As filed with the Securities and Exchange Commission on April 25, 2022.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

bioAffinity Technologies, Inc.

(Exact name of registrant as specified in its charter)

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

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
Suite 1206
San Antonio, Texas 78257
210-698-5334

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

Copies to:

Wilhelm E. Liebmann, Esq.
Dykema Gossett PLLC
112 E. Pecan Street
Suite 1800
San Antonio, Texas 78205
(210) 554-5414

Ross David Carmel, Esq.
Carmel, Milazzo & Feil LLP
55 West 39th Street
18th Floor
New York, New York 10018
(212) 658-0458

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

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

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

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

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

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

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

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment 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 April 25, 2022.

PRELIMINARY PROSPECTUS

____ Shares

bioAffinity Technologies, Inc.
Common Stock

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 our Common Stock, $0.001 par value per share (the "***Common Stock***"). We are offering _____ shares of our Common Stock at an anticipated initial public offering price between $_____ and $_____ per share. The actual public offering price of the Common Stock 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.

Prior to this Offering, there has been no public market for our Common Stock. We have applied to list our Common Stock on the Nasdaq Capital Market ("***Nasdaq***") under the symbol "BIAF".

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.

Immediately after this Offering, our officers and directors will control approximately 70% 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 95 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 immediately prior to the closing of this Offering. 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 Common Stock 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 Shares	Total
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, or the Representative's Warrant, to WallachBeth Capital, LLC, the representative of the underwriters, to purchase an amount equal to eight percent (8.0%) of the aggregate number of shares of Common Stock 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 Common Stock. 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

representative of the underwriters or upon the exercise of the warrants we will issue to the representative of the underwriters, as described herein.

We have granted the representative of the underwriters a 45-day option to purchase up to a total of ___ additional shares of Common Stock from us at the initial public offering price less the underwriting discounts.

The underwriters expect to deliver the shares of Common Stock to purchasers on or about [Date], 2022 through the book-entry facilities of The Depository Trust Company.

Sole Book-Running Manager

WallachBeth Capital, LLC

The date of this prospectus is April 25, 2022.

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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.

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 111.

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.

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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 December 31, 2021, we had an accumulated deficit of approximately $28.5 million. We currently have a total negative working capital of $11.6 million, including $8.7 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.

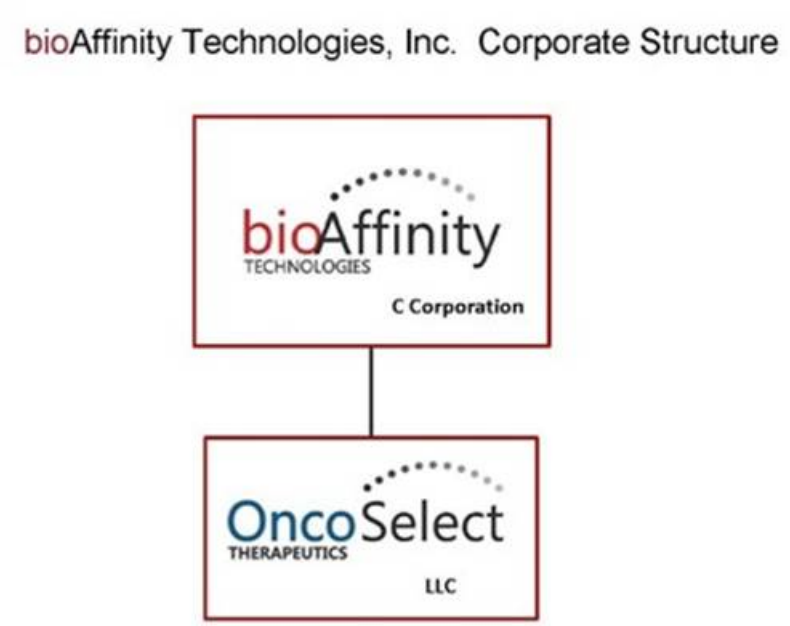
Corporate Information

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.

Organizational Structure

The following organizational chart depicts our principal operating subsidiaries:



Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" (an "***EGC***") as defined in the Jumpstart Our Business Startups Act of 2012. 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]

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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.

A 150-patient test validation trial of people at high risk for lung cancer including patients with the disease and those cancer-free 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 high-risk 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. The detection of small lung nodules in people who have early-stage cancer can increase lung cancer survival.[12] CyPath® Lung can be used with LDCT to find early-stage lung cancer. The CyPath® technology is based on scientific work 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] The Los Alamos studies examined the active ingredient of CyPath®, the synthetic 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 manmade, 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]

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 have been identified for reimbursement for 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 Mohamed Al-Far and Neville Pimstone: 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 170: 661–672, 1984.
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 61.

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 ("*IP*") Portfolio

As of April 25, 2022, the Company and its subsidiary OncoSelect® have a patent estate that includes 12 issued U.S. and foreign counterpart patents, including three U.S. patents and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, 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. One therapeutic patent accepted in Australia expires in 2037 once issued. One therapeutic patent application that has been accepted in Mexico expires in 2037 once issued.

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. patent application and eight foreign counterpart patent applications in Australia, Canada, China, European Patent Office, Hong Kong, Japan, Mexico, and Singapore filed in 2019, and one provisional patent application filed in 2021. 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, three pending Patent Cooperation Treaty International patent applications, and ten foreign applications pending in Australia, Canada, China, European Patent Office, Hong Kong, India, Japan, and Mexico. The therapeutic IP 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, Etxeberria J and Hao Y: Global Patterns and Trends in Lung Cancer Incidence: A Population-Based Study. J Thorac Oncol 16: 933–944, 2021.
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 a 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 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 licensing 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 approval 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. 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 request for *de novo* classification to the FDA within six months of study completion. If the *de novo* request is granted by the FDA, we expect FDA clearance will result in a larger market and greater market share for CyPath® Lung. FDA clearance 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 61.

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 approval;
- 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.	[Total number] of shares of Common Stock, at $_____ per share. The actual number of shares we will offer will be determined based on the actual public offering price.
Over-Allotment Option.	We have granted a 45-day option to the underwriters to purchase up to [ ] additional shares of Common Stock (equal to 15% of the shares in this Offering) at the public offering price per share, less the underwriting discounts payable by us, solely to cover over-allotments, if any (the "***Over-Allotment Option***").
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 "***Series A Preferred Stock***"), 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 "***Series A Director Designation Right***"; such director, the "***Series A Representative***"). 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 1 but is subject to 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 70% 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 shares of our Common Stock in this Offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This assumes a public offering price of $ per share (the midpoint of the range of prices set forth on the cover page of this prospectus). If the underwriters exercise their option to purchase additional shares in full, the net proceeds to us will be approximately $ 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 nine percent (9.0%) (subject to reduction) of the offering price of the shares in this Offering. If more than twenty-five percent (25.0%) of the shares 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. In addition, we have agreed to reimburse certain accountable expenses of WallachBeth Capital, LLC (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 106 of this prospectus.
Representative's Warrants.	The registration statement of which this prospectus is a part also registers for sale warrants (the

	"***Representative's Warrants***") to purchase up to 8.0% (subject to reduction) of the shares of our Common Stock sold in this Offering to the Representative, as a portion of the underwriting compensation in connection with this Offering. The Representative's Warrants will be exercisable at any time, and from time to time, in whole or in part, during the period commencing 180 days from the commencement of sales of the public securities and expiring five years from the effective date of this Offering at an exercise price of $ [ ] (115% of the assumed public offering price per share). We are registering the Representative's Warrants and the shares of Common Stock underlying the Representative's Warrants in the registration statement of which this prospectus is a part. See "Underwriting—Representative's Warrants" on page 107 of this prospectus for a description of these Warrants.
Placement Agent's Warrants	In connection with the sale of our convertible bridge notes, our placement agent, WallachBeth Capital, LLC (the "***Placement Agent***"), will receive commissions of nine percent (9.0%) and will be issued Common Stock purchase warrants equal to ten percent (10.0%) of the Common Stock issuable by the Company in relation to the convertible bridge notes that the Company sold in a private placement in the fourth quarter of 2021 and the first quarter of 2022 (the "***Placement Agent's Warrants***"). For noteholders who were not introduced to the Company by the Placement Agent, we will pay commissions of four and one-half percent (4.5%) and will issue our Placement Agent Common Stock purchase warrants equal to two and one-half percent (2.5%) of the Common Stock issuable by the Company in the private placement. The warrants that will be issued to our Placement Agent will have substantially the same terms as those issued to our noteholders. The warrants, which are considered as compensation to the Placement Agent, are exercisable, starting 180 days after the commencement of the sale of the public securities in this Offering, for shares of our Common Stock at an exercise price equal to the purchase price of the Common Stock in this Offering (369,791 shares based on the price of $____ per share of Common Stock, which is the midpoint of the price range set forth on the cover page of this prospectus) or $0.75 per share if the Company does not complete an initial public offering (an "***IPO***") by the maturity date of _____, 2022. We are registering the shares of Common Stock underlying the Placement Agent's Warrants 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 one year 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 108 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 shares of Common Stock.
Proposed Nasdaq Capital Market Listing.	We have applied to have our Common Stock listed on the Nasdaq Capital Market under the symbol "**BIAF**." No assurance can be given that our Nasdaq listing application will be approved, or that a trading market will develop for our Common Stock. **We will not proceed with this Offering if our application to list our Common Stock on Nasdaq is not approved.**
Transfer Agent.	The transfer agent and registrar for our Common Stock 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 $0.60 per share, (ii) 5,296,044 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) 14,427,392 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 January 2022 with a weighted average exercise price equal to the initial offering price in this Offering, and (iv) 6,159,096 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 December 2021.

