacement of lost Warrant Certificates, which shall be charged only once in instances where a single surety bond obtained covers multiple certificates. The Warrant Agent may receive compensation from the surety companies or surety agents for administrative services provided to them.

2.2.7. Proxies. The Holder of a Warrant may grant proxies or otherwise authorize any Person, including the Participants and beneficial holders that may own interests through the Participants in the case of Tradeable Warrants, to take any action that a Holder is entitled to take under this Agreement or the Warrants; provided, however, that at all times that Tradeable Warrants are evidenced by a Tradeable Global Certificate, exercise of those Tradeable Warrants shall be effected on their behalf by Participants through DTC in accordance the procedures administered by DTC.

3. Terms and Exercise of Warrants.

3.1. Exercise Price. Each Warrant shall entitle the Holder, subject to the provisions of the applicable Warrant Certificate and of this Warrant Agreement, to purchase from the Company the number of Shares of Common Stock stated therein, at the price of (i) \$7.35 per whole Share (120% of the assumed per-Unit public offering price of \$6.125, which is the midpoint of the Price Range) upon exercise of a Tradeable Warrant, and (ii) \$7.656 per whole Share (125% of the assumed per-Unit public offering price of \$6.125) upon exercise of a Non-tradeable Warrant, subject in both cases to the subsequent adjustments provided in Section 4 hereof. The term “Exercise Price” as used in this Warrant Agreement refers to the price per Share at which Shares of Common Stock may be purchased at the time a Warrant is exercised.

3.2. Duration of Warrants. Warrants may be exercised only during the period (“Exercise Period”) commencing on the Issuance Date and terminating at 5:00 P.M., New York City Time (the “close of business”) on [●], 2027 (“Expiration Date”). Each Warrant not exercised on or before the Expiration Date shall become void, and all rights thereunder and all rights in respect thereof under this Warrant Agreement shall cease at the close of business on the Expiration Date.

3.3. Exercise of Warrants.

3.3.1. Exercise and Payment. (a) Subject to the provisions of this Warrant Agreement, a Holder (or a Participant or a designee of a Participant acting on behalf of a Holder) may exercise Warrants by delivering to the Warrant Agent, not later than 5:00 P.M., New York City Time, on any Business Day during the Exercise Period an election to purchase the Warrant Shares underlying the Warrants to be exercised (i) in the form included in Exhibit C to this Warrant Agreement or (ii) in the case of a Tradeable Warrant, via an electronic warrant exercise through the DTC system (each, an “Election to Purchase”). No later than one (1) Trading Day following delivery of an Election to Purchase, the Holder (or a Participant acting on behalf of a Holder in accordance with DTC procedures) shall: (i) (A) surrender the Warrant Certificate evidencing the Warrants to the Warrant Agent at its office designated for such purpose or (B) deliver the Warrants to an account of the Warrant Agent at DTC designated for such purpose in writing by the Warrant Agent to DTC from time to time, and (ii) deliver to the Company the Exercise Price for each Warrant to be exercised, in lawful money of the United States of America by certified or official bank check payable to the Company or bank wire transfer in immediately available funds to:

Receiving Bank:

Account Name:

Address:

Any Person so designated by the Holder (or a Participant or designee of a Participant on behalf of a Holder) to receive Warrant Shares shall be deemed to have become holder of record of such Warrant Shares as of the time that an appropriately completed and duly signed Election to Purchase has been delivered to the Warrant Agent, provided that the Holder (or Participant on behalf of the Holder) makes delivery of the deliverables referenced in the immediately preceding sentence by the date that is one (1) Trading Day after the delivery of the Election to Purchase. If the Holder (or Participant on behalf of the Holder) fails to make delivery of such deliverables on or prior to the Trading Day following delivery of the Election to Purchase, such Election to Purchase shall be void *ab initio*.

(b) If any of (i) the Warrants, (ii) the Election to Purchase, or (iii) the Exercise Price therefor, is received by the Warrant Agent on any date after 5:00 P.M., New York City Time, or on a date that is not a Trading Day, the Warrants with respect thereto will be deemed to have been received and exercised on the Trading Day next succeeding such date. “Business Day” means a day other than a Saturday or Sunday on which commercial Banks in New York City 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 generally are open for use by customers on such day. The “Exercise Date” will be the date on which the materials in the foregoing sentence are received by the Warrant Agent (if by 5:00 P.M., New York City time), or the following Trading Day (if after 5:00 P.M., New York City time), regardless of any earlier date written on the materials. If the Warrants are received or deemed to be received after the Expiration Date, the exercise thereof will be null and void and any funds delivered to the Company will be returned to the Holder or Participant, as the case may be, as soon as practicable. In no event will interest accrue on any funds deposited with the Company in respect of an exercise or attempted exercise of Warrants.

(c) If less than all the Warrants evidenced by a surrendered Warrant Certificate are exercised, the Warrant Agent shall split up the surrendered Warrant Certificate and return to the Holder a Warrant Certificate evidencing the Warrants that were not exercised.

3.3.2. Issuance of Warrant Shares. (a) The Warrant Agent shall, by 11:00 a.m., New York City time, on the Trading Day following the Exercise Date of any Warrant, advise the Company, the transfer agent and registrar for the Company's Common Stock, in respect of (i) the number of Warrant Shares indicated on the Election to Purchase as issuable upon such exercise with respect to such exercised Warrants, (ii) the instructions of the Holder or Participant, as the case may be, provided to the Warrant Agent with respect to the delivery of the Warrant Shares and the number of Warrants that remain outstanding after such exercise, and (iii) such other information as the Company or such transfer agent and registrar shall reasonably request.

(b) The Company shall, by no later than 5:00 P.M., New York City Time, on the third Trading Day following the Exercise Date of any Tradeable Warrant and the clearance of the funds in payment of the Exercise Price (such date and time, the "Delivery Time"), cause its registrar to electronically transmit the Warrant Shares issuable upon that exercise to DTC by crediting the account of DTC or of the Participant, as the case may be, through its Deposit Withdrawal Agent Commission system.

3.3.3. Valid Issuance. All Warrant Shares issued by the Company upon the proper exercise of a Warrant in conformity with this Warrant Agreement shall be duly authorized, validly issued, fully paid and non-assessable.

3.3.4. No Fractional Exercise. No fractional Warrant Shares will be issued upon the exercise of the Warrant. If, by reason of any adjustment made pursuant to Section 4, a Holder would be entitled, upon the exercise of such Warrant, to receive a fractional interest in a share, the Company shall, upon such exercise, 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.

3.3.5. No Transfer Taxes. 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, the Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached to the Warrant 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.