(2) The number of shares of Common Stock to be outstanding immediately following this Offering excludes:

- [ ] shares of Common Stock issuable upon the exercise of the Over-Allotment Option;
- [ ] shares of Common Stock issuable upon the exercise of the Representative's Warrants and [ ] shares of Common Stock issuable upon the exercise of the Placement Agent's Warrants;
- 5,296,044 shares of Common Stock issuable upon the conversion of Series A Preferred Stock;
- 14,427,392 shares of Common Stock issuable upon the exercise of Common Stock purchase warrants with a weighted average exercise price equal to the initial offering price in this Offering; and
- 6,159,096 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 $0.60 per share.

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

- no exercise of any options under the Company's 2014 Equity Incentive Plan;
- no exercise of the Representative's Warrants or the Placement Agent's Warrants; 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 balance sheet data as of December 31, 2021 and 2020, from our audited consolidated financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

You should read the following summary financial data together with our 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 (amounts in thousands, except share and per share data):

	Year Ended December 31,	
	2021	**2020**
Operating Expenses		
Research and development	$ 1,196	$ 1,415
Clinical development	130	195
General and administrative	881	994
Total operating expense	2,207	2,604
Loss from Operations	(2,207)	(2,604)
Other income (expense), including tax	(4,119)	(4,665)
Net loss	$ (6,326)	$ (7,269)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.39)
Weighted average common shares outstanding, basic and diluted	18,727,066	18,724,187

The following table summarizes our balance sheets at December 31, 2021 and 2020 (amounts in thousands):

	As of December 31, 2020	**As of December 31, 2021**	
	Actual	Actual	As Adjusted[1][2]
Cash and cash equivalents	$ 83	$ 1,361	$
Working capital (deficit)[3]	$ (11,002)	$ (11,593)	$
Total assets	$ 146	$ 1,453	$
Total liabilities	$ 11,174	$ 13,200	$
Total convertible preferred stock	$ (4,044)	$ (4,044)	
Accumulated deficit	$ (22,187)	$ (28,513)	$
Total stockholders' deficit	$ (15,073)	$ (15,791)	$

(1) The as adjusted balance sheet data gives effect to the issuance and sale of Common Stock in this Offering at an assumed IPO price of $____ per share of Common Stock, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Each $1.00 increase (decrease) in the assumed IPO price of $___ per share, would increase (decrease) as adjusted cash and cash equivalents, working capital, total assets, and total equity by approximately $___ million, assuming that the number of shares of Common Stock 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 IPO price and other terms of our Offering determined at pricing.

(3) We define working capital as current assets less prepaid offering costs and less current liabilities.

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;

- 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. 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 June 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 approval 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 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.

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 maybe 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.

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 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. 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 approval. Even if we succeed in bringing any tests or products to the market, they may not be considered cost-effective, and third-party reimbursement might not be available or sufficient. If adequate 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 approval 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.

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.

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 shares of our Common Stock 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 Pathology Laboratory Services pursuant to a licensing 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 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 approval, 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 clearance, 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, Pathology Laboratory 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 Pathology Laboratory 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 seeks regulatory approval in foreign countries, they may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

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

In addition to regulations in the 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 approval 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

- 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, the stock price of our Common Stock may be volatile or may decline regardless of our operating performance and you may not be able to resell your shares at or above the IPO price.

There has been no public market for our Common Stock prior to this Offering. The IPO price for our Common Stock will be determined through negotiations between the underwriter and us and may vary from the market price of our Common Stock following this Offering. If you purchase shares of our Common Stock in this Offering, you may not be able to resell those shares at or above the IPO price. An active or liquid market in our Common Stock 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 shares of our Common Stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of 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.

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 the shares of Common Stock by existing shareholders could adversely affect the price of our Common Stock.

If our existing shareholders sell substantial amounts of the shares following an IPO, the market price of our Common Stock 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 offered in this Offering will be eligible for immediate resale in the public market without restrictions. All remaining shares, 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 shares could be adversely affected.

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

The IPO price will be substantially higher than the net tangible book value per share of our Common Stock. Investors purchasing Common Stock in this Offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Common Stock in this Offering will incur immediate dilution of $ per share, based on the assumed IPO price of $ per share of our Common Stock, which is the midpoint of the price range set forth on the cover page of this prospectus. Further, investors purchasing Common Stock in this Offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the total number of shares of our Common Stock outstanding after this Offering.

This dilution is due to our investors who purchased shares 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 Common Stock 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 public 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 shares may decline following our public offering. The stock market in general has been, and the market price of our Common Stock shares 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 shares 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 shares are 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 shares 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 Shares; 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 shares 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 amended and restated certificate of incorporation and 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 under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the DGCL, our A&R Charter, or our A&R Bylaws, (4) any other action against us or any of our directors, officers or other employees asserting a claim that is governed by the internal affairs doctrine, or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, 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 or the Securities Exchange Act of 1934, as amended (the Exchange Act).

To the extent that any such claims may be based upon federal law claims, 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.

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 contains 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.

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 70% 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 common shares 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 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated bylaws that will be in effect 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 amended and restated 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 amended and restated certificate of incorporation and amended and restated 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 funds to satisfy third-party claims and may adversely impact our cash position.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of shares of our Common Stock in this Offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This assumes a public offering price of $ per share. If the underwriters exercise their option to purchase additional shares in full, the net proceeds to us will be approximately $ 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 clearance 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 public offering price of $ per share would increase or decrease the net proceeds to us from this Offering by approximately $ 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 underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this Offering by approximately $ million, assuming that the assumed public offering price of $ per share 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 December 31, 2021:

- on an actual basis
- on an as adjusted basis to give effect to the issuance and sale of shares of our Common Stock in this Offering at an assumed IPO price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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 IPO price, the number of shares of Common Stock 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 December 31, 2021	
	Actual	As Adjusted[(1)]
Cash and cash equivalents	$ 1,361	$
Total indebtedness	11,364	
Convertible preferred stock	4,044	
Stockholders' deficit:		
Common stock	19	
Additional paid-in capital	12,704	
Accumulated deficit	(28,513)	
Total stockholders' equity (deficit)	$ (15,791)	$
Total capitalization	$ (383)	$

A $1.00 increase (decrease) in the assumed IPO price of $ per share of Common Stock, which is the midpoint of the price range set forth on the cover page of this prospectus, 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 $ 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 1.0 million shares in the number of shares of Common Stock offered by us would increase (decrease) each of our pro forma as adjusted cash, cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming the assumed IPO price of $ per share of Common Stock remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

DILUTION

If you invest in our Common Stock in this Offering, your ownership interest will be immediately diluted to the extent of the difference between the IPO price per share of our Common Stock 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 shares of Common Stock 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 December 31, 2021 was approximately $(12.8) million, or $(0.67) 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 18,988,278, the number of shares of our Common Stock outstanding as of December 31, 2021.

After giving effect to the (i) sale and issuance by us of shares of our Common Stock in this Offering, based on an assumed IPO price of $___ per share (the midpoint of the range of offering prices set forth on the cover page of this prospectus) 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 _____, 2022 would have been $_____, or $____per share. This represents an immediate increase in pro forma net tangible book value of $____ per share to our existing stockholders and immediate dilution of $___ per share to investors purchasing shares of our Common Stock in this Offering at the assumed IPO price. The following table illustrates this dilution:

Assumed initial public offering price per share	$
Net tangible book value per share as of _____, 2022	$
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this Offering	
Pro forma as adjusted net tangible book value per share immediately after this Offering	
Dilution per share to new investors in this Offering	$

(1) The number of shares of Common Stock to be outstanding immediately before this Offering excludes any shares of Common Stock issuable upon the mandatory conversion of the approximately $6.8 million in convertible notes and related interest issued by us to a number of investors in private placements between December 2018 and December 2021 at a conversion price equal to $0.60 per share.

(2) The number of shares of Common Stock as of December 31, 2021, to be outstanding immediately following this Offering excludes:

- [ ] shares of Common Stock issuable upon the exercise of the Over-Allotment Option;
- [ ] shares of Common Stock issuable upon the exercise of the Representative's Warrants and [ ] shares of Common Stock issuable upon the exercise of the Placement Agent's Warrants;
- 5,296,044 shares of Common stock issuable upon the conversion of Series A Preferred Stock;
- 5,799,096 shares of Common Stock issuable on the exercise of stock options; and
- 13,231,562 shares of Common Stock issuable on the exercise of a warrant.

Each $1.00 increase or decrease in the assumed IPO price of $___ per share (the midpoint of the range of offering prices set forth on the cover page of this prospectus) would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to new investors by approximately $___, and would increase or decrease, as applicable, dilution per share to new investors in this Offering by approximately $___, assuming that the number of shares of our Common Stock 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 our 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 $____ per share, and the dilution in pro forma net tangible book value per share to new investors in this Offering would be $____ per share.