3.3.6. Date of Issuance. The Company will treat an exercising Holder as a beneficial owner of the Warrant Shares as of the Exercise Date, except that, if the Exercise Date is a date when the stock transfer books of the Company are closed, such Person shall be deemed to have become the holder of such shares at the open of business on the next succeeding date on which the stock transfer books are open.

3.3.7. Restrictive Legend Events; Cashless Exercise Under Certain Circumstances (a) The Company shall use its reasonable best efforts to maintain the effectiveness of the Registration Statement and the current status of the prospectus included therein or to file and maintain the effectiveness of another registration statement and another current prospectus covering the Tradeable Warrants and the Tradeable Warrant Shares at any time that the Tradeable Warrants are exercisable. The Company shall provide to the Warrant Agent and each Holder prompt written notice of any time that the Company is unable to deliver the Tradeable Warrant Shares via DTC transfer or otherwise without restrictive legend because: (i) the Commission has issued a stop order with respect to the Registration Statement, (ii) the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, (iii) the Company has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, (iv) the prospectus contained in the Registration Statement is not available for the issuance of the Tradeable Warrant Shares to the Holder, or (v) otherwise (each a "Restrictive Legend Event"). To the extent that the Tradeable Warrants cannot be exercised as a result of a Restrictive Legend Event or a Restrictive Legend Event occurs after a Holder has exercised Tradeable Warrants in accordance with the terms of the Tradeable Warrants but prior to the delivery of the Tradeable Warrant Shares, the Company shall, at the election of the Holder, which shall be given within five (5) days of receipt of such notice of the Restrictive Legend Event, either (i) rescind the previously submitted Election to Purchase and the Company shall return all consideration paid by registered holder for such shares upon such rescission, or (ii) treat the attempted exercise as a cashless exercise as described in paragraph (b) below and refund the cash portion of the exercise price to the Holder.

(b) If a Restrictive Legend Event has occurred, the Tradeable Warrant shall only be exercisable on a cashless basis. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments or net cash settlement to the Holder in lieu of delivery of the Tradeable Warrant Shares. Upon a "cashless exercise", the Holder shall be entitled to receive the number of Tradeable 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 Exercise Date if the Holder's Election to Purchase is (1) both executed and delivered pursuant to Section 3.37(a) hereof on a day that is not a Trading Day, or (2) both executed and delivered pursuant to Section 3.37(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(68) 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 Election to Purchase, or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Election to Purchase if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 3.37(a) hereof, or (iii) the VWAP on the date of the applicable Election to Purchase if the date of such Notice of Exercise is a Trading Day and such Election to Purchase is both executed and delivered pursuant to Section 3.37(a) hereof after the close of "regular trading hours" on such Trading Day;
- (B) = the Exercise Price of the Tradeable Warrant, as adjusted as set forth herein; and
- (X) = the number of Tradeable Warrant Shares that would be issuable upon exercise of the Tradeable Warrant in accordance with the terms of the Tradeable Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If the Tradeable Warrant Shares are issued in such a cashless exercise, the Company acknowledges and agrees that, in accordance with Section 3(a)(9) of the Securities Act, the Tradeable Warrant Shares shall take on the registered characteristics of the Tradeable Warrants being exercised and the Company agrees not to take any position contrary thereto. Upon receipt of an Election to Purchase for a cashless exercise, the Warrant Agent will promptly deliver a copy of the Election to Purchase to the Company to confirm the number of Tradeable Warrant Shares issuable in connection with the cashless exercise. The Company shall calculate and transmit to the Warrant Agent in a written notice, and the Warrant Agent shall have no duty, responsibility or obligation under this section to calculate, the number of Tradeable Warrant Shares issuable in connection with any cashless exercise. The Warrant Agent shall be entitled to rely conclusively on any such written notice provided by the Company, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with such written instructions or pursuant to this Warrant Agreement.

3.3.8. Restrictive Legend of Non-tradeable Warrants. No registration is required for the offer and sale of the Non-tradeable Warrants by the Company to the Holders. The Non-tradeable Warrants may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Non-tradeable Warrants other than pursuant to an effective registration statement or Rule 144 promulgated under the Securities Act, the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Non-tradeable Warrant under the Securities Act. Certificates evidencing the

Non-tradeable Warrants shall not contain any legend: (i) while a registration statement covering the resale of such security is effective under the Securities Act; (ii) following any sale of such Non-tradeable Warrants pursuant to Rule 144 (assuming cashless exercise of the Non-tradeable Warrants); (iii) if such Non-tradeable Warrants are eligible for sale under Rule 144 (assuming cashless exercise of the Non-tradeable Warrants); or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Warrant Agent or the Holder promptly if required by the Warrant Agent to effect the removal of the legend hereunder, or if requested by a Holder, respectively. If all or any portion of a Non-tradeable Warrant is exercised at a time when a legend is not required pursuant to clauses (i)-(iv) above, then such Non-tradeable Warrants shall be issued free of all legends.

3.3.9. Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the number of Warrant Shares issuable in connection with any exercise, the Company shall promptly deliver to the Holder the number of Warrant Shares that are not disputed.

3.3.10. Beneficial Ownership Limitation. A Holder shall not have the right to exercise any Warrants to the extent that after giving effect to the issuance of Warrant Shares after exercise as set forth on the applicable Election to Purchase, such Holder or a Person holding through such Holder (together with such Holder's or Person's Affiliates (as defined in Rule 405 under the Securities Act), and any other Persons acting as a group together with that Holder or person or any of that Holder's or person's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of 9.99% ("Beneficial Ownership Limitation") of the Company's Common Stock. 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 Warrant Shares that would be owned by that Person issuable upon exercise of the Warrants with respect to which such determination is being made, but shall exclude the number of shares of Common Stock (a) which would be issuable upon exercise of the remaining, non-exercised Warrants beneficially owned by that Holder or any of its Affiliates or Attribution Parties and (b) which would be issuable upon 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 3.3.10, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rule and regulations promulgated thereunder (the "Exchange Act"), it being acknowledged by the Holder that neither the Warrant Agent nor the Company is representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder or beneficial owner is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 3.3.10 applies, the determination of whether a Warrant is exercisable and of which portion of the Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of an Election to Purchase shall be deemed to be the Holder's determination of whether such Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and which portion of the Warrant is exercisable, and neither the Warrant Agent nor the Company shall have any obligation to verify or confirm the accuracy of such determination and neither of them shall have any liability for any error made by the Holder or any other Person. 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 3.3.10, in determining the number of outstanding shares of Common Stock, a Holder or other Person 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 Securities and Exchange 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 Company's transfer agent setting forth the number of shares of Common Stock outstanding. For any reason at any time, upon the written or oral request of a Person that represents that it is or is acting on behalf of a Holder, the Company shall, within one (1) Trading Day, confirm orally or in writing or by e-mail to that Person 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 the 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 the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. Upon delivery of a written notice to the Company, the Holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 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 3.3.10 shall continue to apply, as specified in such notice, provided that 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 and any such increase or decrease will apply only to the Holder and its Affiliates and Attribution Parties and not to any other holder of Warrants. The provisions of this Section 3.3.10 shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 3.3.10 to correct this subsection (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained. The limitations contained in this paragraph shall apply to a successor holder of the Warrant.