We may also increase or decrease the number of shares we are offering. A one million share increase in the number of shares 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 $___ and decrease the dilution per share to investors participating in this Offering by $____, assuming the assumed IPO price of $____ per share (the midpoint of the range of offering prices 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. A one million 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 $___ and increase the dilution per share to new investors participating in this Offering by $_____, assuming the assumed IPO price of $____ per share (the midpoint of the range of offering prices 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. sensitivity

The following table presents, on a pro forma as adjusted basis as of _____, 2022, after giving effect to the new investors purchasing shares of our Common Stock 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 IPO price of ____ per share (the midpoint of the range of offering prices set forth on the cover page of this prospectus) before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchase		Total Consideration		Average Price Share
	Number	Percent	Amount	Percent	
			(in thousands)		
Existing stockholders		%	$	%	$
New investors		%	$	%	$
Totals		100%	$	100%	$

Each $1.00 increase or decrease in the assumed IPO price of $____ per share (the midpoint of the range of offering prices set forth on the cover page of this prospectus) would increase or decrease, as applicable, the total consideration paid by new investors and total consideration paid by all stockholders by approximately $_____, assuming that the number of shares of Common Stock 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 ___% and our new investors would own ___% 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 _____ shares of our Common Stock outstanding as of _____, 2022, and excludes _____ shares of Common Stock reserved for issuance under our 2014 Equity Incentive Plan and _____ shares of Common Stock reserved for issuance for _____.

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."

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, 2020 and 2021 has been derived from our audited consolidated financial statements appearing at the end of this prospectus.

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 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 December 31, 2021, we had total negative working capital of $11.6 million, including $8.7 million of convertible notes, and an accumulated deficit of approximately $28.5 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 IPO, or at the noteholder's option, at $0.60 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%) and have a maturity date of May 31, 2022. 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 the Company's IPO price or $0.75 per share if the Company does not complete an IPO by the maturity date. In connection with the sale of our convertible bridge notes, we will pay commissions of nine percent (9.0%) and will issue to WallachBeth Capital, LLC, Placement Agent's Warrants equal to ten percent (10.0%) of the Common Stock issuable by the Company in the private placement with substantially the same terms as the warrants issued to our noteholders. For noteholders who were not introduced to the Company by the Placement Agent, we will pay commissions of four and one-half percent (4.5%) and will issue Placement Agent's Warrants to our Placement Agent equal to two and one-half percent (2.5%) of the Common Stock issuable by the Company in the private placement. The warrants will have substantially the same terms as those issued to our noteholders.

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

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	$ 2,207	$ 2,604	$ (397)	-15%

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)

	Year Ended December 31,		Change in 2021 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)	$ (4,118)	$ (4,662)	$ 544	-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 $1.4 million as of December 31, 2021.

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 $0.60 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%) and have a maturity date of May 31, 2022. 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 the Company's IPO price or $0.75 per share if the Company does not complete an IPO by the maturity date. In connection with the sale of our convertible bridge notes, we will pay commissions of nine percent (9.0%) and will issue Placement Agent's Warrants to our Placement Agent equal to ten percent (10%) of the Common Stock issuable by the Company in the private placement with substantially the same terms as our noteholders.

Based on our current level of expected operating expenditures, we expect to be able to fund our operations until June 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 years presented:

	Year Ended December 31,	
	2021	**2020**
	(amounts in thousands)	
Cash and cash equivalents at beginning of year	$ 83	$ 578
Net cash used in operating activities	(2,049)	(2,207)
Net cash used in investing activities	—	(3)
Net cash provided by financing activities	3,327	1,715
Cash and cash equivalents at end of year	$ 1,361	$ 83

Net Cash Used in Operating Activities

Net cash used in operating activities was $2.0 million and $2.2 million during the years ended 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 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

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 follow FASB 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 years 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.

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).

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 2020.[21] 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., CA Cancer J Clin 2021; 71: 209-249.
21 World Health Organization (WHO), Cancer Fact Sheet (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.

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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 Mohamed Al-Far and Neville Pimstone: 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 170: 661–672, 1984.

A test validation clinical trial of CyPath® Lung[32] 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 an LDCT to confirm they did not have lung cancer. Those in the cancer cohort had a biopsy that confirmed lung cancer. 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 were analyzed from high-risk individuals with and without lung cancer and their results were comparable to those from test validation trial with a sensitivity, specificity, and accuracy equal or greater than 80% and a very robust 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 IP to Precision Pathology that has developed the test as an LDT and completed 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 a request for *de novo* classification 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 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. 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 request for *de novo* classification 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.

Porphyrins and Cancer

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] of an earlier version of CyPath® Lung used a microscope to directly identify CyPath® Lung-labeled cells in one-third or less of the sputum sample which resulted in 81% test accuracy. This earlier 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, Journal of Thoracic Oncology, 2015.

Studies performed to date are summarized in the table below.

CyPath® Lung Studies and Clinical Trials

Study Description	Results
Porphyrin's localization and evaluation of cancer cell uptake of four different porphyrins	TCPP porphyrin localizes more than other porphyrins in cancer cells; higher uptake of TCPP in cancer cells than in normal cells
Blinded study to diagnose lung cancer by labeling sputum with TCPP and identifying red fluorescing cells under a microscope	Study of uranium miners (cancer N=8 / healthy N=4) labeling sputum labeled with TCPP resulted in 100% sensitivity and 100% specificity; one patient entering study as a healthy subject was correctly diagnosed with cancer by the test
Internal validation study with microscopy-based assay completed to optimize TCPP labeling of sputum containing cancer and cancer-related cells in lung cancer samples	By measuring florescence intensity of TCPP-labeled cells in sputum under a microscope, researchers correctly identified samples from lung cancer patients (cancer N=15 / healthy N=12) resulting in 100% sensitivity and 100% specificity
Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum[37]	Clinical trial of 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; this trial led to optimization of CyPath® Lung using flow cytometry
Analysis of sputum by flow cytometry elucidates the lung environment (Bederka, et al., 2022, submitted for publication)	Research confirms that bioAffinity has developed and tested a novel flow cytometry assay including quality controls that analyzes sputum in a high-throughput manner for diagnosis of lung cancer (N=164)
Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning (Lemieux, et al., 2022, submitted for publication)	Test validation trial 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

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. 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 are established and available for lab billing with the CyPath® Lung test. See "Business—Reimbursement" on page 63.

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.

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 have been identified for reimbursement as an LDT.

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. 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 request for *de novo* classification to the FDA within six months of study completion and anticipate FDA clearance 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 FDA clearance 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. 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 are available for use with CyPath® Lung that are associated with the technology used by the test, specifically flow cytometry tests used to detect solid tumors. 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 63.

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 license 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 clearance 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 request for *de novo* classification to the FDA for CyPath® Lung. If the *de novo* request is granted by the FDA, we expect FDA clearance will result in a larger market and greater market share for CyPath® Lung. FDA clearance 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. 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 request for *de novo* classification 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 clearance 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 test is reimbursed by third-party payers, including commercial health insurers and government health benefits programs (such as Medicare and Medicaid). 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 we 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 condition 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 if obtained, 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 reimbursed 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]; Nuclexi[50]; Savicell[51]; Visongate[52]) 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, Munafo 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 IONIQ 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 Biodesix, are rule-out tests, meaning the tests aims to exclude patients without cancer. The REVEAL test is a blood test intended for patients with indeterminant nodules. In their 97-patient clinical validation trial,[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 a 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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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.

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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.

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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 and Jemal A: Recent Global Patterns in Prostate Cancer Incidence and Mortality Rates. Eur Urol 77: 38–52, 2020.

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.

71 SEER, Cancer Fact Sheet: Prostate Cancer, (2021).

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.[76] 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.[77] 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 (Link) (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 - ResearchAndMarkets.com. 2021.

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.

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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.

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

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91 Mohamed Al-Far, Neville Pimstone. 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.

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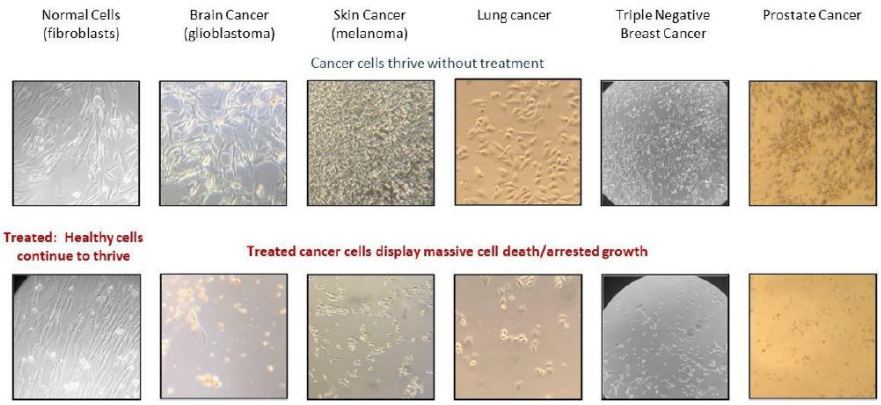
93 Hiyama K, Matsui H, Tamura M, et al. Cancer cells uptake porphyrins via heme carrier protein 1. J. Porphyrins Phthalocyanines 2012;17:36–43.

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.

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96 Setten, R.L., Rossi, J.J. & Han, Sp. The current state and future directions of RNAi-based therapeutics. Nat Rev Drug Discov 18, 421–446 (2019).

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-2α 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-β1 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-β1 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 April 25, 2022, the Company and its subsidiary OncoSelect® have a patent estate that includes 12 issued U.S. and foreign counterpart patents including three U.S. patents and nine foreign counterpart patents in Canada, China, France, Germany, Hong Kong, Italy, Spain, Sweden, and the United Kingdom. The Company wholly owns all patents and trademarks in its IP 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. One therapeutic patent has been accepted in Australia that expires in 2037 once issued. One therapeutic patent application that has been accepted in Mexico expires in 2037 once issued. The expiring patents will not have a material adverse effect on the Company's business, financial condition or operations. The patents related to a method of making a solution of TCPP and using the TCPP solution for labeling cancer cells for detection. 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 ten foreign counterpart patents in Canada, China, European Patent Office, 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 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, and one provision patent application filed in 2021. 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, three pending Patent Cooperation Treaty International patent applications, and ten foreign applications pending in Australia, Canada, China, European Patent Office, Hong Kong, India, Japan, and Mexico. The therapeutic IP 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 accepted in Australia that expires in 2037 once issued. Another therapeutic patent application that has been accepted in Mexico expires in 2037 once issued.

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 approval 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 directed at a molecular target determined by the FDA to be substantially relevant to the growth or progression of a pediatric cancer.

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 fulfilment of these requirements must be provided by the manufacturer prior to placing a test on the EU market. The manufacturer is required to establish a Quality Management System (QMS) as well as processes for manufacturing, importing, distribution, post-market surveillance, and vigilance. Regulations also require that the product is fully documented. In addition, it is likely that our 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 April 25, 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.	57	Chief Science and Medical Officer, Executive Vice President	n/a
Michael Edwards, MBA, CPA	55	Chief Financial Officer	n/a
Timothy P. Zannes, J.D.	69	Executive Vice President, Secretary and General Counsel	n/a
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 compensated in cash 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;

- 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;

- 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 December 31, 2020:

Name and Principal Position	Year	Salary	Bonus	Equity Awards[(1)]	All Other Compensation	Total Compensation
Maria Zannes, J.D.	2021	$ 220,000	$ 0	$ 49,701	$ 7, 196	$ 263,204
President and Chief Executive Officer	2020	$ 220,000	$ 0	$ 36,003	$ 16,280	$ 285,989
Vivienne I. Rebel, M.D., Ph.D.	2021	$ 225,000	$ 0	$ 13,200	$ 11,590	$ 249,790
Executive Vice President and Chief Science and Medical Officer	2020	$ 225,000	$ 0	$ 15,116	$ 12,196	$ 252,312
Steven Girgenti	2021	$ 60,000(2)	$ 30,000(3)	$ 90,000(4)	$ 0	$ 180,000
Executive Chairman	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 Option Awards: Number of Shares of Stock or Units (#)	All Other Stock 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	$	$	$				-	50,000(1)	$ 1.10	[____]
	7/26/2021	$	$	$				25,000(2)	-	-	[____]
	12/16/2021	$	$	$				-	50,000(3)	$ 0.60	[____]
Vivienne I. Rebel, M.D., Ph.D.	7/26/2021	$	$	$				30,000(4)	-	-	[____]
Steven Girgenti	2/19/2021	$	$	$				27,273(5)	-	-	[____]
	12/16/2021	$	$	$				-	50,000(6)	$ 0.60	[____]
	12/31/2021	$	$	$				100,000(7)	-	-	[____]

(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:

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares of Units of Stock that Have Not Vested ($)	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	453,940	0	0	$ 0.165	4/28/2024		$		$
	25,000	0	0	$ 0.60	7/27/2025		$		$
	25,000	0	0	$ 1.00	7/25/2026		$		$
	25,000	0	0	$ 1.00	4/24/2027		$		$
	50,000	0	0	$ 1.10	5/7/2028		$		$
	20,000	0	0	$ 1.10	2/25/2029		$		$
	50,000	0	0	$ 1.10	7/29/2029		$		$
	50,000	0	0	$ 1.10	2/5/2030		$		$
	50,000	0	0	$ 1.10	7/27/2030		$		$
	8,328	41,672	0	$ 1.10	7/26/2031		$		$
	4,166	45,834	0	$ 0.60	12/16/2031		$		$
	20,000	0	0	$ 1.00	7/25/2026		$		$
	20,000	0	0	$ 1.10	4/24/2027		$		$

Vivienne I. Rebel, M.D., Ph.D.	30,000	0	0	$	1.10	2/25/2029	$	$
	30,000	0	0	$	1.10	2/5/2030	$	$
	453,940	0	0	$	0.165	4/28/2024	$	$
	25,000	0	0	$	0.60	7/27/2025	$	$
Steven Girgenti	25,000	0	0	$	1.00	7/25/2026	$	$
	25,000	0	0	$	1.00	4/24/2027	$	$
	50,000	0	0	$	1.10	5/7/2028	$	$
	50,000	0	0	$	1.10	7/29/2029	$	$
	50,000	0	0	$	1.10	7/27/2030	$	$
	4,166	45,834	0	$	0.60	12/16/2031	$	$

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 50,000 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 $0.60 exercise price, and expire on December 16, 2031.

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	13,222	0	0	0	13,222
Stuart Diamond	0	0	0	0	0	0	0
Peter Knight	0	0	13,222	0	0	0	13,222
Mohsin Meghji	0	0	13,222	0	0	0	13,222
Gary Rubin	0	0	13,222	0	0	0	13,222

PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us regarding the beneficial ownership of Common Stock as of March 31, 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 March 31, 2022. These shares were not deemed outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

The beneficial ownership of our Common Stock is based on 19,093,278 shares of our Common Stock outstanding as of March 31, 2022.

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	Number of Shares of Common Stock	Percent of Class	Number of Shares of Common Stock After this Offering	Percent of Class Owned After Offering
Directors and Executive Officers:				
Maria Zannes[(1)]	808,650	4.07%	808,650	%
Vivienne Rebel[(2)]	150,000	0.78%	150,000	%
Steven Girgenti[(3)]	8,342,093	32.60%	8,342,093	%
Michael Edwards[(4)]	300,371	1.56%	300,371	%
Timothy Zannes[(5)]	536,440	2.73%	536,440	%
Robert Anderson[(6)]	699,770	3.54%	699,770	%
Stuart Diamond	8,332	0.04%	8,332	%
Mohsin Meghji[(7)]	607,179	3.11%	607,179	%
Peter Knight[(8)]	270,830	1.41%	270,830	%
Gary Rubin[(9)]	14,371,764	52.26%	14,371,764	%
All Directors and Executive Officers as a Group (10 individuals)	26,095,429	70.89%	26,095,429	%
Five Percent Holders:				
The Harvey Sandler Revocable Trust[(10)]	13,732,093	50.65%	13,732,093	%
Nathan Perlmutter[(11)]	3,105,031	14.76%	3,105,031	%

(1) Includes (i) 25,000 shares of Common Stock issued to Ms. Zannes as restricted stock; and (ii) 783,650 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $0.52 per share granted to Ms. Zannes that are either immediately exercisable or exercisable within 60 days of this prospectus.

(2) Includes (i) 50,000 shares of Common Stock issued to Dr. Rebel as restricted stock; and (ii) 100,000 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $1.08 per share granted to Dr. Rebel that are either immediately exercisable or exercisable within 60 days of this prospectus.

(3) Includes (i) 1,535,877 shares of Common Stock owned directly by Mr. Girgenti of record; (ii) 209,091 shares of Common Stock issued to Mr. Girgenti as restricted stock; (iii) 972,957 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Girgenti of record; (iv) 2,654,694 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Girgenti; (v) 2,166,796 shares of Common Stock underlying warrants having an exercise price equal to the initial offering price in this Offering; (v) 699,770 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $0.452 per share granted to Mr. Girgenti that are either immediately exercisable or exercisable within 60 days of this prospectus; (vi) 9,091 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; (vii) 52,151 shares of Common Stock issuable upon conversion of convertible promissory notes held by the Cranye Girgenti Testamentary Trust; and (viii) 41,666 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.

(4) Includes (i) 195,134 shares of Common Stock owned directly by Mr. Edwards of record; (ii) 15,243 shares of Common Stock issuable upon conversion of a convertible promissory note held directly by Mr. Edwards; (iii) 13,324 shares of Common Stock underlying a warrant having an exercise price equal to the initial offering price in this Offering; and (iv) 76,670 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $1.10 per share granted to Mr. Edwards that are either immediately exercisable or exercisable within 60 days of this prospectus.

(5) Includes 536,440 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $0.303 per share granted to Mr. Zannes that are either immediately exercisable or exercisable within 60 days of this prospectus.

(6) Includes 699,770 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $0.452 per share granted to Mr. Anderson that are either immediately exercisable or exercisable within 60 days of this prospectus.

(7) Includes (i) 200,000 shares of Common Stock owned directly by Mr. Meghji of record; (ii) 286,349 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Meghji of record; and (iii) 120,830 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $1.044 per share granted to Mr. Meghji that are either immediately exercisable or exercisable within 60 days of this prospectus.

(8) Includes (i) 100,000 shares of Common Stock owned directly by Mr. Knight of record; and (ii) 170,830 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $1.062 per share granted to Mr. Knight that are either immediately exercisable or exercisable within 60 days of this prospectus.