4. Adjustments.

4.1. Adjustment upon Subdivisions or Combinations. If the Company, at any time while a 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 the 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 4.1 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. The Company shall promptly notify Warrant Agent of any such adjustment and give specific instructions to Warrant Agent with respect to any adjustments to the warrant register.

4.2. Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 4.1 above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to 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 such Holder's 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).

4.3. Pro Rata Distributions. During such time as a Holder's 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 such Holder's 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 the 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).

4.4. Reclassification, Consolidation, Purchase, Combination, Sale or Conveyance. If, at any time while the Warrants are outstanding, (a) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (b) the Company, 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, (c) 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, (d) 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, or (e) 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 or scheme of arrangement) with another Person or group of Persons, whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of a Warrant, each 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 3.3.10 on the exercise of the Warrants), 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 each Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 3.3.10 on the exercise of the Warrants). 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 that such Holder receives upon any exercise of each 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 Agreement in accordance with the provisions of this Section 4.4 pursuant to written agreements in form and substance reasonably satisfactory to the Holders of a majority in interest of the Warrants then outstanding and approved by such Holder or Holders (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option and written request of such Holder, deliver to such Holder in exchange for the applicable Warrants created by this Warrant Agreement a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to the Warrants which are 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 the 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 the Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holders of a majority in interest of the Warrants then outstanding. Upon the occurrence of any such Fundamental Transaction the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant Agreement and the Warrants referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant Agreement and the Warrants with the same effect as if such Successor Entity had been named as the Company herein and therein. The Company shall instruct the Warrant Agent in writing to mail by first class mail, postage prepaid, to each Holder, written notice of the execution of any such amendment, supplement or agreement with the Successor Entity. Any supplemented or amended agreement entered into by the successor corporation or transferee shall provide for adjustments, which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Section 4.4. The Warrant Agent shall have no duty, responsibility or obligation to determine the correctness of any provisions contained in such agreement or such notice, including but not limited to any provisions relating either to the kind or amount of securities or other property receivable upon exercise of Warrants or with respect to the method employed and provided therein for any adjustments, and shall be entitled to rely conclusively for all purposes upon the provisions contained in any such agreement. The provisions of this Section 4.4 shall similarly apply to successive reclassifications, changes, consolidations, mergers, sales and conveyances of the kind described above.

4.5. Calculations. All calculations under this Section 4 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 4, 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.

4.6. Notices of Changes in Warrant. Upon every adjustment of the Exercise Price or the number of Warrant Shares issuable upon exercise of a Warrant, the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of Warrant Shares purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Upon the occurrence of any event specified in Sections 4.1, 4.2, 4.3 or 4.4, then, in any such event, the Company shall give written notice to each Holder, at the last address set forth for such holder in the Warrant Register, as of the record date or the effective date of the event. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event. The Warrant Agent shall be entitled to rely conclusively on, and shall be fully protected in relying on, any certificate, notice or instructions provided by the Company with respect to any adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant, or any related matter, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with any such certificate, notice or instructions or pursuant to this Warrant Agreement. The Warrant Agent shall not be deemed to have knowledge of any such adjustment unless and until it shall have received written notice thereof from the Company.

5. Restrictive Legends; Fractional Warrants. In the event that a Warrant Certificate surrendered for transfer bears a restrictive legend, the Warrant Agent shall not register that transfer until the Warrant Agent has received an opinion of counsel for the Company stating that such transfer may be made and indicating whether the Warrants must also bear a restrictive legend upon that transfer. The Warrant Agent shall not be required to effect any registration of transfer or exchange which will result in the transfer of or delivery of a Warrant Certificate for a fraction of a Warrant.

6. Other Provisions Relating to Rights of Holders of Warrants.

6.1. No Rights as Stockholder. Except as otherwise specifically provided herein, a Holder, solely in its capacity as a holder of Warrants, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant Agreement be construed to confer upon a Holder, solely in its capacity as the registered holder of Warrants, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of share capital, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights or rights to participate in new issues of shares, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of Warrants.

6.2. Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants issued pursuant to this Warrant Agreement.

7. Concerning the Warrant Agent and Other Matters.

7.1. Any instructions given to the Warrant Agent orally, as permitted by any provision of this Warrant Agreement, shall be confirmed in writing by the Company as soon as practicable. The Warrant Agent shall not be liable or responsible and shall be fully authorized and protected for acting, or failing to act, in accordance with any oral instructions which do not conform with the written confirmation received in accordance with this Section 7.1.

7.2. (a) Whether or not any Warrants are exercised, for the Warrant Agent's services as agent for the Company hereunder, the Company shall pay to the Warrant Agent such fees as may be separately agreed between the Company and Warrant Agent and the Warrant Agent's out of pocket expenses in connection with this Warrant Agreement, including, without limitation, the fees and expenses of the Warrant Agent's counsel. While the Warrant Agent endeavors to maintain out-of-pocket charges (both internal and external) at competitive rates, these charges may not reflect actual out-of-pocket costs, and may include handling charges to cover internal processing and use of the Warrant Agent's billing systems.

(b) All amounts owed by the Company to the Warrant Agent under this Warrant Agreement are due within 30 days of the invoice date. Delinquent payments are subject to a late payment charge of one and one-half percent (1.5%) per month commencing 45 days from the invoice date. The Company agrees to reimburse the Warrant Agent for any attorney's fees and any other costs associated with collecting delinquent payments.

(c) No provision of this Warrant Agreement shall require Warrant Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties under this Warrant Agreement or in the exercise of its rights.