(9) Includes (i) 250,000 shares of Common Stock owned directly by Mr. Rubin of record; (ii) 108,152 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Rubin; (iii) 85,689 shares of Common Stock underlying warrants having an exercise price equal to the initial offering price in this Offering; (iv) 195,830 shares of Common Stock issuable upon exercise of options with a weighted average exercise price of $1.067 per share granted to Mr. Rubin that are either immediately exercisable or exercisable within 60 days of this prospectus; (v) 5,712,122 shares of Common Stock owned by the Harvey Sandler Revocable Trust, for which Mr. Rubin serves as co-trustee; (vii) 1,612,166 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned by the Harvey Sandler Revocable Trust; (viii) 3,550,912 shares of Common Stock issuable upon conversion of convertible promissory notes held by the Harvey Sandler Revocable Trust; and (ix) 2,856,893 shares of Common Stock underlying warrants having an exercise price equal to the initial offering price in this Offering held by the Harvey Sandler Revocable Trust.

(10) Includes (i) 5,712,122 shares of Common Stock owned directly by the Trust of record; (ii) 1,612,166 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by the Trust of record; (iii) 3,550,912 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by the Trust; and (iv) 2,856,893 shares of Common Stock underlying warrants having an exercise price equal to the initial offering price 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.

(11) Includes (i) 1,162,627 shares of Common Stock owned directly by Mr. Perlmutter of record; (ii) 103,682 shares of Common Stock issuable upon conversion of Series A Preferred Stock owned directly by Mr. Perlmutter of record; (iii) 999,837 shares of Common Stock issuable upon conversion of convertible promissory notes held directly by Mr. Perlmutter; and (iv) 838,885 shares of Common Stock underlying warrants having an exercise price equal to the initial offering price in this Offering.

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, 2021 and each currently proposed transaction in which:

- the Company has been or is to be a participant;
- the amount involved exceeds or will exceed $120,000; 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.

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)]
January 13, 2021	$ 10,000.00	May 31, 2022	18,281
March 10, 2021	$ 50,000.00	May 31, 2022	90,384
March 24, 2021	$ 40,000.00	May 31, 2022	72,102
June 8, 2021	$ 150,000.00	May 31, 2022	266,219
July 3, 2021	$ 60,000.00	December 31, 2022	67,263
Total	$ 1,360,080.52		514,250

(1) The number of shares of the Company's Common Stock expected to be issued upon the automatic conversion of the notes upon the completion of this Offering is based on the outstanding principal balance and accrued and unpaid interest under such notes as of March 31, 2022 and is dependent upon the per share price of this Offering. To estimate the number of shares of Common Stock expected to be issued upon conversion of the notes, the midpoint of the assumed offering price range was used.

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 $0.60 per share. The notes will automatically convert into shares of the Company's Common Stock upon the completion of this Offering.

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

The following summary describes the material terms of our capital stock and provisions of our Pre-IPO Charter and our Pre-IPO Bylaws, as amended and currently in effect prior to 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 Pre-IPO Charter and our Pre-IPO Bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

Authorized Capital Stock

We are currently authorized to issue up to 100,000,000 shares of Common Stock, par value $0.001 per share, and 20,000,000 shares of Preferred Stock, par value $0.001 per share.

As of March 31, 2022, there were 19,093,278 shares of Common Stock issued and outstanding that were held of record by 46 stockholders. As of March 31, 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)(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 1 but is subject to 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 full paid and non-assessable.

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, $1.10 per share. 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. As such, 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. The conversion rate of Series A Preferred Stock into Common Stock is initially 1 for 1 but is subject to 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.

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.

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.

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."

Convertible 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 $0.60 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%) and have a maturity date of May 31, 2022. 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 the Company's IPO price or $0.75 per share if the Company does not complete an IPO by the maturity date.

Placement Agent's Warrants

In connection with the sale of our convertible bridge notes, we will pay commissions of nine percent (9.0%) and will issue to WallachBeth Capital, LLC Placement Agent's Warrants equal to ten percent (10%) of the Common Stock issuable by the Company in the private placement with substantially the same terms as the warrants issued to our noteholders. For noteholders who were not introduced to the Company by the Placement Agent, we will pay commissions of four and one-half percent (4.5%) and will issue Placement Agent's Warrants to our Placement Agent equal to two and one-half percent (2.5%) of the Common Stock issuable by the Company in the private placement. The warrants will have substantially the same terms as those issued to our bridge noteholders.

Representative's Warrants

As additional compensation to the underwriters, upon consummation of this Offering, we will issue to the Representative or its designees non-redeemable Representative's Warrants to purchase an aggregate number of shares of our Common Stock equal to eight percent (8.0%) of the number of shares of Common Stock issued in this Offering, at an exercise price per share equal to 115% of the IPO 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 Warrants will cover only two-and-one-half percent (2.5%) of the number of shares of Common Stock purchased by the existing investors.

The Representative's Warrants 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. See "Underwriting—Representative's Warrants."

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 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 March 31, 2022, upon the closing of this Offering, [ ] shares of our Common Stock will be outstanding assuming: (i) the filing of our A&R Charter and the effectiveness of our A&R Bylaws upon the closing of this Offering; (ii) the automatic conversion of all outstanding shares of our convertible Series A Preferred Stock into an aggregate of [ ] shares of Common Stock immediately prior to the closing of this Offering; and (iii) the automatic conversion of all outstanding convertible promissory notes into an aggregate of [ ] 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 tradable 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. These restricted securities will be subject to a lock-up period under the lock-up agreements described below and may be offered and sold to the public only if registered under the Securities Act or if an exemption from registration is available, including the exemptions provided by Rule 144 or Rule 701 under the Securities Act, summarized below.

Lock-Up Agreements

We have agreed with the underwriters not to sell additional equity securities for a period of one year 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 108.

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.

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 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.

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 shares indicated below:

Underwriter	Number of Shares	Number of Shares if Over-Allotment Option is Fully Exercised
WallachBeth Capital, LLC		
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 shares of Common Stock subject to their acceptance of the shares 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 shares of Common Stock 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 shares of Common Stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' Over-Allotment Option described below.

The underwriters initially propose to offer part of the shares of Common Stock 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 shares of Common Stock, 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 option, exercisable for 45 days from the date of this prospectus, to purchase up to [ ] additional shares of Common Stock, or 15% of the shares offered hereby, at the public offering price listed on the cover page of this prospectus, less 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 shares of Common Stock 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 as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of Common Stock 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. If more than twenty-five percent (25.0%) of the shares 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.

The Representative has advised us that the underwriters propose to offer the shares directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the Representative may offer some of the shares to other securities dealers at such price less a concession of up to $[ ] per share. 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 shares.

The following table shows the public 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 public offering price per share less the amount per share the underwriters pay us for the shares.

	Per Share of Common Stock	Total without Over-Allotment Option	Total with Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts[(1)]	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) If more than twenty-five percent (25.0%) of the shares 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 $[ ]. 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 Warrants

As additional compensation to the underwriters, upon consummation of this Offering, we will issue to the Representative or its designees non-redeemable warrants to purchase an aggregate number of shares of our Common Stock equal to eight percent (8.0%) of the number of shares of Common Stock issued in this Offering, at an exercise price per share equal to 115% of the IPO price (referred to in this prospectus as the "***Representative's Warrants***") 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 Warrants will cover only two-and-one-half percent (2.5%) of the number of shares of Common Stock purchased by the existing investors. The Representative's Warrants 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 Warrants 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 three years from the effective date of the registration statement related to the Offering in compliance with FINRA Rule 5110(G)(8)(D).

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 one share of Common Stock based on the investors' bridge note principal balance investment, or a total of 369,791 shares of our Common Stock (based on the assumed initial public offering price of $ per share, which isthe midpoint of the price range set forth on the cover page of this prospectus).The exercise price of the Placement Agent's Warrant is equal to the price of our Common Stock 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, 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 three years from the effective date of the registration statement related to the Offering in compliance with FINRA Rule 5110(G)(8)(D). 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 an 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 IPO 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 Common Stock 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 IPO 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 this 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, on or before May 3, 2022, 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 Shares

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 shares 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 shares 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 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 or purchasing shares of our Common Stock 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. The underwriters must close out any naked short position by purchasing shares 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 shares of Common Stock 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