7.3. As agent for the Company hereunder the Warrant Agent: (a) shall have no duties or obligations other than those specifically set forth herein or as may subsequently be agreed to in writing by the Warrant Agent and the Company; (b) shall be regarded as making no representations and having no responsibilities as to the validity, sufficiency, value, or genuineness of the Warrants or any Warrant Shares; (c) shall not be obligated to take any legal action hereunder; if, however, the Warrant Agent determines to take any legal action hereunder, and where the taking of such action might, in its judgment, subject or expose it to any expense or liability it shall not be required to act unless it has been furnished with an indemnity reasonably satisfactory to it; (e) may rely on and shall be fully authorized and protected in acting or failing to act upon any certificate, instrument, opinion, notice, letter, telegram, telex, facsimile transmission or other document or security delivered to the Warrant Agent and believed by it to be genuine and to have been signed by the proper party or parties; (f) shall not be liable or responsible for any recital or statement contained in the Registration Statement or any other documents relating thereto; (g) shall not be liable or responsible for any failure on the part of the Company to comply with any of its covenants and obligations relating to the Warrants, including without limitation obligations under applicable securities laws; (h) may rely on and shall be fully authorized and protected in acting or failing to act upon the written, telephonic or oral instructions with respect to any matter relating to its duties as Warrant Agent covered by this Warrant Agreement (or supplementing or qualifying any such actions) of officers of the Company, and is hereby authorized and directed to accept instructions with respect to the performance of its duties hereunder from the Company or counsel to the Company, and may apply to the Company, for advice or instructions in connection with the Warrant Agent's duties hereunder, and the Warrant Agent shall not be liable for any delay in acting while waiting for those instructions; any applications by the Warrant Agent for written instructions from the Company may, at the option of the Agent, set forth in writing any action proposed to be taken or omitted by the Warrant Agent under this Warrant Agreement and the date on or after which such action shall be taken or such omission shall be effective; the Warrant Agent shall not be liable for any action taken by, or omission of, the Warrant Agent in accordance with a proposal included in such application on or after the date specified in such application (which date shall not be less than five Business Days after the date such application is sent to the Company, unless the Company shall have consented in writing to any earlier date) unless prior to taking any such action, the Warrant Agent shall have received written instructions in response to such application specifying the action to be taken or omitted; (i) may consult with counsel satisfactory to the Warrant Agent, including its in-house counsel, and the advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered, or omitted by it hereunder in good faith and in accordance with the advice of such counsel; (j) may perform any of its duties hereunder either directly or by or through nominees, correspondents, designees, or subagents, and it shall not be liable or responsible for any misconduct or negligence on the part of any nominee, correspondent, designee, or subagent appointed with reasonable care by it in connection with this Warrant Agreement; (k) is not authorized, and shall have no obligation, to pay any brokers, dealers, or soliciting fees to any Person; and (l) shall not be required hereunder to comply with the laws or regulations of any country other than the United States of America or any political subdivision thereof.

7.4. (a) In the absence of gross negligence or willful or illegal misconduct on its part, the Warrant Agent shall not be liable for any action taken, suffered, or omitted by it or for any error of judgment made by it in the performance of its duties under this Warrant Agreement. Anything in this Warrant Agreement to the contrary notwithstanding, in no event shall Warrant Agent be liable for special, indirect, incidental, consequential or punitive losses or damages of any kind whatsoever (including but not limited to lost profits), even if the Warrant Agent has been advised of the possibility of such losses or damages and regardless of the form of action. Any liability of the Warrant Agent will be limited in the aggregate to the amount of fees paid by the Company hereunder. The Warrant Agent shall not be liable for any failures, delays or losses, arising directly or indirectly out of conditions beyond its reasonable control including, but not limited to, acts of government, exchange or market ruling, suspension of trading, work stoppages or labor disputes, fires, civil disobedience, riots, rebellions, storms, electrical or mechanical failure, computer hardware or software failure, communications facilities failures including telephone failure, war, terrorism, insurrection, earthquakes, floods, acts of God or similar occurrences. (b) In the event any question or dispute arises with respect to the proper interpretation of the Warrants or the Warrant Agent's duties under this Warrant Agreement or the rights of the Company or of any Holder, the Warrant Agent shall not be required to act and shall not be held liable or responsible for its refusal to act until the question or dispute has been judicially settled (and, if appropriate, it may file a suit in interpleader or for a declaratory judgment for such purpose) by final judgment rendered by a court of competent jurisdiction, binding on all Persons interested in the matter which is no longer subject to review or appeal, or settled by a written document in form and substance satisfactory to Warrant Agent and executed by the Company and each such Holder. In addition, the Warrant Agent may require for such purpose, but shall not be obligated to require, the execution of such written settlement by all the Holders and all other Persons that may have an interest in the settlement.

7.5. The Company covenants to indemnify the Warrant Agent and hold it harmless from and against any loss, liability, claim or expense ("Loss") arising out of or in connection with the Warrant Agent's duties under this Warrant Agreement, including the costs and expenses of defending itself against any Loss, unless such Loss shall have been determined by a court of competent jurisdiction to be a result of the Warrant Agent's gross negligence or willful misconduct.

7.6. Unless terminated earlier by the parties hereto, this Agreement shall terminate 90 days after the earlier of the Expiration Date and the date on which no Warrants remain outstanding (the "Termination Date"). On the Business Day following the Termination Date, the Agent shall deliver to the Company any entitlements, if any, held by the Warrant Agent under this Warrant Agreement. The Agent's right to be reimbursed for fees, charges and out-of-pocket expenses as provided in this Section 7 shall survive the termination of this Warrant Agreement.

7.7. If any provision of this Warrant Agreement shall be held illegal, invalid, or unenforceable by any court, this Warrant Agreement shall be construed and enforced as if such provision had not been contained herein and shall be deemed an Agreement among the parties to it to the full extent permitted by applicable law.

7.8. The Company represents and warrants that: (a) it is duly incorporated and validly existing under the laws of its jurisdiction of incorporation; (b) the offer and sale of the Warrants and the execution, delivery and performance of all transactions contemplated thereby (including this Warrant Agreement) have been duly authorized by all necessary corporate action and will not result in a breach of or constitute a default under the articles of association, bylaws or any similar document of the Company or any indenture, agreement or instrument to which it is a party or is bound; (c) this Warrant Agreement has been duly executed and delivered by the Company and constitutes the legal, valid, binding and enforceable obligation of the Company; (d) the Warrants will comply in all material respects with all applicable requirements of law; and (e) to the best

of its knowledge, there is no litigation pending or threatened as of the date hereof in connection with the offering of the Warrants.

7.9. In the event of inconsistency between this Warrant Agreement and the descriptions in the Registration Statement, as they may from time to time be amended, the terms of this Warrant Agreement shall control.

7.10. Set forth in Exhibit C hereto is a list of the names and specimen signatures of the Persons authorized to act for the Company under this Warrant Agreement (the “Authorized Representatives”). The Company shall, from time to time, certify to you the names and signatures of any other Persons authorized to act for the Company under this Warrant Agreement.