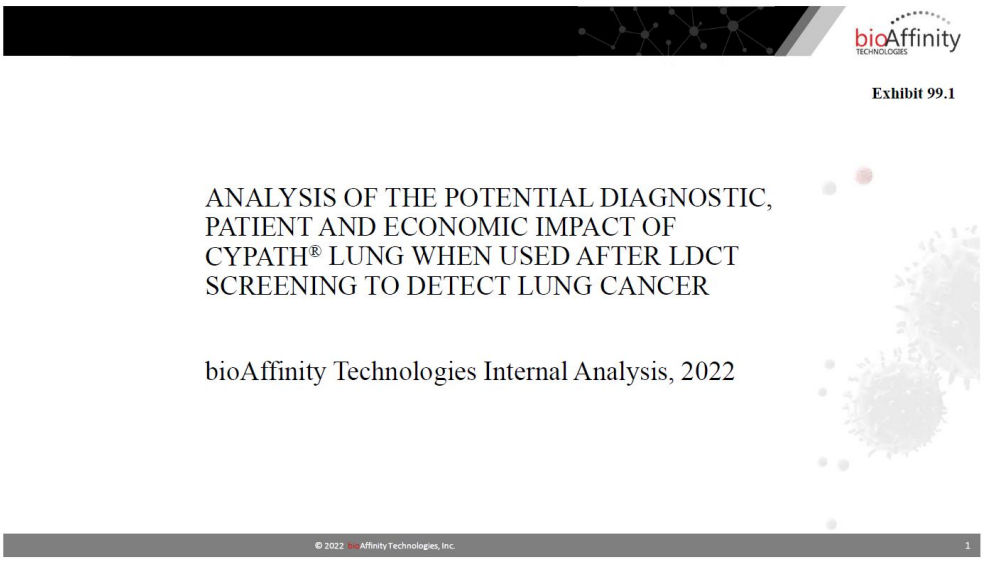
Adenocarcinoma	A form of cancer that forms in the tissue that lines certain internal organs. Most cancers of the breast, pancreas, lung, prostate, colon, esophagus, and stomach are adenocarcinomas.
Antibody	A protein that is produced by a person's immune system to target and destroy alien substances 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' (Conformitè Europëenne) on a product signifies that products sold in the European Union have been assessed to meet high safety, health, and environmental protection requirements.
CLIA	The Clinical Laboratory Improvement Amendments of 1989 (CLIA). These amendments to U.S. law grant authority to the Centers for Medicare and Medicaid to issue regulations and guidance governing commercial laboratories. CLIA regulations are often associated with CAP guidance. (See also "Laboratory Developed Test (LDT)").

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

LRP2 Gene	A gene that provides instructions for making the LRP2 receptor that facilitates the uptake of many proteins and some nutrients that includes vitamin B12. Cancer cells can express a large number of LRP2 receptors on their cell surface.
Metabolism	The set of life-sustaining chemical reactions used by organisms to convert the energy in food to energy available for the body to stay alive, grow and reproduce, maintain the body's structures, and respond to its environments.
Negative predictive value	The probability that a patient with a negative diagnostic or screening test truly does not have the disease. Negative predictive value is a function of the incidence of a disease in a population (i.e., the estimated percentage of people who are expected to have the disease in the population) and the specificity of a test (See "Specificity").
Nodules	Abnormal tissue growths that can be found anywhere in the body. Although they are often benign, some nodules are symptoms of an underlying health condition such as cancer.
Organic compound	Organic compounds are the complex compounds of carbon. These compounds can occur naturally or can be man-made (synthesized) in a laboratory.
Pathology	The branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic or forensic purposes.
Pivotal trial	A clinical study seeking to demonstrate the efficacy of a new diagnostic test in order to obtain approval by the U.S. FDA to market the test directly by its manufacturer.
Plasma	The liquid portion of blood. Its main role is to take nutrients, hormones, and proteins to the parts of the body that need it. Cells also excrete their waste products into the plasma.
Porphyrins	A class of pigments that can be either lab-produced or naturally occurring, many of which are essential to life, such as the green chlorophyll for photosynthesis in plants and the oxygen carrier, hemoglobin, that gives blood its red color. The molecular structure of all porphyrins is a large ring composed of four linked nitrogen-containing rings known as pyrroles.
Positive predictive value	The probability that a patient with a positive diagnostic or screening test truly has the disease. Positive predictive value is a function of the incidence of a disease in a population (i.e., the estimated percentage of people who are expected to have the disease in the population) and the sensitivity of a test (See "Sensitivity").

Pre-malignant	A term used to describe a condition that may (or is likely to) become cancer. Also called precancerous.
RNA interference (RNAi)	A natural process in which small pieces of RNA shut down a cell's ability to make certain proteins. To do so, RNAi binds to the messenger RNA (mRNA) that carries instructions for that protein.
RNA	Ribonucleic acid, a naturally occurring chemical compound present in all living cells. RNA's principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins. Several types of RNA sequences are often mentioned, including:
mRNA	Messenger RNA (mRNA), the molecule that carries protein-building instructions from DNA to the ribosome, the part of the cell where proteins are assembled.
siRNA	Small interfering RNA (siRNA), short molecules that bind to an mRNA and target it for destruction.
Sensitivity	In a diagnostic test, sensitivity is a measure of how well a test can identify true positives, meaning the test's ability to detect a disease in a person with that disease. There is a trade-off between sensitivity and specificity, such that higher sensitivities will mean lower specificities and vice versa.
Specificity	Specificity is a measure of how well a test can identify someone who does not have a disease is negative for that disease.
Squamous cell carcinoma	A type of cancer that begins in squamous cells. Squamous cells are thin, flat cells that look like fish scales, and are found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the lining of the respiratory and digestive tracts. Most cancers of the anus, cervix, head and neck, and vagina are squamous cell carcinomas.
Stage I–IV	Staging describes where cancer is located, how far the primary tumor (where the cancer started) has spread and to where, and its size. 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 *meso*-tetra(4-carboxyphenyl)porphine.
Transfection	A laboratory technique that is used to insert foreign nucleic acid (DNA or RNA) into a cell, typically with the intention of producing a specific protein within the cell.
Vitamin B12	An essential dietary nutrient that the body needs daily in small amounts to function and stay healthy. Vitamin B12 helps make red blood cells, DNA, RNA, energy, and tissues, and keeps nerve cells healthy. It is found in liver, meat, eggs, poultry, shellfish, milk, and milk products. Chronic lack of vitamin B12 can result in anemia and central nervous system problems.

APPENDIX I


bioAffinity
TECHNOLOGIES
Exhibit 99.1
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
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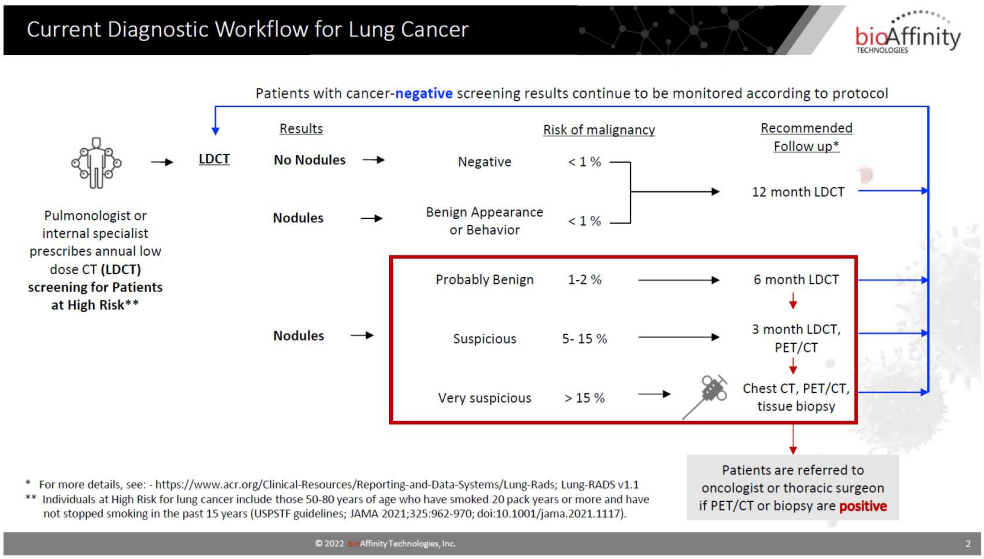
Current Diagnostic Workflow for Lung Cancer
bioAffinity TECHNOLOGIES
Patients with cancer-negative screening results continue to be monitored according to protocol
Pulmonologist or internal specialist prescribes annual low dose CT (LDCT) screening for Patients at High Risk**
LDCT
Results
No Nodules
Nodules
Nodules
Risk of malignancy
Negative
< 1 %
Benign Appearance or Behavior
< 1 %
Probably Benign
1-2 %
Suspicious
5- 15 %
Very suspicious
> 15 %
Recommended Follow up*
12 month LDCT
6 month LDCT
3 month LDCT, PET/CT
Chest CT, PET/CT, tissue biopsy
Patients are referred to oncologist or thoracic surgeon if PET/CT or biopsy are positive
* For more details, see: - https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads; Lung-RADS v1.1
** Individuals at High Risk for lung cancer include those 50-80 years of age who have smoked 20 pack years or more and have not stopped smoking in the past 15 years (USPSTF guidelines; JAMA 2021;325:962-970; doi:10.1001/jama.2021.1117).
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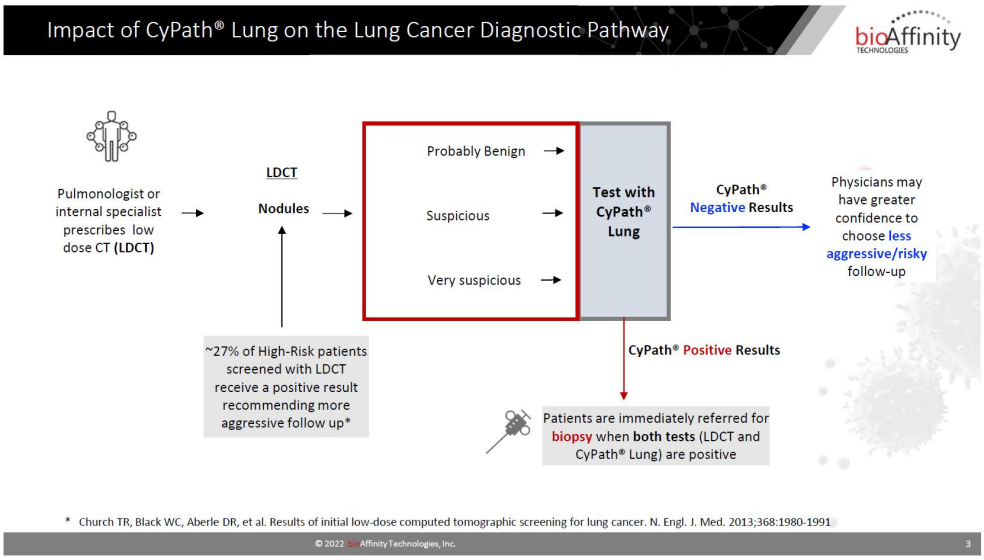
Impact of CyPath® Lung on the Lung Cancer Diagnostic Pathway
bioAffinity TECHNOLOGIES
Pulmonologist or internal specialist prescribes low dose CT (LDCT)
LDCT
Nodules
Probably Benign
Suspicious
Very suspicious
Test with CyPath® Lung
CyPath® Negative Results
Physicians may have greater confidence to choose less aggressive/risky follow-up
~27% of High-Risk patients screened with LDCT receive a positive result recommending more aggressive follow up*
CyPath® Positive Results
Patients are immediately referred for biopsy when both tests (LDCT and CyPath® Lung) are positive
* 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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Potential Benefits to Patients and Physicians Who Use CyPath® Lung

<u>When BOTH LDCT and CyPath® Lung results are POSITIVE</u>

- 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

<u>When LDCT results are positive but CyPath® Lung results are NEGATIVE</u>

- 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)

CyPath® Lung Test Validation Trial*

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.

The Numbers: CyPath® Lung and LDCT Performance Considered Separately

bioAffinity TECHNOLOGIES

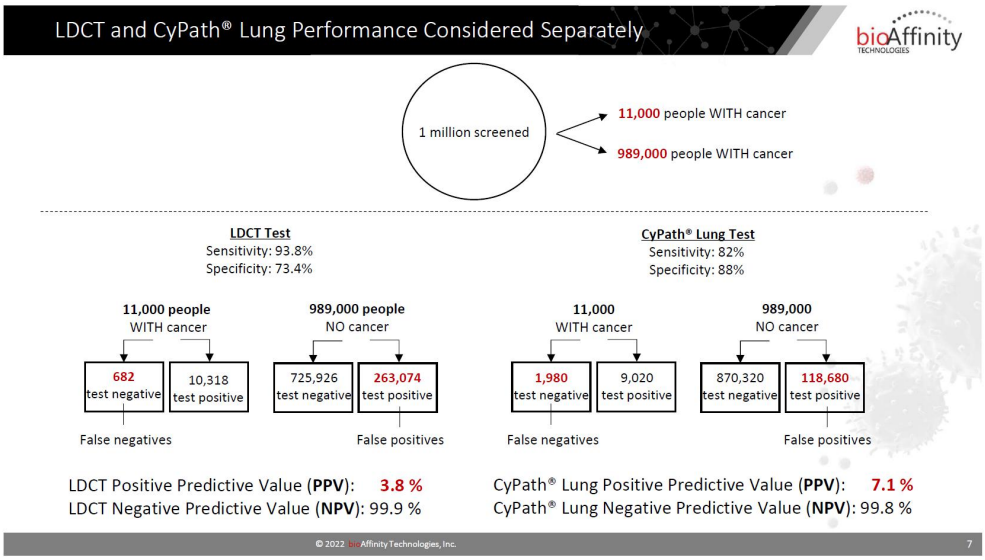
Applying Overall Test Sensitivity and Specificity to 1 Million People at High Risk

LDCT Test*
Sensitivity: 93.8%
Specificity: 73.4%

CyPath® Lung Test**
Sensitivity: 82%
Specificity: 88%

* 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):1980-91 1.

** 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.


LDCT and CyPath® Lung Performance Considered Separately
bioAffinity
TECHNOLOGIES
1 million screened
11,000 people WITH cancer
989,000 people WITH cancer
LDCT Test
Sensitivity: 93.8%
Specificity: 73.4%
11,000 people
WITH cancer
989,000 people
NO cancer
682
test negative
10,318
test positive
725,926
test negative
263,074
test positive
False negatives
False positives
CyPath® Lung Test
Sensitivity: 82%
Specificity: 88%
11,000
WITH cancer
989,000
NO cancer
1,980
test negative
9,020
test positive
870,320
test negative
118,680
test positive
False negatives
False positives
LDCT Positive Predictive Value (PPV): 3.8 %
LDCT Negative Predictive Value (NPV): 99.9 %
CyPath® Lung Positive Predictive Value (PPV): 7.1 %
CyPath® Lung Negative Predictive Value (NPV): 99.8 %
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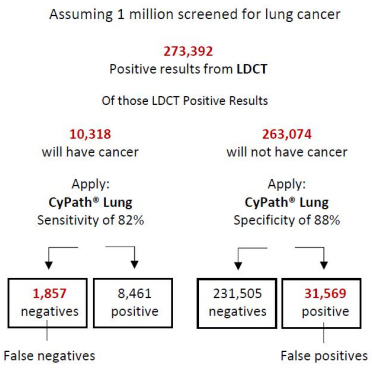
Potential Impact of CyPath® Lung on patients when it is used after LDCT



→ 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):1980-91 1.

Medicare Cost Analysis Provides Basis for Economic Impact Calculation

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*Biology*Physics. 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.

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**

→ 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

Assumptions

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

Diagnostic, Patient and Economic Impacts of CyPath® Lung after LDCT

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) PPV	NPV	Reference **
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; *J Trans Med.* 2015 [1]
	400	0.86	38.3	96.0	Mazzone et al; *Biomar Insights* 2018 [2]
Biodesix	141	0.62	11.3	95.7	Vachani et al; *J Thorac Oncol.* 2015 [3]
	172	0.76	16.1	99.2	Silvestry et al; *Chest* 2018 [4]
MagArray	97	0.86	13.5	98.0	Trivedi et al; Biomed Res Rev. 2018 [5]
Veracyte [‡]	264	ND	16.9	99.3	Lamb et al; *Chest* 2019 [6]
Oncimmune	836	ND	34.5	93.9	Chapman et al, *Tumour Biol.* 2012 [7]
	847	ND	31.4	92.9	Jett et al; *Lung Cancer* 2014 [8]

* 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
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bioAffinity Technologies, Inc.

Index to the Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance 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
PCAOB ID No. 100

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

BIOAFFINITY TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 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	84,007	34,017
Total current assets	1,446,175	118,655
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; 5,296,044 issued and outstanding as of December 31, 2021 and 2020, respectively; aggregate liquidation preference of $5,825,648	4,044,318	4,044,318
Stockholders' deficit:		
Common Stock, par value $0.001 per share; 100,000,000 shares authorized; 18,740,157 and 18,724,187 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.

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	$ (0.34)	$ (0.39)
Weighted average common shares outstanding	18,727,066	18,724,187

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

bioAffinity Technologies, Inc.
consolidated Statements of Changes in Convertible preferred stock and Stockholders' Deficit

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019	5,296,044	$ 4,044,318	18,724,187	$ 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	5,296,044	$ 4,044,318	18,724,187	$ 18,724	$ 7,095,355	$ (22,186,942)	$ (15,072,863)
Stock-based compensation expense	—	—	15,970	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	5,296,044	$ 4,044,318	18,740,157	$ 18,740	$ 12,703,896	$ (28,513,355)	$ (15,790,719)

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

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	(2,048,978)	(2,207,639)
Cash flows from investing activities		
Purchase of property and equipment	—	(2,888)
Net cash used in investing activities	—	(2,888)
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	3,326,508	1,715,152
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	$ 1,360,638	$ 83,108
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.

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 a 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 June 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.

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.

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.

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.

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	5,296,044	5,296,044
Shares underlying options outstanding	6,149,096	5,769,096
Shares underlying warrants outstanding	13,231,562	45,000
Shares underlying convertible notes outstanding	16,505,581	6,441,590
	41,182,283	17,551,730

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.

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 approval 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.

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	December 31, 2020
Prepaid insurance	$ 16,765	$ 11,574
Legal and professional	55,081	16,778
Offering costs	7,943	—
Other	4,218	5,665
Total prepaid expenses and other current assets	$ 84,007	$ 34,017

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment at December 31, 2021 and 2020 are summarized below:

	December 31, 2021	December 31, 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	$ 4,633	$ 9,450

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	December 31, 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	$ 483,501	$ 375,757

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

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	90%/10%
			Applied discount rate	79.1%
			Common share class volatility	46.1%
			Preferred stock class volatility	3.9%
			Negotiation discount	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	90%/10%
			Applied discount rate	30.0%
			Common share class volatility	68.5%
			Preferred stock class volatility	40.5%
			Negotiation discount	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.

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 $0.945 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 $0.945 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 $0.945 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.

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 $0.60 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 $0.60 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 $0.75 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 two and one-half (2.5) 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 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.