7.11. Except as expressly set forth elsewhere in this Warrant Agreement, all notices, instructions and communications under this Agreement shall be in writing, shall be effective upon receipt and shall be addressed, if to the Company, to its address set forth beneath its signature to this Agreement, or, if to the Warrant Agent, to VStock Transfer, LLC 18 Lafayette Place, Woodmere, New York 11598, or to such other address of which a party hereto has notified the other party.

7.12. (a) This Warrant Agreement shall be governed by and construed in accordance with the laws of the State of New York. All actions and proceedings relating to or arising from, directly or indirectly, this Warrant Agreement may be litigated in courts located within the Borough of Manhattan in the City and State of New York. The Company hereby submits to the personal jurisdiction of such courts and consents that any service of process may be made by certified or registered mail, return receipt requested, directed to the Company at its address last specified for notices hereunder. Each of the parties hereto hereby waives the right to a trial by jury in any action or proceeding arising out of or relating to this Warrant Agreement.

(b) This Warrant Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto. This Warrant Agreement may not be assigned, or otherwise transferred, in whole or in part, by either party without the prior written consent of the other party, which the other party will not unreasonably withhold, condition or delay; except that (i) consent is not required for an assignment or delegation of duties by Warrant Agent to any affiliate of Warrant Agent and (ii) any reorganization, merger, consolidation, sale of assets or other form of business combination by Warrant Agent or the Company shall not be deemed to constitute an assignment of this Warrant Agreement.

(c) No provision of this Warrant Agreement may be amended, modified or waived, except in a written document signed by both parties. The Company and the Warrant Agent may amend or supplement this Warrant Agreement without the consent of any Holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained herein or adding or changing any other provisions with respect to matters or questions arising under this Agreement as the parties may deem necessary or desirable and that the parties determine, in good faith, shall not adversely affect the interest of the Holders. All other amendments and supplements shall require the vote or written consent of Holders of at least 50.1% of the then outstanding Warrants, provided that adjustments may be made to the Warrant terms and rights in accordance with Section 4 without the consent of the Holders unless otherwise stated herein.

7.13. Payment of Taxes. The Company will from time to time promptly pay all taxes and charges that may be imposed upon the Company or the Warrant Agent in respect of the issuance or delivery of Warrant Shares upon the exercise of Warrants, but the Company may require the Holders to pay any transfer taxes in respect of the Warrants or such shares. The Warrant Agent may refrain from registering any transfer of Warrants or any delivery of any Warrant Shares unless or until the Persons requesting the registration or issuance shall have paid to the Warrant Agent for the account of the Company the amount of such tax or charge, if any, or shall have established to the reasonable satisfaction of the Company and the Warrant Agent that such tax or charge, if any, has been paid.

7.14. Resignation of Warrant Agent.

7.14.1. Appointment of Successor Warrant Agent. The Warrant Agent, or any successor to it hereafter appointed, may resign its duties and be discharged from all further duties and liabilities hereunder after giving thirty (30) days’ notice in writing to the Company, or such shorter period of time agreed to by the Company. The Company may terminate the services of the Warrant Agent, or any successor Warrant Agent, after giving thirty (30) days’ notice in writing to the Warrant Agent or successor Warrant Agent, or such shorter period of time as agreed. If the office of the Warrant Agent becomes vacant by resignation, termination or incapacity to act or otherwise, the Company shall appoint in writing a successor Warrant Agent in place of the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after it has been notified in writing of such resignation or incapacity by the Warrant Agent, then the Warrant Agent or any Holder may apply to any court of competent jurisdiction for the appointment of a successor Warrant Agent at the Company’s cost. Pending appointment of a successor to such Warrant Agent, either by the Company or by such a court, the duties of the Warrant Agent shall be carried out by the Company. Any successor Warrant Agent (but not including the initial Warrant Agent), whether appointed by the Company or by such court, shall be a Person organized and existing under the laws of any state of the United States of America, in good standing, and authorized under such laws to exercise corporate trust powers and subject to supervision or examination by federal or state authority. After appointment, any successor Warrant Agent shall be vested with all the authority, powers, rights, immunities, duties, and obligations of its predecessor Warrant Agent with like effect as if originally named as Warrant Agent hereunder, without any further act or deed, and except for executing and delivering documents as provided in the sentence that follows, the predecessor Warrant Agent shall have no further duties, obligations, responsibilities or liabilities hereunder, but shall be entitled to all rights that survive the termination of this Warrant Agreement and the resignation or removal of the Warrant Agent, including but not limited to its right to indemnity hereunder. If for any reason it becomes necessary or appropriate or at the request of the Company, the predecessor Warrant Agent shall execute and deliver, at the expense of the Company, an instrument transferring to such successor Warrant Agent all the authority, powers, and rights of such predecessor Warrant Agent hereunder; and upon request of any successor Warrant Agent the Company shall make, execute, acknowledge, and deliver any and all instruments in writing for more fully and effectually vesting in and confirming to such successor Warrant Agent all such authority, powers, rights, immunities, duties, and obligations.

7.14.2. Notice of Successor Warrant Agent. In the event a successor Warrant Agent shall be appointed, the Company shall give notice thereof to the predecessor Warrant Agent and the transfer agent for the Common Stock not later than the effective date of any such appointment.

7.14.3. Merger or Consolidation of Warrant Agent. Any Person into which the Warrant Agent may be merged or converted or with which it may be consolidated or any Person resulting from any merger, conversion or consolidation to which the Warrant Agent shall be a party or any Person succeeding to the shareowner services business of the Warrant Agent or any successor Warrant Agent shall be the successor Warrant Agent under this Warrant Agreement, without any further act or deed.

8. Miscellaneous Provisions.

8.1. Persons Having Rights under this Warrant Agreement. Nothing in this Warrant Agreement expressed and nothing that may be implied from any of the provisions hereof is intended, or shall be construed, to confer upon, or give to, any Person or corporation other than the parties hereto and the Holders any right, remedy, or claim under or by reason of this Warrant Agreement or of any covenant, condition, stipulation, promise, or agreement hereof.

8.2. Examination of the Warrant Agreement. A copy of this Warrant Agreement shall be available at all reasonable times at the office of the Warrant Agent designated for such purpose for inspection by any Holder. Prior to such inspection, the Warrant Agent may require any such holder to provide reasonable evidence of its interest in the Warrants.

8.3. Counterparts. This Warrant Agreement may be executed in any number of original, facsimile or electronic counterparts and each of such counterparts shall for all

purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

8.4. Effect of Headings. The Section headings herein are for convenience only and are not part of this Warrant Agreement and shall not affect the interpretation thereof.

9. Certain Definitions. As used herein, the following terms shall have the following meanings:

(a) “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.

(b) “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 listed or quoted on 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 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.

(c) “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

(d) “Board of Directors” means the board of directors of the Company.

(e) “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.

(f) “Trading Day” means a day on which the Common Stock is traded on a Trading Market.

(g) “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: NYSE MKT, 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).

(h) “VWAP” means, for any date, the price determined by the first of the following clauses that applies: (i) 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)); (ii) 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, ; (iii) if the Common Stock are not then listed or quoted for trading on the 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 (iv) 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 Company, the fees and expenses of which shall be paid by the Company.

[Signature Page to Follow]

IN WITNESS WHEREOF, this Warrant Agent Agreement has been duly executed by the parties hereto as of the day and year first above written.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: President & CEO

VSTOCK TRANSFER, LLC

By: _____
Name: _____
Title: _____

EXHIBIT A

[TO BE INCLUDED IN THE TRADEABLE GLOBAL CERTIFICATE]

UNLESS THIS CERTIFICATE IS PRESENTED BY AN AUTHORIZED REPRESENTATIVE OF THE DEPOSITORY TRUST COMPANY, A NEW YORK CORPORATION (“DTC”), TO ISSUER OR ITS AGENT FOR REGISTRATION OF TRANSFER, EXCHANGE, OR PAYMENT, AND ANY CERTIFICATE ISSUED IS REGISTERED IN THE NAME OF CEDE & CO. OR IN SUCH OTHER NAME AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF DTC (AND ANY PAYMENT IS MADE TO CEDE & CO. OR TO SUCH OTHER ENTITY AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF DTC), ANY TRANSFER, PLEDGE, OR OTHER USE HEREOF FOR VALUE OR OTHERWISE BY OR TO ANY PERSON IS WRONGFUL INASMUCH AS THE REGISTERED OWNER HEREOF, CEDE & CO., HAS AN INTEREST HEREIN.

BIOAFFINITY TECHNOLOGIES, INC.
WARRANT CERTIFICATE
NOT EXERCISABLE AFTER [●], 2027

This certifies that the Person whose name and address appears below, or registered assigns, is the registered owner of the number of Warrants set forth below. Each

Warrant entitles its registered holder to purchase from bioAffinity Technologies, Inc., a company incorporated under the laws of the State of Delaware (the “**Company**”), at any time prior to 5:00 P.M. (Eastern Standard Time) on [●], 2027, one share of common stock, par value \$0.007 per share, of the Company (each, a “**Warrant Share**” and collectively, the “**Warrant Shares**”), at an exercise price of \$7.35 per share, subject to possible adjustments as provided in the Warrant Agreement (as defined below).

This Warrant Certificate, with or without other Warrant Certificates, upon surrender at the designated office of the Warrant Agent, may be exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants as the Warrant Certificate or Warrant Certificates surrendered. A transfer of the Warrants evidenced hereby may be registered upon surrender of this Warrant Certificate at the designated office of the Warrant Agent by the registered holder in person or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer, a signature guarantee, and such other and further documentation as the Warrant Agent may reasonably request and duly stamped as may be required by the laws of the State of New York and of the United States of America.

The terms and conditions of the Warrants and the rights and obligations of the holder of this Warrant Certificate are set forth in the Warrant Agent Agreement dated as of [●], 2022 (the “**Warrant Agreement**”) between the Company and VStock Transfer, LLC (the “**Warrant Agent**”). A copy of the Warrant Agreement is available for inspection during business hours at the office of the Warrant Agent.

This Warrant Certificate shall not be valid or obligatory for any purpose until it shall have been countersigned by an authorized signatory of the Warrant Agent.

WITNESS the facsimile signature of a proper officer of the Company.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: President & CEO

Dated: _____

Countersigned:

VSTOCK TRANSFER, LLC

By: _____
Name: _____
Title: _____

PLEASE DETACH HERE

Certificate No.: _____ Number of Warrants: _____

WARRANT CUSIP NO.: _09076W 117

BIOAFFINITY TECHNOLOGIES, INC.

EXHIBIT B

[TO BE INCLUDED IN THE NON-TRADEABLE GLOBAL CERTIFICATE]

BIOAFFINITY TECHNOLOGIES, INC.
WARRANT CERTIFICATE
NOT EXERCISABLE AFTER [●], 2027

This certifies that the Person whose name and address appears below, or registered assigns, is the registered owner of the number of Warrants set forth below. Each Warrant entitles its registered holder to purchase from bioAffinity Technologies, Inc., a company incorporated under the laws of the State of Delaware (the “**Company**”), at any time prior to 5:00 P.M. (Eastern Standard Time) on [●], 2027, one share of common stock, par value \$0.007 per share, of the Company (each, a “**Warrant Share**” and collectively, the “**Warrant Shares**”), at an exercise price of \$7.656 per share, subject to possible adjustments as provided in the Warrant Agreement (as defined below).

This Warrant Certificate, with or without other Warrant Certificates, upon surrender at the designated office of the Warrant Agent, may be exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants as the Warrant Certificate or Warrant Certificates surrendered. A transfer of the Warrants evidenced hereby may be registered upon surrender of this Warrant Certificate at the designated office of the Warrant Agent by the registered holder in person or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer, a signature guarantee, and such other and further documentation as the Warrant Agent may reasonably request and duly stamped as may be required by the laws of the State of New York and of the United States of America.

The terms and conditions of the Warrants and the rights and obligations of the holder of this Warrant Certificate are set forth in the Warrant Agent Agreement dated as of [●], 2022 (the “**Warrant Agreement**”) between the Company and VStock Transfer, LLC (the “**Warrant Agent**”). A copy of the Warrant Agreement is available for inspection during business hours at the office of the Warrant Agent.

This Warrant Certificate shall not be valid or obligatory for any purpose until it shall have been countersigned by an authorized signatory of the Warrant Agent.

WITNESS the facsimile signature of a proper officer of the Company.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____
Name: Maria Zannes
Title: President & CEO

Dated: _____

Countersigned:

VSTOCK TRANSFER, LLC

By: _____
Name: _____
Title: _____

PLEASE DETACH HERE

Certificate No.: _____ Number of Warrants: _____

BIOAFFINITY TECHNOLOGIES, INC.