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 5,296,044 shares of preferred stock, designated as Series A. In July 2017, the Company completed a private placement of securities in which 1.4 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 3.9 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 5,296,044 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 $1.10 per share (as adjusted for any stock dividend, stock split, combination or other recapitalization with respect to such shares) 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.

Common Stock

The Company has authorized a total of 100,000,000 shares of $0.001 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 18,740,157 shares of Common Stock.

In November 2021, the Company received shareholder approval to increase the number of authorized shares from 50,000,000 to a total of 100,000,000 shares of $0.001 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 eight (8.0) million shares of Common Stock, or twenty percent (20%) of the total issued and outstanding Common Stock, whichever is greater. The Company has reserved eight (8.0) 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 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	$ 43,012	$ 275,732

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	5,149,096	$ 0.52		
Granted	620,000	1.10		
Exercised	—	—		
Forfeited	—	—		
Outstanding at December 31, 2020	5,769,096	$ 0.52		
Granted	555,000	0.78		
Exercised	—	—		
Forfeited	(175,000)	1.10		
Outstanding at December 31, 2021	6,149,096	$ 0.59	4.8	$ 1,324,740
Vested and exercisable at December 31, 2021	5,665,624	$ 0.58	2.3	$ 1,324,740

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 555,000 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 $0.32 on the date of grant.

During the year ended December 31, 2021, the Company issued restricted stock units (RSUs) for 55,000 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 39,000 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 620,000 shares of Common Stock to employees. The per share weighted-average fair value of the options granted during 2020 was estimated at $0.50 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	$ 0.54	$ 0.92
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.

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 45,000 Common Stock purchase warrants, which are classified as equity. The warrants were issued with an exercise price of $1.00 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 $0.60 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 an unpaid interest into Common Stock and at $0.60 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 $0.75 per share if the IPO is not completed by the maturity date.

The Company issued an aggregate of 3,249,991 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 $0.60 per share. As an inducement to amending the notes, the Company issued 9,936,571 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	$	0.75
Fair market closing price per share of Common Stock	$	0.60
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	$ —	—

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 $0.60 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 $0.60 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 $0.75 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 two and one-half (2.5) 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 8.0 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.

PRELIMINARY PROSPECTUS

bioAffinity Technologies, Inc.

[ ] Shares of Common Stock

Sole Book-Running Manager

WallachBeth Capital, LLC

April 25, 2022

Until [ ], 2022 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade shares of our Common Stock, 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	$	1,746.19
FINRA filing fee	$	3,950.00
Nasdaq Capital Market listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer agent and registrar fees		*
Miscellaneous		*
Total	$	*

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers

bioAffinity Technologies, Inc. is incorporated under the laws of the State of Delaware. Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends or unlawful stock purchase or redemptions, or (4) for any transaction from which the director derived an improper personal benefit.

Section 145(a) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the adjudicating court shall deem proper.

Section 145(g) of the DGCL provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether 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 amended and restated certificate of incorporation 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 amended and restated certificate of incorporation 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.

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 have a maturity date of May 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 $0.60 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 have a maturity date of May 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 $0.60 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 $0.60 per share. Pursuant to the terms of these notes, each of these notes are 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 0.60. Accordingly, warrants to purchase up to 1,450,000 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 $0.75 per share. The warrants have a term of 5 years.

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 have a maturity date of May 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 $0.60 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 0.60. Accordingly, warrants to purchase up to 4,041,666 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 $0.75 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 369,791 shares of our Common Stock at an exercise price equal to the 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 equal to the original principal amount of the notes divided by 0.60. Accordingly, we issued warrants to purchase 9,936,569 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 $0.75 per share. The warrants have a term of 5 years.

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 369,791 shares of our Common Stock (based on the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus).The exercise price of the Placement Agent's Warrant is equal to the price of our Common Stock 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 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, 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 three years from the effective date of the registration statement related to the Offering in compliance with FINRA Rule 5110(G)(8)(D). 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 December 2021, we issued non-statutory stock options under our 2014 Stock Incentive Plan to certain of our employees, directors and consultants to purchase up to 6,737,998 shares of our Common Stock. Some of those options were exercised, resulting in the issuance of 241,208 shares of our Common Stock. Options to purchase 337,694 shares of our Common Stock were forfeited when the recipients' service to the Company was terminated. Options to purchase 6,159,096 shares of our Common Stock at a weighted average exercise price of approximately $0.59 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 289,925 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*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of Registrant, to be in effect immediately prior to completion of the Offering.
3.3*	Amended and Restated Bylaws of Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of Registrant, to be in effect immediately prior to completion of the Offering.
3.5*	Code of Business Conduct.
4.1*	Form of Registrant's Common Stock Certificate.
4.2*	Form of Investor Warrant.
4.3*	Warrant Issued to San Antonio Economic Development Corporation dated March 17, 2017.
4.4*	Form of Placement Agent Warrant.
4.5*	Form of Secured, Convertible Promissory Note of Registrant.
4.6*	Form of Unsecured, Convertible Promissory Note of Registrant.
4.7*	Form of Convertible Bridge Promissory Note of Registrant.
4.8*	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant.
5.1*	Opinion of Dykema Gossett, PLLC.
10.1*	2014 Equity Incentive Plan of Registrant and forms of agreement thereunder.
10.2+*	Executive Chairman Employment Agreement dated January 1, 2020 between Registrant and Steven Girgenti, as amended.
10.3+*	Employment Agreement dated February 1, 2015 between Registrant and Maria Zannes.
10.4+*	Employment Agreement dated April 4, 2016 between Registrant and Vivienne Rebel.
10.5*	Note Purchase Agreement dated December 21, 2018, as amended.
10.6*	Form of Note Purchase Agreement for Convertible Bridge Note Investors.
10.7*	Form of Secured Convertible Promissory Note.
10.8*	Form of Unsecured Convertible Promissory Note.
10.9*	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.
10.10*	Agreement between Registrant and GO2 Partners dated October 17, 2020.
16.1	Letter re Change in Certifying Accountant from Ernst & Young dated April 25, 2022.
21.1	List of Subsidiaries.
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 (included on the signature page to this Registration Statement).
107	Filing Fee Table.

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of San Antonio, Texas, on April 25, 2022.

bioAffinity Technologies, Inc.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Maria Zannes and Steven Girgenti and each of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement and to sign any registration statement for the same offering covered by the Registration Statement that is to be effective upon filing pursuant to Rule 462 promulgated under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or such person's substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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
/s/ Maria Zannes Maria Zannes	Founder, President, Chief Executive Officer, and Director (Principal Executive Officer)	April 25, 2022
/s/ Michael Edwards Michael Edwards	Chief Financial Officer	April 25, 2022
/s/ Steven Girgenti Steven Girgenti	Founder, Executive Chairman, and Director	April 25, 2022
/s/ Robert Anderson Robert Anderson	Director	April 25, 2022
/s/ Stuart Diamond Stuart Diamond	Director	April 25, 2022
/s/ Peter S. Knight Peter S. Knight	Director	April 25, 2022
/s/ Mohsin Meghji Mohsin Meghji	Director	April 25, 2022
/s/ Gary Rubin Gary Rubin	Director	April 25, 2022

EXHIBIT 16.1

April 25, 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 April 25, 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

Exhibit 21.1

Subsidiaries of bioAffinity Technologies, Inc.

1. OncoSelect Therapeutics, LLC (a Delaware limited liability company)

Exhibit 23.2

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, in the Registration Statement (Form S-1) and related Prospectus of bioAffinity Technologies, Inc. for the registration of shares of its common stock.

Our report dated January 10, 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
April 22, 2022

Exhibit 23.3

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in the Prospectus constituting a part of this Registration Statement on Form S-1 of our report dated April 22, 2022, relating to the financial statements 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
April 22, 2022

Exhibit 107

Calculation of Filing Fee Tables

Form S-1
(Form Type)

bioAffinity Technologies, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered 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 to be Paid	Equity	Common Stock, $0.000142857142857 par value per share[1]	457(o)	—	—	$ 15,000,000 [2]	0.0000927	$ 1390.50[7]
		Over-Allotment Option	457(o)			$ 2,250,000[2][3]	0.0000927	208.58[7]
	Other	Representative's Warrants[4]	457(g)	—	—	—	—	—
	Equity	Common Stock, $0.0001 par value per share, issuable upon exercise of the Representative's Warrants[5]	457(o)	—	—	$ 1,587,000[2]	0.0000927	$ 147.11[7]
	Other	Placement Agent's Warrants[4]	457(g)	—	—	—	—	—
	Equity	Common Stock, $0.0001 par value per share, issuable upon exercise of the Placement Agent's Warrants[6]	457(a)	369,791[8]		—	0.0000927	—
		Total Offering Amount				$ 18,837,000		$ 1,746.19
		Total Fees Previously Paid						$ —
		Net Fee Due						$ 1,746.19

(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 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 warrants to purchase a number of securities equal to 8% of the shares of Common Stock sold in this offering at an exercise price equal to 115% of the public offering price per share.

(6) Represents warrants to purchase 369,791 shares of Common Stock issued to our Placement Agent at an exercise price equal to the price in this Offering or $0.75 per share if the Company does not complete an initial public offering by the warrants' maturity date.

(7) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.

(8) To be calculated and paid in accordance with Rule 457(a) under the Securities Act when the price in this Offering is determined.