EXHIBIT C

[Form of Election to Purchase]

(To Be Executed Upon Exercise Of Warrants not evidenced by a Global Certificate)

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:

(4) Accredited Investor. If the Warrant is being exercised via cash exercise, the undersigned is an “accredited investor” as defined in Regulation D promulgated under the Securities Act of 1933, as amended.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

EXHIBIT D

AUTHORIZED REPRESENTATIVES

Name	Title	Signature
Maria Zannes	President/Chief Executive Officer	_____



Dykema Gossett PLLC
 Weston Centre
 112 E. Pecan Street, Suite 1800
 San Antonio, TX 78205
 www.dykema.com
 Tel: (210) 554-5500
 Fax: (210) 226-8395

August 4, 2022

bioAffinity Technologies, Inc.
 22211 W Interstate 10, Suite 1206
 San Antonio, Texas 78257

Gentlepersons:

We have acted as legal counsel to bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), in connection with the filing by the Company of a Registration Statement (File No. 333-264463) on Form S-1, as amended by Amendments Nos. 1, 2, 3, 4, and 5 thereto (the “Registration Statement”) with the Securities and Exchange Commission (the “Commission”), including a related prospectus included in the Registration Statement (the “Prospectus”), covering an underwritten public offering of (i) up to 1,285,325 Units (the “Units”), each Unit consisting of (a) one share of common stock of the Company, par value \$0.007 per share (“Common Stock”), (b) one tradeable warrant (a “Tradeable Warrant”) exercisable for the purchase of one share of Common Stock, and (c) one non-tradeable warrant (a “Non-tradeable Warrant”; together with each Tradeable Warrant, the “Warrants”) exercisable for the purchase of one share of Common Stock; (ii) a warrant to purchase up to 25,707 shares of Common Stock (the “Representative’s Warrant”); (iii) a warrant to purchase up to 29,464 shares of Common Stock (the “Placement Agent’s Warrant”); and (iv) up to an additional 192,799 shares of Common Stock (the “Option Shares”), up to 192,799 Tradeable Warrants (the “Option Tradeable Warrants”), and up to 192,799 Non-tradeable Warrants (the “Option Non-tradeable Warrants,” and together with the Option Tradeable Warrants, the “Option Warrants”), any or all of which may be sold pursuant to the exercise of an over-allotment option granted to the underwriters.

In connection with this opinion, we have: (i) examined and relied upon (a) the Registration Statement and the Prospectus, (b) the Company’s Certificate of Incorporation, as amended, and Amended and Restated Bylaws, each as currently in effect, (c) the forms of the Company’s Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, filed as Exhibits 3.3 and 3.6 to the Registration Statement, respectively, each of which is to be in effect prior to the closing of the offering contemplated by the Registration Statement, and (d) originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below, including without limitation, the forms of Tradeable Warrant, Non-tradeable Warrant, Representative’s Warrant, Placement Agent’s Warrant and underwriting agreement most recently filed as exhibits to the Registration Statement; and (ii) assumed that (a) the Common Stock will be sold at a price established by the Board of Directors of the Company or a duly authorized committee thereof, and (b) the Amended and Restated Certificate of Incorporation referred to in clause (i)(c) is filed with the Secretary of State of the State of Delaware before issuance of the Common Stock.

We have assumed the genuineness of all signatures, and the legal capacity of all signatories, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials; and the due authorization, execution and delivery of all documents by all persons other than by the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

California | Illinois | Michigan | Minnesota | Texas | Washington, D.C. | Wisconsin

WallachBeth Capital, LLC
 August 4, 2022
 Page 2

Based upon the foregoing and subject to the qualifications and assumptions stated herein, we are of the opinion that:

- Units.** When the Registration Statement becomes effective and when the offering is completed as contemplated by the Registration Statement and Prospectus and according to the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the Units will be valid and legally binding obligations of the Company enforceable in accordance with their terms except: (a) as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting creditors’ rights generally and by general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law); (b) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (c) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.
- Common Stock.** When the Registration Statement becomes effective and when the Common Stock, included as part of the Units, and/or the Option Shares are issued and delivered against payment therefor as contemplated by the Registration Statement and according to the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the issue and sale of the Common Stock and the Option Shares will have been duly authorized by all necessary corporate action of the Company, and the shares of Common Stock and Option Shares will be duly authorized and validly issued and will be fully paid and nonassessable.
- Warrants and Option Warrants.** When the Registration Statement becomes effective, and when the Warrant Agent Agreement between the Company and VStock Transfer, LLC has been duly executed and delivered and the Warrants underlying the Units and/or the Option Warrants are duly executed, issued, delivered and paid for as part of the Units or exercise of the over-allotment option, as applicable, as contemplated by the Warrant Agent Agreement, the Registration Statement and the Prospectus and according to the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, such Warrants and Option Warrants will be valid and legally binding obligations of the Company enforceable in accordance with their terms except: (a) as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting creditors’ rights generally and by general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law); (b) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; (c) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought; (d) 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 provided for in the Warrant Agent Agreement; (e) with respect to the Common Stock underlying the Warrants and/or the Option Warrants, we express no opinion to the extent that, notwithstanding its current reservation of shares of Common Stock, future issuances of securities, including the Common Stock, of the Company and/or adjustments to outstanding securities, including the Warrants and Option Warrants, of the Company may cause the Warrants or Option Warrants to be exercisable for more shares of Common Stock than the number that remain authorized but unissued; and (f) we have assumed the Exercise Price (as defined in the Warrant Agent Agreement) will not be adjusted to an amount below the par value per share of the Common Stock.

4. **Representative's Warrant and Placement Agent's Warrant.** When the Registration Statement becomes effective, and when the Representative's Warrant and the Placement Agent's Warrant are duly executed, issued, and delivered as contemplated by the Registration Statement and the Prospectus, such Representative's Warrant and Placement Agent's Warrant will be a valid and legally binding obligation of the Company enforceable in accordance with its terms except: (a) as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting creditors' rights generally and by general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law); (b) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; (c) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought; (d) 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 provided for in the Warrant Agent Agreement; (e) with respect to the Common Stock underlying the Representative's Warrant and Placement Agent's Warrant, we express no opinion to the extent that, notwithstanding its current reservation of shares of Common Stock, future issuances of securities, including the Common Stock, of the Company and/or adjustments to outstanding securities, including the Representative's Warrant and Placement Agent's Warrant, of the Company may cause the Representative's Warrant and Placement Agent's Warrant to be exercisable for more shares of Common Stock than the number that remain authorized but unissued; and (f) we have assumed the Exercise Price (as defined in the Representative's Warrant and Placement Agent's Warrant) will not be adjusted to an amount below the par value per share of the Common Stock.
5. **Warrant Shares.** The shares of Common Stock underlying the Warrants, the Option Warrants, the Representative's Warrant, and the Placement Agent's Warrant (the "Warrant Shares") have been duly authorized and reserved for issuance, and upon proper exercise and payment therefor as contemplated by the terms of the Warrants, Option Warrants, the Warrant Agent Agreement, the Representative's Warrant, or the Placement Agent's Warrant, as applicable, and assuming that there is a sufficient number of authorized and unissued shares of Common Stock at the time of the Warrant, Option Warrant, Representative's Warrant, or Placement Agent's Warrant exercise, when and if issued, the Warrant Shares will be validly issued, fully paid and nonassessable.

The foregoing opinions are expressed solely with respect to the Delaware General Corporation Law and, as to the Units and the Warrants constituting valid and legally binding obligations of the Company, solely with respect to the Laws of the State of New York. We do not express any opinion as to any other laws. No opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issuance of the Common Stock, the Option Shares, the Warrants, the Option Warrants, the Representative's Warrant, the Placement Agent's Warrant, and the Warrant Shares.

We consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and further consent to the reference to our firm under the caption "Legal Matters" in the Prospectus included in the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended, or the rules and regulations of the Commission thereunder.

Respectfully Submitted,

/s/ **Dykema Gossett PLLC**

Dykema Gossett PLLC

August 4, 2022

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Ladies and Gentlemen:

We have read bioAffinity Technologies, Inc.'s statements included in its Form S-1 dated August 4, 2022, and are in agreement with the statements contained in the Management's Discussion and Analysis of Financial Conditions and Results of Operations section titled "Change in Auditors" in the first four paragraphs of that section therein. We have no basis to agree or disagree with other statements of the registrant contained therein.

/s/ Ernst & Young LLP

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated January 10, 2022 (except Note 16, as to which the date is June 23, 2022), in the Registration Statement (Amendment No. 5 to Form S-1) and related Prospectus of bioAffinity Technologies, Inc. for the registration of shares of its common stock and warrants.

Our report dated January 10, 2022 (except Note 16, as to which the date is June 23, 2022) contains an explanatory paragraph that states the Company has suffered recurring losses from operations and negative cash flows from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

San Antonio, Texas
August 4, 2022

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in the Prospectus constituting a part of this Registration Statement on Amendment No. 5 to Form S-1 of our report dated April 22, 2022 except as to Note 16, as to which the date is June 23, 2022, relating to the financial statements of bioAffinity Technologies, Inc., which is contained in that Prospectus. We also consent the reference to our Firm under the caption “Experts” in the Prospectus.

/s/ WithumSmith+Brown, PC

New York, New York
August 4, 2022

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 Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees Previously Paid	Equity	Units consisting of shares of Common Stock, par value \$0.007 per share ("Common Shares"), Tradeable Warrants to purchase Common Shares, and Non-tradeable Warrants to purchase Common Shares ⁽¹⁾	457(o)	1,285,325		\$ 8,033,281.25 ⁽²⁾	0.0000927	\$ 744.69 ⁽⁷⁾
	Equity	Common Stock, par value \$0.007 per share, included as part of the Units	457(o)	—	—	Included with above Units.	—	—
	Other	Tradable Warrants to purchase Common Shares, included as part of the Units	457(o) and 457(g)	—	—	Included with above Units.	—	—
	Other	Non-tradeable Warrants to purchase Common Shares, included as part of the Units	457(o) and 457(g)	—	—	Included with above Units.	—	—
	Equity	Common Shares issuable upon exercise of the Tradeable Warrants included as part of the Units	457(o)	1,285,325	—	\$ 9,447,138.75 ⁽²⁾	0.0000927	\$ 875.75 ⁽⁷⁾
	Equity	Common Shares issuable upon exercise of the Non-tradeable Warrants included as part of the Units	457(o)	1,285,325	—	\$ 9,840,448.20 ⁽²⁾	0.0000927	\$ 912.21 ⁽⁷⁾
	Other	Over-Allotment Option	457(o)	192,799		\$ 1,204,993.75 ⁽²⁾⁽³⁾	0.0000927	111.70 ⁽⁷⁾
	Other	Common Stock, par value \$0.007 per share, included as part of the Over-Allotment Option	457(o)	—	—	Included with above Over-Allotment Option.	—	—
	Other	Tradable Warrants to purchase Common Shares, included as part of the Over-Allotment Option	457(o) and 457(g)	—	—	Included with above Over-Allotment Option.	—	—
	Other	Non-tradeable Warrants to purchase Common Shares, included as part of the Over-Allotment Option	457(o) and 457(g)	—	—	Included with above Over-Allotment Option.	—	—
	Other	Common Shares issuable upon exercise of the Tradeable Warrants included as part of the Over-Allotment Option	457(o)	192,799		\$ 1,417,072.65 ⁽²⁾	0.0000927	131.36 ⁽⁷⁾

	Common Shares issuable upon exercise of the Non-tradable Warrants, included as part of the Over-							
Other	Allotment Option Representative's	457(o)	192,799		\$ 1,476,069.14(2)	0.0000927		136.83(7)
Other	Warrant ⁽⁴⁾	457(g)	—	—	—	—		—
	Common Stock issuable upon exercise of the Representative's							
Equity	Warrant ⁽⁵⁾	457(o)	25,707	—	\$ 181,080.11(2)	0.0000927	\$	16.79(7)
	Placement Agent's							
Other	Warrant ⁽⁴⁾	457(g)	—	—	—	—		—
	Common Stock issuable upon exercise of the Placement Agent's							
Equity	Warrant ⁽⁶⁾	457(a)	29,464		\$ 216,560.40	—	\$	20.08
Total Offering Amount					\$ 31,816,644.25		\$	2,949.40
Total Fees Previously Paid							\$	3,008.26
Net Fee Due							\$	0.00

- (1) This registration statement also includes an indeterminate number of securities that may become offered, issuable or sold to prevent dilution resulting from stock splits, stock dividends and similar transactions, which are included pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act.
- (3) Includes the offering price of additional shares of Common Stock and Warrants that are part of the Units that the underwriters have the option to purchase to cover over-allotments, if any.
- (4) No fee required pursuant to Rule 457(g) under the Securities Act.
- (5) Represents a warrant to purchase a number of securities equal to 2% of the shares of Common Stock sold in this Offering at an exercise price equal to 115% of the assumed public offering price per Unit. These are not warrants that were issued in connection with the Company's Bridge Note financing described in Note 12 to the Company's financial statements on page F-17. These warrants will be issued to pursuant to the underwriting agreement.
- (6) Represents a warrant to purchase 29,464 shares of Common Stock issued to our Placement Agent at an exercise price equal to 120% of the per-Unit offering price in this Offering, or \$7.35 per share based on the assumed offering price of \$6.125 per Unit.
- (7) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.